Human Fertilisation & Embryology Authority

Authority meeting - agenda

13 November 2019

ETC.venues Victoria, 1 Drummond Gate SW1V 2QQ

Agenda item	Time
1. Welcome, apologies and declaration of interests	12.45pm
2. Minutes of 11 September 2019 Authority meeting **HFEA (13/11/19) 929** For decision	12.50pm
3. Chair's report (verbal)	12.55pm
4. Chief Executive's report incorporating EU exit (verbal)	1.00pm
5. Committee chairs' report (verbal) Licensing activity report **HFEA (13/11/19) 930** For information	1.05pm
6. Performance report **HFEA (13/11/19) 931** For information	1.20pm
7. Strategic risk register **HFEA (13/11/19) 932** For information	1.30pm
8. Strategy 2020 – 2023 **HFEA (13/11/19) 933** For decision	1.40pm
Break	2.15pm
9. Opening The Register (OTR) annual report **HFEA (13/11/19) 934** For information	2.30pm
10. Donor Conceived Register (DCR) **HFEA (13/11/19) 935** For information	2.50pm
11. Update on Storage Consent **HFEA (13/11/19) 936** For decision	3.00pm
12. Register Research Panel annual report **HFEA (13/11/19) 937** For decision	3.30pm

13. Any other business	3.50pm
14. Close	3.55pm

Minutes of Authority meeting 11 September 2019

Strategic delivery:	☐ Safe, ethical, effective treatment	☐ Consistent outcomes and support	☐ Improving standards through intelligence
Details:			
Meeting	Authority		
Agenda item	2		
Paper number	HFEA (13/11/19) 929		
Meeting date	13 November 2019		
Author	Debbie Okutubo, Governance Manager		
Output:			
For information or decision?	For decision		
Recommendation	Members are asked to confirm the minutes as a true record of the meeting		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☒ Low	☐ Medium	☐ High
Annexes			

Minutes of the Authority meeting on 11 September 2019 held at ETC.venues Victoria, 1 Drummond Gate SW1V 2QQ

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

Members

There were 14 members at the meeting – 10 lay members and 4 professional members.

1. Welcome, apologies and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members, the public and staff present. She stated that the meeting was audio recorded in line with previous meetings and the recording would be made available on our website to allow members of the public who were not at the meeting to listen to deliberations.

1.2. There were no apologies for absence.

1.3. Declarations of interest were made by;

- Rachel Cutting (Person Responsible (PR) at a licensed centre)
- Yacoub Khalaf (PR at a licensed clinic)
- Anthony Rutherford (Clinician at a licensed clinic).

2. Minutes of Authority meeting held on 3 July 2019

2.1. Members agreed that the minutes of the meeting held on 3 July 2019 be signed by the Chair subject to an amendment in Minute 8.6 to read:

'… *an overview of treatment income issues* ….'

3. Chair's report

3.1. The Chair thanked staff for holding the fort in the absence of the third director, especially with the HFEA being a small organisation. She formally announced that Rachel Cutting had been appointed as the new Director of Compliance and Information from early November 2019, which meant that this would be her last meeting as an Authority member.

3.2. The Chair advised that on 9 July, she chaired a Remuneration Committee meeting.

3.3. Later that day, the Chair and Chief Executive (CE) had the annual accountability meeting with the Department of Health and Social Care (DHSC). The Chair described it as a positive meeting and explained that the DHSC recognised our achievements and gave positive feedback.

3.4. On 17 July, the Chair and Director of Strategy and Corporate Affairs met Helen Stokes-Lampard, the Chair of the Royal College of General Practioners (GPs). The discussion centered around the current links with primary care staff; feedback from the patient survey and actions to be taken; and future opportunities to work together.

3.5. On 25 July, the Chair and CE along with the CE of the Human Tissue Authority and HFEA Head of Human Resources held the interviews for the Director of Compliance and Information post at which Rachel Cutting was appointed.

4. Chief Executive's report

4.1. The CE also welcomed Rachel Cutting as the new Director and commented that her unique experience placed her as the best person for the role at this time.

4.2. On 5 July, the CE went to Manchester to visit Daniel Brison and Raj Mathur.

4.3. On 9 July, he attended the Remuneration Committee meeting. Later that day he met with Shaun Rodgers, the PR of City Fertility.

4.4. On 15 July, he had a meeting with James Duffy, NHS England and they discussed how to improve the identification of fertility research priorities.

4.5. On 31 July, he had an EU Exit telephone conference meeting and later that day he attended the Healthcare Leaders Senior Talent board meeting.

4.6. On 6 August, he met with James Nicopoullos, PR at the Lister Fertility clinic to discuss treatment add-ons.

5. Committee Chairs' reports

Licence Committee

5.1. The Chair of the Licence Committee reported that the committee met on 11 July and considered six items: two renewal research, two renewals for treatment and storage, one interim treatment and storage and one additional inspection for treatment and storage, all of which were granted.

5.2. The Committee also met on 5 September and considered four items: one renewal for treatment and storage, two interim treatment and storage and one executive update. The minutes were still in draft.

5.3. The Chair and Deputy Chair of the Committee commented on the accuracy of clinic websites. It was noted that the websites were increasingly becoming an issue for the Committee and that the Deputy Chair had written to the CE about their concerns.

Decision

5.4. Members noted their concerns and that the CE would discuss this matter with the inspectorate.

Statutory Approvals Committee

5.5. The Chair of Statutory Approvals Committee (SAC) noted that the items considered at the 27 June 2019 meeting, two PGD applications and two Special Directions, were all approved.

5.6. It was further reported that the Committee met on 25 July and considered four PGD applications which were all approved.

5.7. They also met on 29 August and considered four items: one mitochondrial donation, two PGD applications and one special direction. The minutes from the meeting were still in draft.

Executive Licensing Panel

5.8. The Chair of the Executive Licensing Panel (ELP) advised members that the panel had met five times since the last Authority meeting on 9 July, 23 July, 6 August, 20 August and 3 September. The Panel considered 26 items: six renewals, 12 interims and eight variations. All items were approved except one renewal which was deferred.

5.9. The Chair of ELP also reported that 16 Licensing Officer considerations were approved: 13 for EU certificates, one for changes of Licence Holder and two for a change of centre name.

Remuneration Committee

5.10. The Chair of the Authority, who was also the Chair of the Remuneration Committee, stated that the Committee met on 9 July 2019 and considered a new pay structure for staff and this year's pay award.

Decision

5.11. Members noted the Committee chairs' reports and the licensing activity report.

6. Performance report

6.1. A report summarising performance data up to the end of July 2019 was presented to the Authority.

6.2. Overall performance was considered to be good.

6.3. The Director of Strategy and Corporate Affairs reported back on a range of initiatives and events that were in progress including two workshops for clinic staff on improving patient support; developing the HFEA response to the Law Commission's consultation on surrogacy and drafting the State of the Sector report.

6.4. The HFEA was highly commended at the recent British Medical Association (BMA) patient information awards for our work on treatment add-ons.

6.5. The Director of Finance and Resources noted that an overspend was forecast against the budget, however the position could change if income remained on its current trajectory. Income

was above budget but below the levels seen in the previous financial year. Expenditure for the first quarter was showing an underspend against the budget.

6.6. There were no additional pressures on the budget at this time and work would be taking place during October to review the activity modelling that underpinned income forecasts, which would likely be completed for November.

6.7. In response to a question, it was noted that clinics were seeing a slight decrease in activity this year. NHS activity had declined but private patients had remained constant. There was a suggestion that any fall in the overall number of cycles funded by the NHS could have been masked in the short term by the transfer of already frozen embryos – but overall numbers might now be falling.

6.8. The CE (in the absence of a Director of Compliance and Information) commented that on the Inspection front we were on schedule. Regarding PGD applications performance varied depending on how complex each application was.

6.9. It was noted that with the development of the new strategy, this key performance indicator (KPI) would be reviewed and benchmarked as it needed to be managed effectively.

6.10. Members commented that the time PGD applications were taking was justified and would help future patients. Also, that peer reviewers were experts in their fields so any delay was a necessary one.

6.11. On another note, Members commented that even though staff turnover remained red on the RAG status it was not overly concerning at present as the position was being kept under review at Audit and Governance Committee meetings (AGC), through the strategic risk register.

Decision

6.12. Authority members noted the performance report.

7. EU Exit

7.1. The CE noted that we regularly assessed our operational readiness and that was reported to the DHSC and they agreed with our green RAG status.

7.2. To prepare for EU exit changes may need to be made to General Directions and decision trees and this may need to be implemented within a short time frame outside of the Authority meeting cycle.

Decision

7.3 Members agreed to delegate responsibility to the Chair and the CE under standing orders paragraph 5.2 with a report back to the Board at the November meeting.

8. Business Planning for 2020 - 2023

8.1. The Head of Business Planning and Governance presented the draft outline of the 2020/2021 business plan to the Authority.

8.2. The paper was a draft outline of a three-year delivery plan and proposed work to be done in the 2020/21 business year.

8.3. It was noted that the process was made more complex as we were simultaneously in the process of developing our new strategy for 2020-2023. However, the feedback received in the course of the strategy consultation indicated strong support, providing a reasonable basis for planning.

8.4. Members were invited to comment. There was a request that in future versions, the objectives should be listed in priority order.

8.5. Regarding being future ready, members suggested that we should be pro-active with meeting the sector and raising awareness on our priorities.

8.6. It was also noted that scoping work had already begun to assess future operational requirements for the Opening the Register (OTR) and Counselling service.

8.7. Members were advised that in November they would receive feedback on the strategy consultation and receive a full draft of the strategy for approval, as well as the first draft of the business plan for 2020/21.

Decision

8.8. Members approved in principle the draft outline business plan activities for 2020/21, as the basis for developing a full draft for the November Authority meeting.

9. Treatment add-ons

9.1. The Scientific Policy Manager presented the proposed aims for the add-ons work, the proposed criteria for an add-on and the proposed direction going forward for this work. It was noted that treatment add-ons were optional extras which claimed to improve patients' chances of having a baby, however the evidence base for many add-ons was either weak or absent.

9.2. Members proposed positive messaging to patients about success rates for core treatments (for example IVF or IUI) alone and that add-ons were not mandatory and not having an add-on would not put them at a disadvantage. The Executive agreed that it was important to have an agreed definition of what we meant by 'core treatment'. Members also considered it important to investigate what treatments clinics included within packages.

9.3. Members highlighted that the current definition for a red traffic light rated add-on was '**there is no evidence that this add-on is effective and safe**' and therefore that the Executive should consider including the commonly opted for holistic therapies (for example massage, acupuncture and nutritional therapy) in the add-ons list.

9.4. Members agreed that there needed to be evidence before any treatment add-on was used in a clinical setting. Also that a meaningful discussion with the sector about offering interventions without evidence needed to happen. They also discussed what could be done to encourage research in this field and agreed that the Scientific and Clinical Advances Advisory Committee (SCAAC) should discuss the evidence base required for a green traffic light rating and to what extent other methods could be used.

9.5. Members had concerns that as we were not routinely aware of the messaging from clinics to patients it was difficult to be fully in control on what information was being provided to patients. A

member highlighted the Montgomery case as a landmark for informed consent. The member added that, as a result of this ruling, the law now required that patients should only be offered 'reasonable' treatment options for which there was a good medical reason and this legal basis could be used in communication with the sector around responsibly offering add-ons. It was therefore imperative to be clear on what was standard treatment and what was an add-on.

9.6. Members suggested adding a tick box into the HFEA's register (PRISM) for clinics to record which treatment add-on a patient had during their fertility treatment and that this data could then be used to look at the success rates when add-ons were used.

Decision

9.7. The Authority agreed that the aims of the add-ons work will be:

9.7.1. to raise awareness of treatment add-ons and the issues therein

9.7.2. to encourage responsible supply and only when a treatment is indicated

9.7.3. to prevent patients from being misled (in terms of potentially exploiting unfounded expectations) by ensuring, through inspections and our own published information, that patients are provided with information that is clear and reliable

9.7.4. to ensure informed consent is obtained

9.7.5. to enhance patient safety by investigating how outcomes and follow ups can be best assessed

9.7.6. to encourage research to assess whether any current or future add-ons increase success rates

9.7.7. to require clinics to provide costed/itemised treatment plans where the costs of treatments and add-ons are clear and to avoid costs being lost in package prices

9.8. The Authority agreed that the criteria for an add-on to be included in the executives list will be:

9.8.1. additional treatments (to the core treatment e.g. IVF or IUI), that patients need unbiased information about effectiveness and risks, that are being offered in fertility clinics;

9.8.2. where evidence on efficacy or safety for the use of the treatment in a clinical setting is lacking or absent.

9.9. The Authority agreed with the way forward for the add-ons work and the Executive will reconvene the Working Group made up of the 11 signatories of the Consensus Statement and involve the General Medical Council (GMC) as appropriate.

10. DNA based matching websites

10.1. The paper reminded members of the September 2018 meeting where the Authority was briefed on the wide-ranging impact of direct-to-consumer genetic testing services offering opt-in matching services on donor anonymity and the managed sharing of information around donor conception, and at which a number of activities including developing new Code guidance were proposed.

10.2. Many DNA testing websites for family history or ancestral ethnicity purposes, or for generalised health information, also offer optional additional services to help identify genetic relatedness between their users, by 'matching' them with other users in their database. The results of this matching, if combined with other information, could also make it possible to infer genetic relatedness with other people who were not on the website database themselves, but who were closely related to those who had been matched.

10.3. Members were reminded that the DNA matching sites were not within the regulatory remit of the HFEA but had important implications for our work.

10.4. We had spoken to three major web-based companies and in response they would be enhancing the information relevant to donor conception on their websites, if they had not already done so. New resources for clinics were being developed for the HFEA website, including podcasts, to support new Code requirements for prospective donors and recipients to be informed by clinics about the implications of such services for the anonymity of donors and donor conceived people and their close genetic relatives.

10.5. A member noted that podcasts were very important and a different way of communicating.

Decision

10.6. Members noted that significant progress has been made and that this would continue as part of business as usual.

11. Update on other strategic priorities

11.1. The Head of Regulatory Policy gave an update to the Authority on the progress made on leadership and patient support, two key strategic priorities resulting in additional guidance in the new edition of the Code of Practice (9.0) published in January 2019.

11.2. Members were advised that these areas would both become part of our inspection regime from 1 October 2019 for the first time, and that clinics' preparation for this had been supported by the provision of workshop events and practical resources placed on the website.

11.3. Members noted and welcomed the update on these two areas.

12. Chair's signature

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

Signature

Chair: **Sally Cheshire**

Date: 13 November 2019

Licensing activity report

Strategic delivery:	☐ Safe, ethical, effective treatment	☐ Consistent outcomes and support	☐ Improving standards through intelligence
Details:			
Meeting	Authority		
Agenda item	5		
Paper number	HFEA (13/11/2019) 930		
Meeting date	13 November 2019		
Author	Paula Robinson, Head of Planning and Governance		
Output:			
For information or decision?	For information		
Recommendation	The Authority is invited to note the latest licensing activity report.		
Resource implications	-		
Implementation date	-		
Communication(s)	-		
Organisational risk	☒ Low	☐ Medium	☐ High
Annexes	Annex A: Licensing activity report		

1. Introduction

1.1. The attached report sets out information about licensing throughput and outcomes in August, September and October 2019.

1.2. We are continuing to keep this recently introduced report under review. For now, we will continue with the report in its current form, so as to allow the data we are tracking to build up over time. Some elements may then benefit from a quarterly or year to year comparison, rather than being shown each time.

2. Recommendation

2.1. Authority members are invited to note this report.

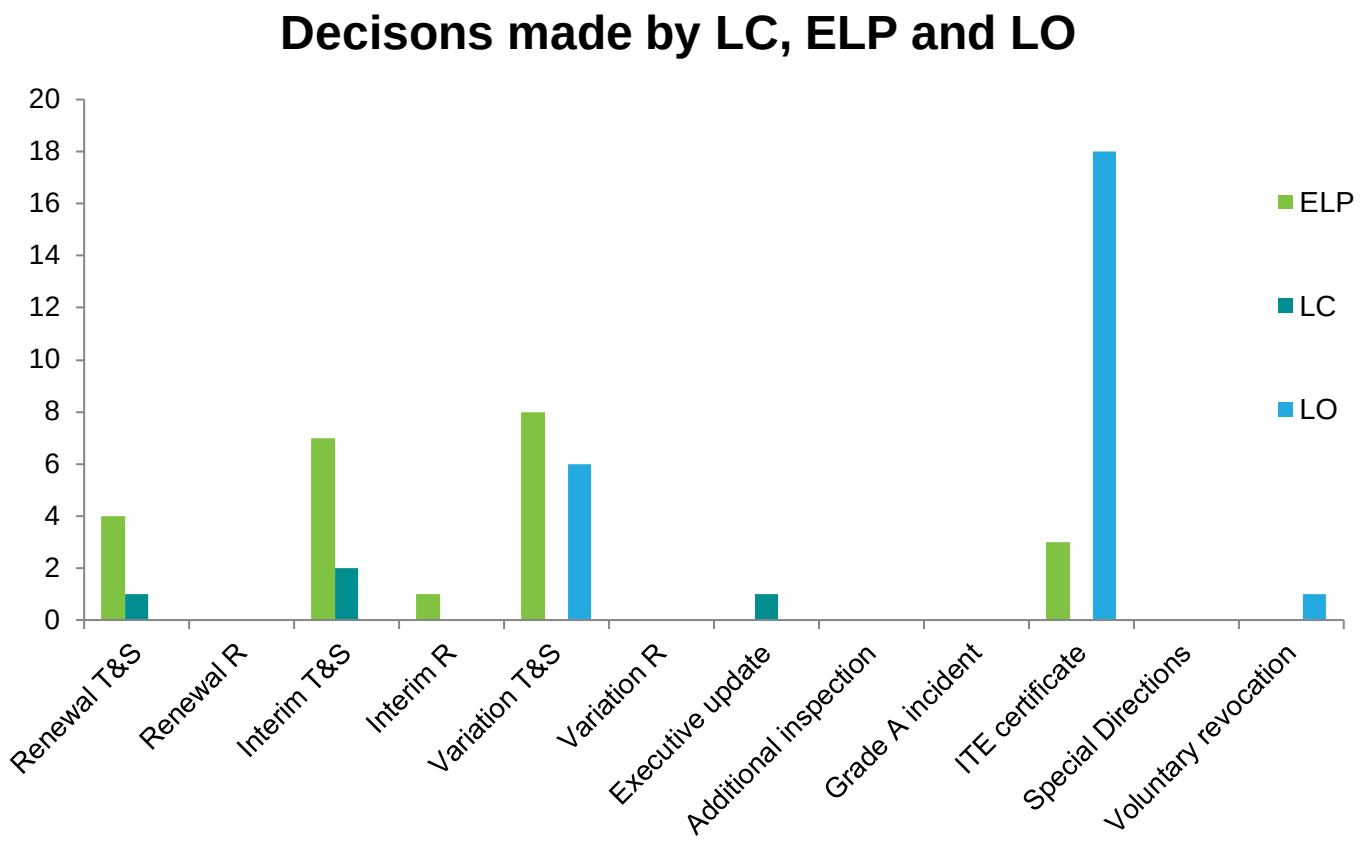
Annex A - Licensing activity report for 1 August 2019 to 31 October 2019

Outcomes of recent items by committee: 1 August – 31 October

Committee[1]	Granted	Other	Not yet confirmed	Comments
LC	3	1	0	One renewal, two interims, and an executive update.
ELP	19	1	0	Typical mix of items, including interims, renewals and a range of variations.
LO	25	0	0	18 EU importing tissue establishment (ITE) certificates and a range of other items.
SAC	10	1	5	Mitochondrial donation applications have resumed. One item in September was adjourned to seek further information. The minutes of the meeting held on 31 October are not yet available.

[1] LC = Licence Committee ELP = Executive Licensing Panel LO = Licensing Officer SAC = Statutory Approvals Committee

Types of items considered by LC, ELP and LO: 1 August – 31 October 2019



Commentary

A typical range of items, still featuring a relatively high number of ITE certificates.

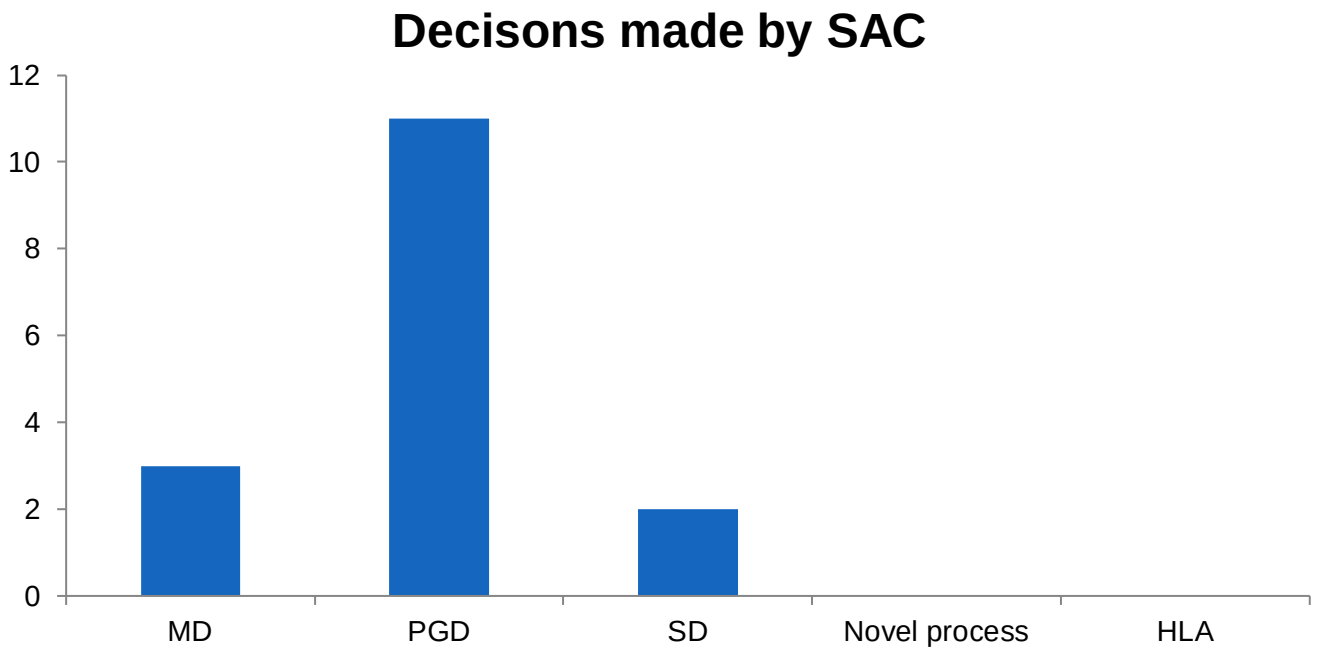
Key:

T&S = treatment and storage

R = research

ITE = importing tissue establishment

Types of items considered by SAC: 1 August – 31 October 2019



Commentary

Applications for mitochondrial donation authorisation have resumed after a quiet period.

Key:

MD = mitochondrial donation

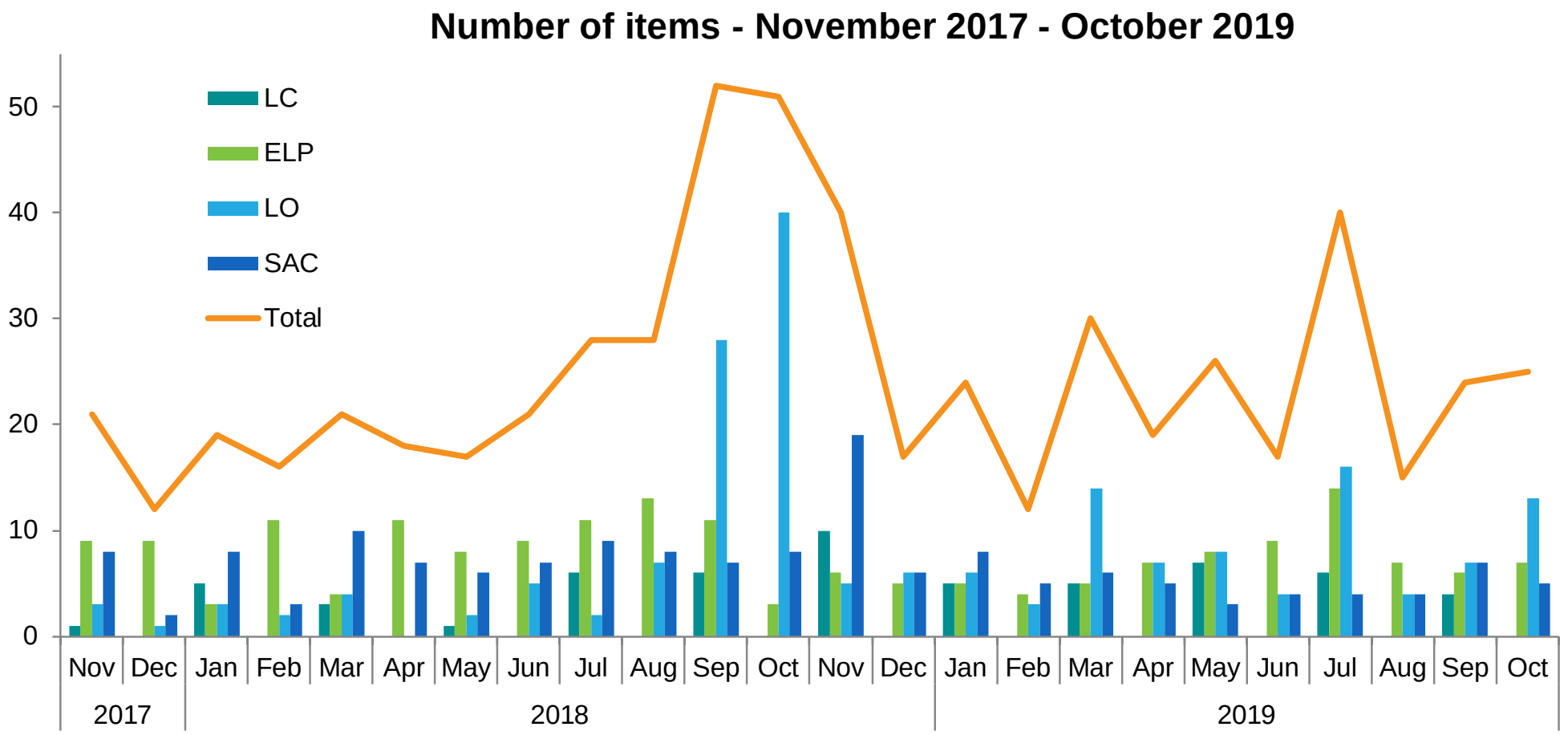
PGD = preimplantation genetic diagnosis

SD = special directions for import or export

HLA = human leucocyte antigen

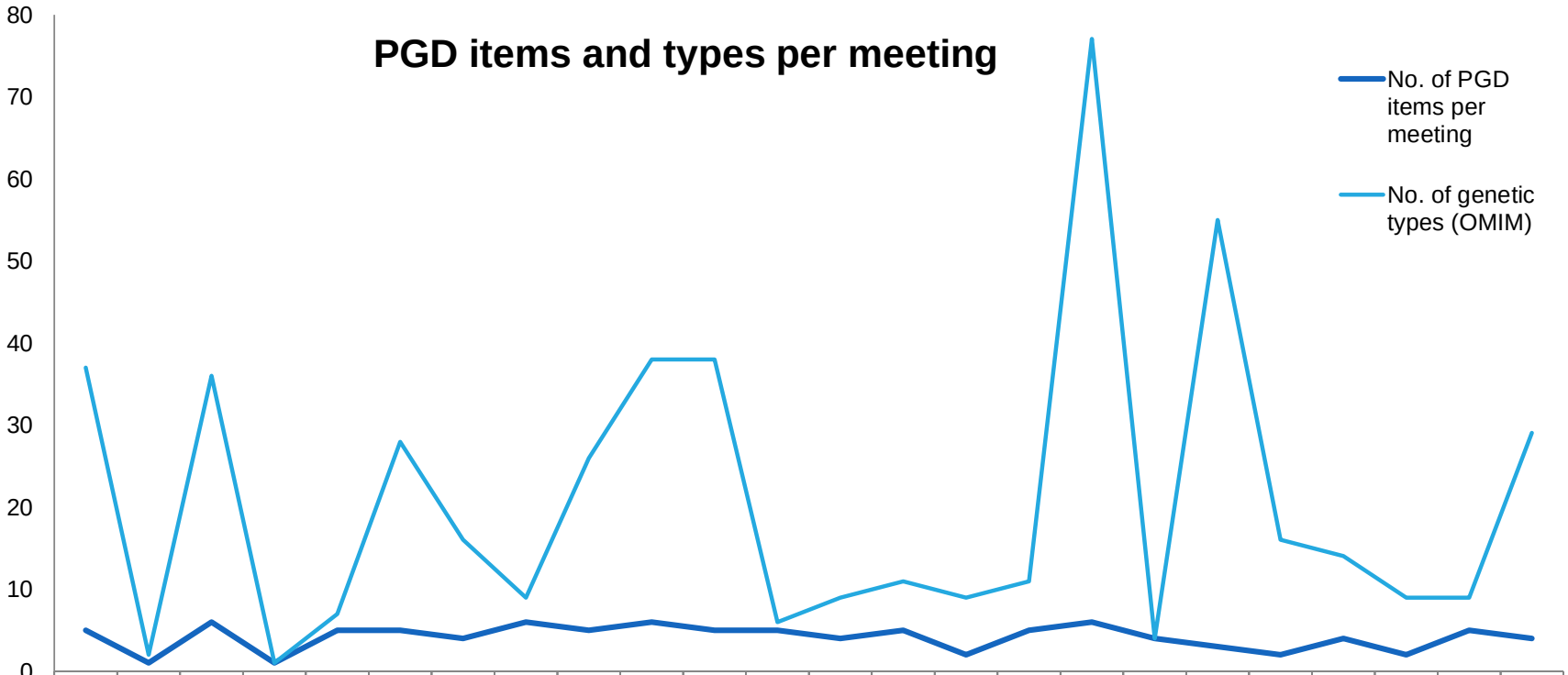
Longer term trends – two year rolling report

Item numbers per committee across the last two years (rolling picture) – all committees



We will continue to monitor for trends.

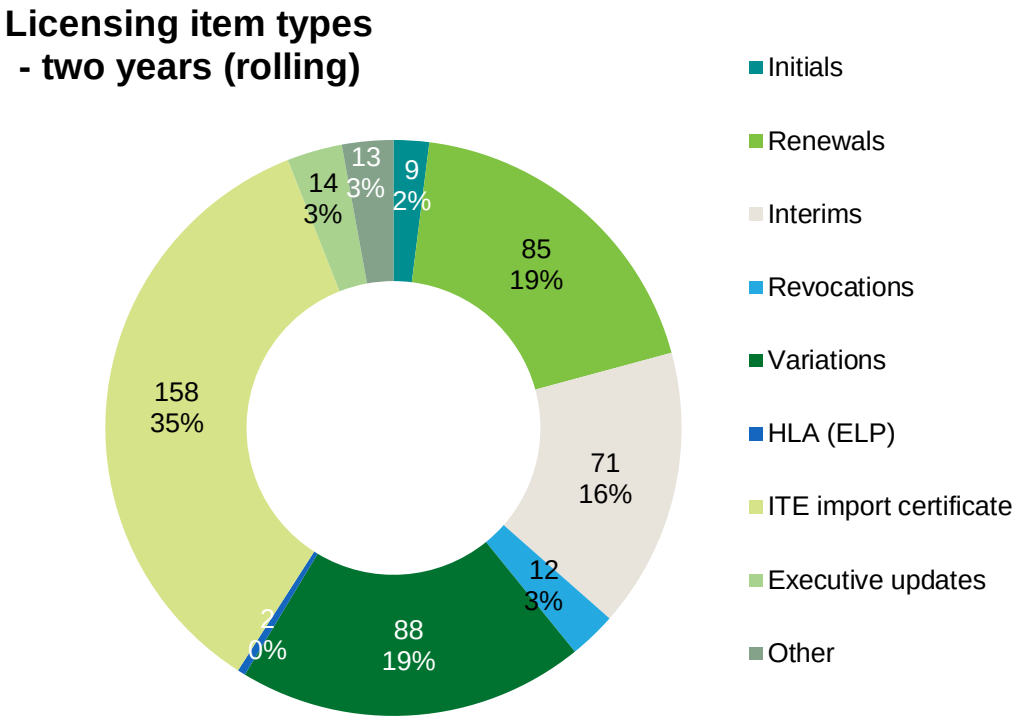
PGD types considered – trend over time: November 2017 – October 2019

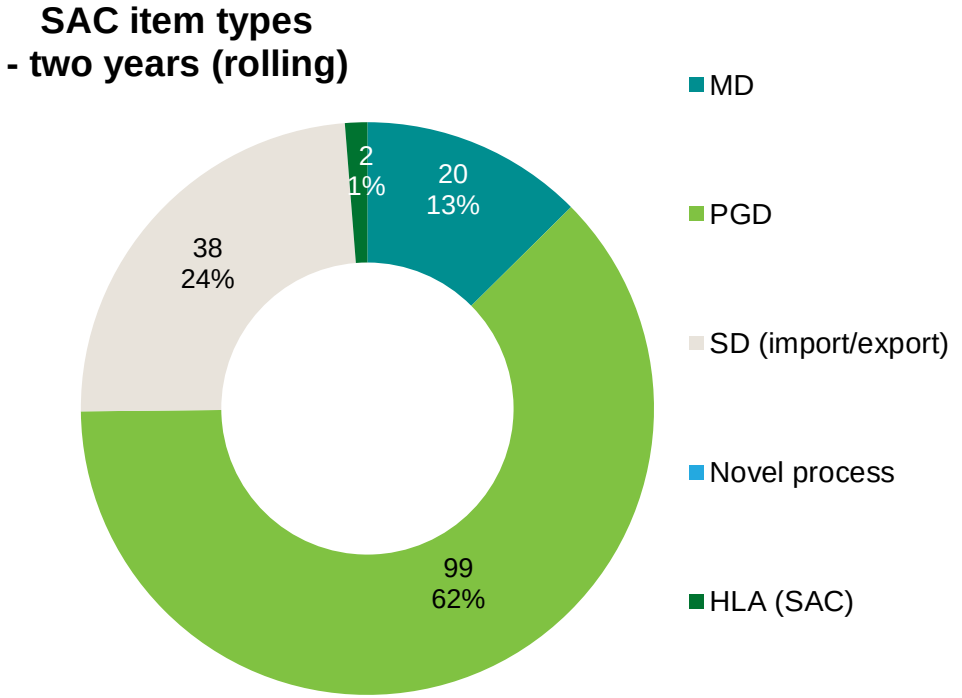


	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct
	2017		2018												2019									
No. of PGD items per meeting	5	1	6	1	5	5	4	6	5	6	5	5	4	5	2	5	6	4	3	2	4	2	5	4
No. of genetic types (OMIM)	37	2	36	1	7	28	16	9	26	38	38	6	9	11	9	11	77	4	55	16	14	9	9	29

There is continuing variation in the number of similar conditions considered with any given PGD application. We will continue to monitor this. The number of PGD applications considered at each meeting continues to vary between one and six. Special directions for import and export are generally more complex in practice (even compared to PGD items with a large number of similar types to consider) as each scenario is unique.

Item types – November 2017 – October 2019





This picture is very similar to that presented at the July and September meetings. We propose to include an annual comparison in future (when this report has been in existence for a year), to show any long-term growth or shrinkage in particular item types.

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 (13/11/2019) 931
Meeting date	13 November 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 September 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 September performance data at its 30 October 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.

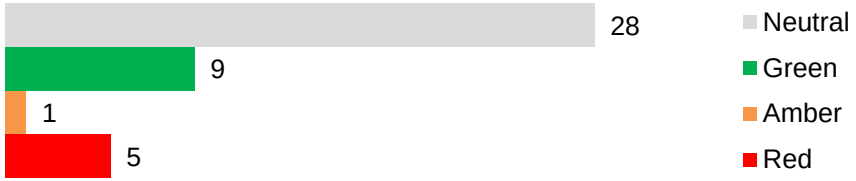
3. Recommendation

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

HFEA performance scorecard

Dashboard – September data

Overall performance – RAG status (all indicators)



People – capacity

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

⇩ Leavers: 1 (21.6%)

Engagement – Website traffic

Website sessions this month
Arrow tracks performance since last month

⇩ 56,801

Licensing end-to-end

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

⇧ 89 working days

Summary Financial Position - September 2019

	Year to Date			Full Year		
	Actual £'000	Budget £'000	Variance £'000	Forecast £'000	Budget £'000	Variance £'000
Income	**3,513**	**3,532**	**19**	**7,089**	**7,063**	**(26)**
Expenditure	**3,433**	**3,605**	**173**	**7,089**	**7,067**	**(22)**
TOTAL Surplus / (Deficit)	**80**	**(73)**	**153**	**(0)**	**(4)**	**4**

Commentary

The position as at 30 September shows a favourable variance against budget of **£153k**. This is largely due to a large variance between the budgeted legal and facilities spends and actual spend over the first half of the year.
We have undertaken a detailed review of planned expenditure over the remainder of the financial year and our forecast has been revised to include the impact of recent staff vacancies and a number of additional pressures resulting from IT projects. Overall our forecast position is to break-even. Discrepancies in the above are due to rounding.

Overall performance – September 2019

SMT reviewed the overall performance picture on 30 October. There were five red indicators. Overall, September performance was generally good. For the first time since June 2018 our performance in processing PGD applications has returned to 100% for both the month and the rolling three-month period to end September.

We have continued to see high numbers of OTR applications. This is being closely monitored so that the team can consider implications and options for handling. We are aware that we are likely to miss the 20-working day processing KPI for some OTRs in October, but applicants have been informed and delays will be managed to a minimum. We may wish to reconsider the KPI in the round if current trends continue.

Red indicators

The 5 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 September was 21.6%. This was a slight decrease from August. As we develop the new performance report for our next strategy, we will baseline this benchmark against other similar organisations.

Information

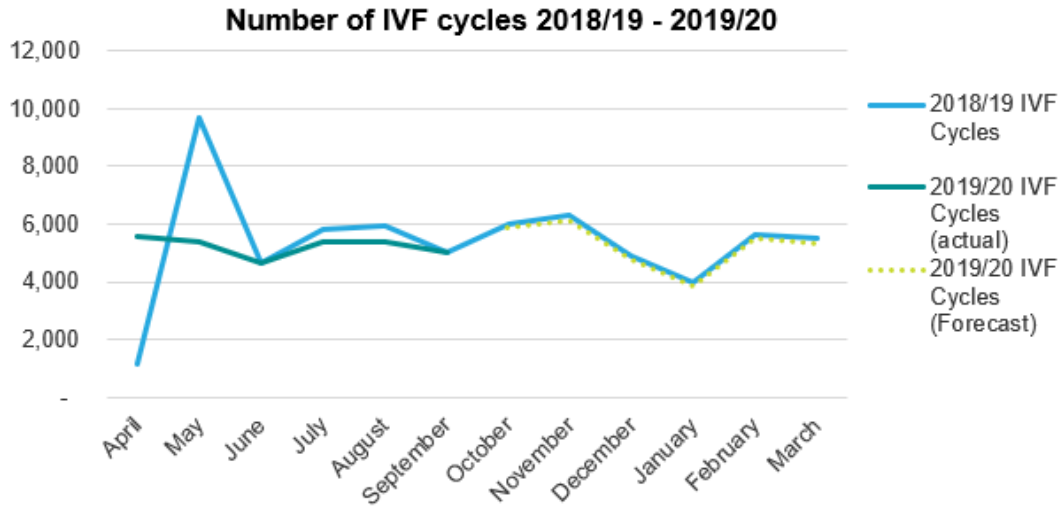
- Outstanding errors - 12 month running total. Total number of outstanding errors in the system taking into account the eight weeks centres are given to resolve (i.e., a snapshot of the number of errors that are 2 to 14 months old). Our target is to reduce the number of errors outstanding by 5%. In September the number of errors that were more than two months old was 2,906, an increase of 5.4%, so this is classed as a red. The increase in outstanding errors is believed to be due to reallocating of resources due to CAFC verification.

Inspection and licensing processes

- Average number of working days from day of inspection to the day the draft report is sent to the PR. Our target is 20 working days. In September two of the four reports sent missed the KPI and the average was 37 working days. The delay to one of the two reports was due to a complex report requiring two management reviews.
- Average number of working days taken for the whole process, from the day of inspection to the decision being finalised (signed by Chair) (including only items starting with an inspection). Our target is 70 working days, but in September the average was 89. The delay to sending reports, mentioned above, affects this KPI, but the average time to schedule reports to committees was also longer than usual at 44 working days. ELP's decision to refer consideration of one renewal application to the next available Licence Committee (LC) increased the timeframe for one report significantly because LC sit only every two months. Another two complex inspections required close supervision of centres' implementation of recommendations before the executive could form an opinion on their recommendation to present to committee.
- Average number of working days between Licence Committee date and minutes being finalised (signed by the Chair). In September the average was 21 days compared with the target of 15 working days, which was due to some particularly complex Licence Committee items leading to a longer minute writing and approval process.

Budget status – September data

2019/20 Income

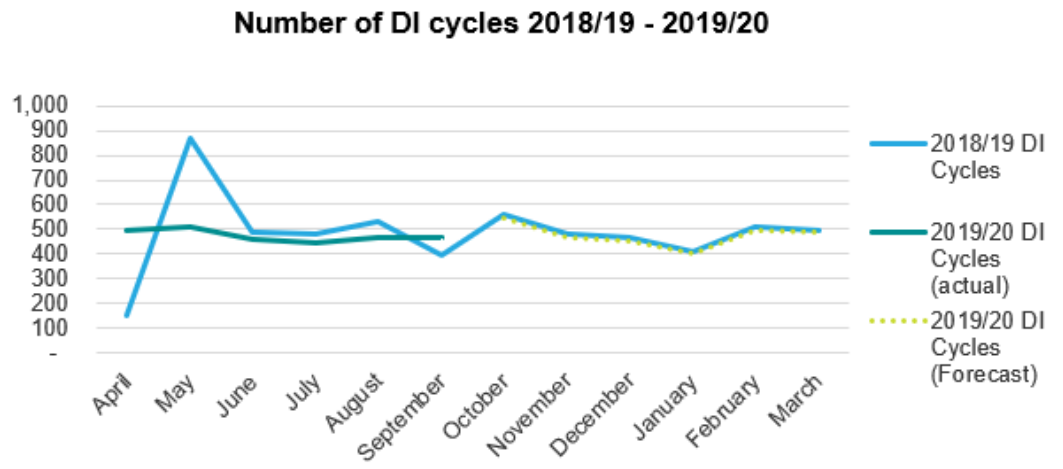


IVF Cycles

	YTD		YE Position	
	Volume	£	Volume	£
2018/19 IVF Cycles	32,332	2,586,560	64,720	5,177,600
2019/20 IVF Cycles	31,383	2,510,640	62,820	5,025,629
Variance	949	75,920	1,900	151,971

At the end of September, the number of billable IVF treatments is about 2.94% lower than the 2018/19 figures. If this trend is maintained, we could see reduction in income of c£152k compared to our initial budgeted figure.

The £ value shown in the management commentary does not translate to the volumes shown due to an adjustment to the calculation we use to estimate missing treatments (our Ether calculation). The effect will be rectified by the next quarter.



DI Cycles

	YTD		YE / Forecast	
	Volume	£	Volume	£
2018/19 DI Cycles	2,918	109,425	5,845	219,188
2019/20 DI Cycles	2,850	106,875	5,709	214,080
Variance	68	2,550	136	5,108

There is a small drop in volumes compared to 2018/19, however current forecast suggests that we should still achieve our budget.

HFEA Income & Expenditure Sep-19

	Year to Date				Full Year		
	Actual	Budget	Variance	Variance YTD	Forecast	Budget	Variance
	£'000	£'000	£'000	%	£'000	£'000	£'000
Income							
Grant-in-aid	517	467	(50)	-11%	934	934	-
Non-cash (Ring-fenced RDEL)	252	252	-	0%	504	504	-
Grant-in-aid - PCSPS contribution	50	50	0	0%	100	100	-
Licence Fees	2,615	2,688	73	3	5,400	5,374	(26)
Other Income	7	5	(2)	(46)	10	10	-
Ring-fenced and seconded income	72	71	(1)		142	142	-
Total Income	3,513	3,532	19	**1**	**7,089**	**7,063**	**(26)**
Revenue Costs							
Salaries (excluding Authority)	2,210	2,210	1	(0)	4,338	4,343	6
Staff Travel & Subsistence	86	73	(12)	16	160	144	(15)
Other Staff Costs	108	51	(57)	113	148	101	(47)
Authority & Other Committees costs	132	133	1	(1)	266	270	4
Facilities Costs incl non-cash	335	444	109	(25)	900	889	(12)
IT Costs	365	351	(15)	4	669	669	-
Legal / Professional Fees	92	201	109	(54)	375	402	27
Other Costs	105	142	37	(26)	234	249	15
Total Revenue Costs	**3,433**	**3,605**	**173**	**(5)**	**7,089**	**7,067**	**(22)**
TOTAL Surplus / (Deficit)	**80**	**(73)**	**153**	210	**(0)**	**(4)**	**4**

Management commentary

Income.
Total income is below budget by **£19k** this made up of an increase in our Grant-in-aid (£50k) relating to increased pension contributions and offsetting this is the short-fall in treatment and licence fee income of (£72k) and a small increase in other income (£3k).

Expenditure.
Expenditure for the six months of the financial year shows an underspend against budget of **£173k**. The profiling of the budget currently is not fully reflective of expenditure activity. By exception:

Staff costs - are on budget year to date, however this is due to an underspend in salaries of (£185k) against an overspend on temporary staff costs of (£184k)**.** There are pressures here relating to the costs of contractors incurred to complete the work on PRISM. These costs are being closely monitored.

Staff Travel and Subsistence and Other staff costs - are over budget by **£12k** and **£57k** respectively. Staff Travel and subsistence is over budget due to inclusion of home to office costs for the previous quarter. Other staff costs are over budget due to additional costs for essential staff training (£42k) and over budget recruitment costs (£15k).

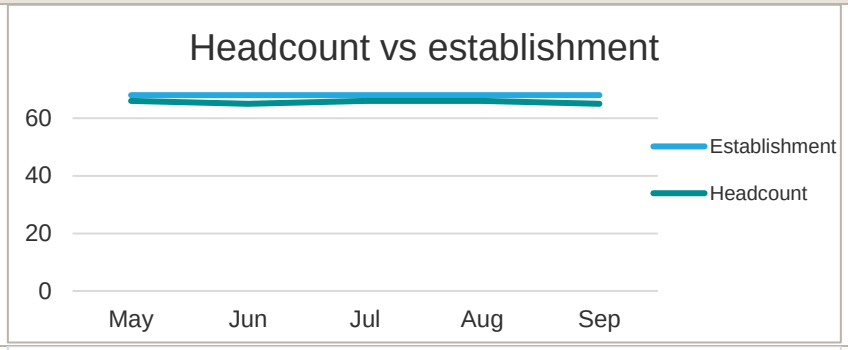
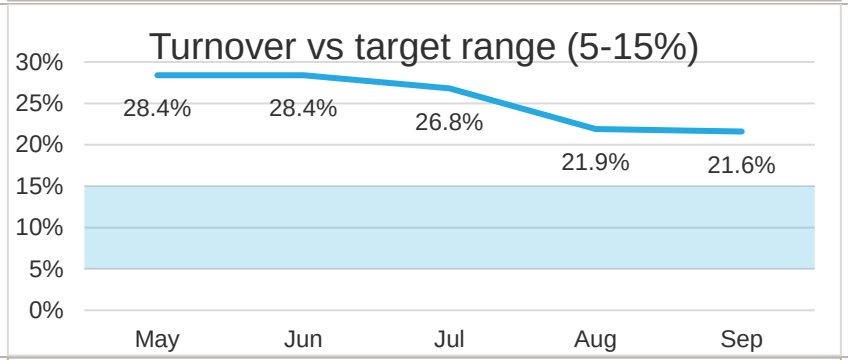
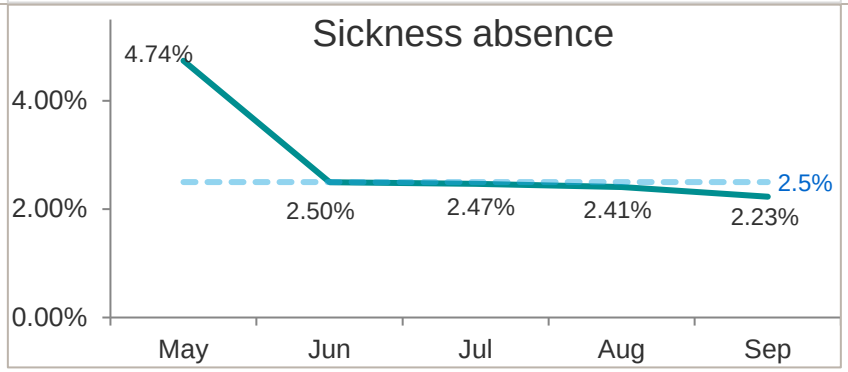
Facilities incl non-cash is under budget due to the delay in capitalisation of PRISM.

IT costs - are over budget by (£15k) which is the result of a number of minor over and underspends across the IT cost codes. We continue to closely monitor the IT Subscription costs which relate to our data storage.

Legal and Professional costs - are underspent by **£109k** is largely due to low levels of legal activity. We will continue to monitor this area over the second half of the financial year.

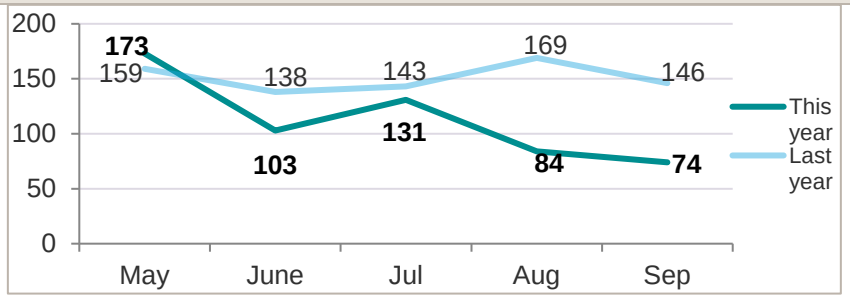
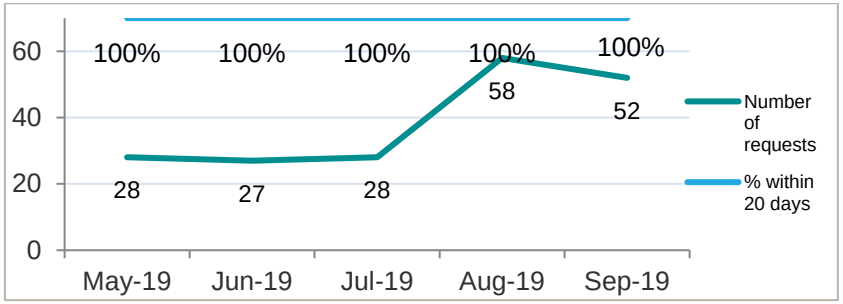
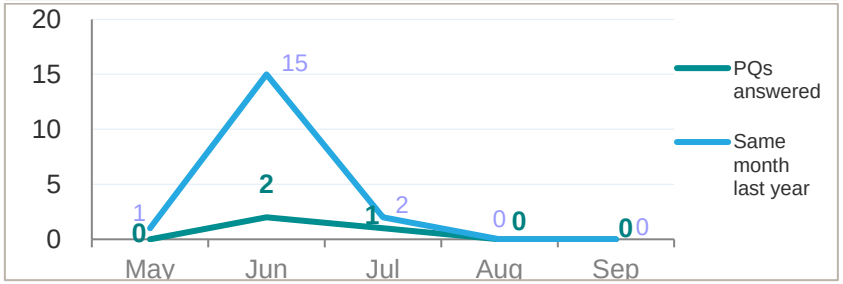
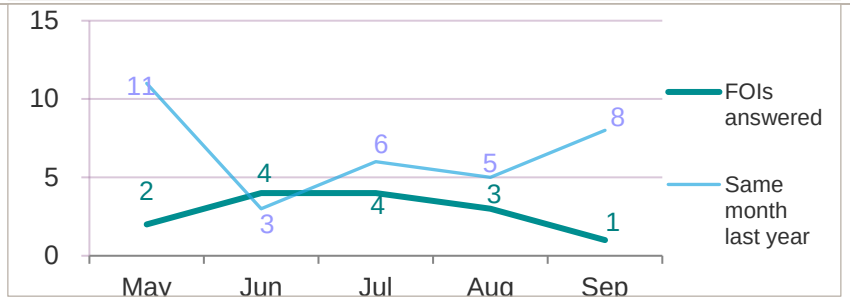
Forecast
We are forecasting break-even against budget, and are monitoring our income forecast and IT expenditure closely to ensure we deliver this forecast at year-end.

People – key performance and volume indicators

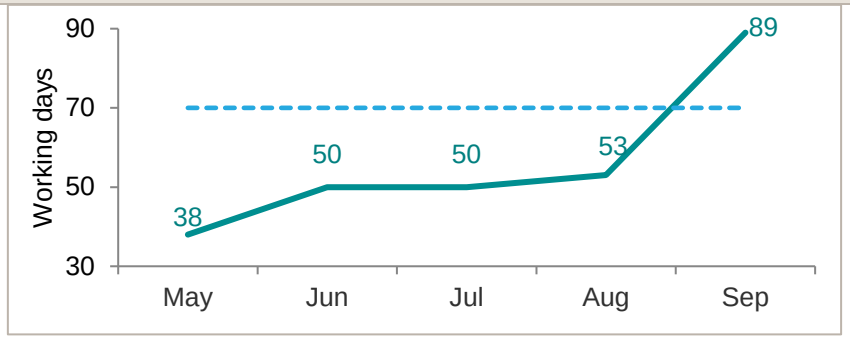
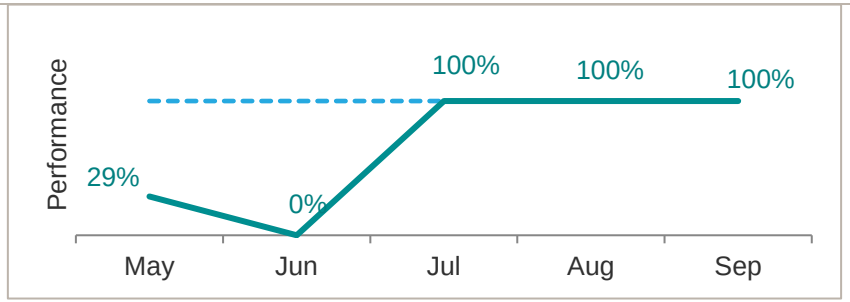
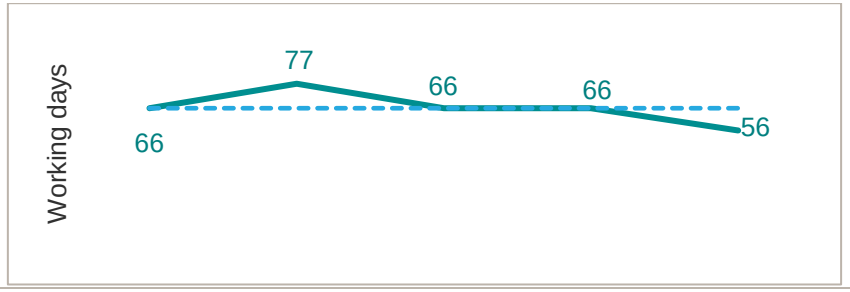
Indicator	Score	RAG	Recent trend[1]	Notes
Current headcount by month Staff in post/headcount	65/68	⇩		Overall volume (capacity) indicator.
Turnover: Establishment ('unplanned') leavers (% establishment turnover for the year). This is done monthly for the rolling year to date.	21.6%	⇩		KPI range: 5-15% 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.	2.23%	★		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

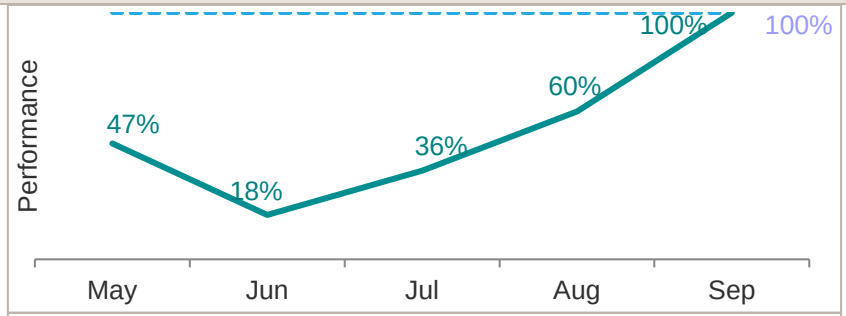
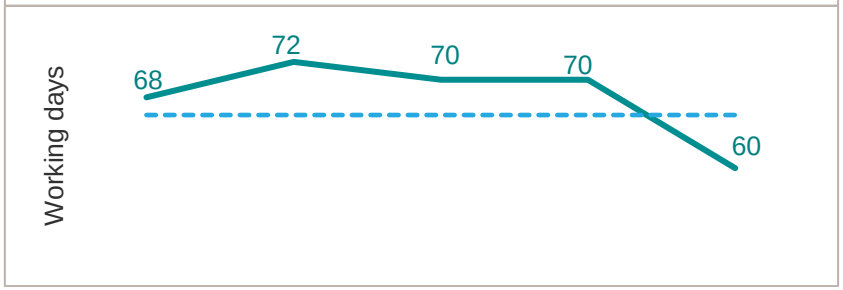
[1] KPIs, where applicable, are shown as a blue dashed line in graphs. This line may be invisible when performance and target are identical (eg, 100%). Our establishment turnover KPI is a range, which is shown as a blue band in the graph.

Indicator	Score	RAG	Recent trend	Notes
Number of emailed public enquiries received (compared with same month last year)	131	⇧		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) The increase in applications received that we reported in September has continued.
Number of requests for contributions to Parliamentary questions	0	⇔		Volume indicator.
Number of Freedom of Information (FOI) requests	1	⇩		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)	89	⇧		KPI: Less than or equal to 70 working days. See above for further commentary - additional complexity meant there were delays to processing several applications in September.
Monthly percentage of PGD applications processed within three months (66 working days).	100% (5/5)	★		KPI: 100% processed (i.e. considered by SAC) within three months (66 working days) of receipt of completed application.
Average number of working days taken (in the month).	56	★		

[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)	100% (8/8)	★		KPI: As above.
Average number of working days taken (cumulative 3 month picture).	60	★		

Strategic risk register

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

Details:	
Meeting	Authority
Agenda item	7
Paper number	HFEA (13/11/2019) 932
Meeting date	13 November 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 8 October and will review it again at its meeting on 3 December.
Organisational risk	☐ Low ☒ Medium ☐ High
Annexes	Annex 1: Strategic risk register

1. Additions to the risk register

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.

1.2. In July, SMT reviewed the strategic risks related to the organisation's office move in 2020 and given the significance of the possible impacts agreed to add a new strategic risk on estates, E1.

2. Latest reviews

2.1. 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 30 October. One of the seven risks was above tolerance.

2.2. The risk register was last discussed at AGC on 8 October. No changes were made to the risk scores at that time, although the committee requested that the Executive consider including a new risk source relating to not achieving possible capability benefits resulting from the office move and our collocation with other bodies. Any comments from the Authority will be fed into the Committee's next review on 3 December.

2.3. SMT and AGC's comments are summarised on page 27 of the risk register, at Annex 1.

2.4. Looking ahead, the process of revisiting the strategic risk register will begin once the Authority's new three-year strategy for 2020-2023 is agreed, so that it aligns with the new set of objectives. The new register will come to Authority in May 2020.

3. Recommendation

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

Latest review date – 30/10/2019

Strategic risk register 2019/20

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	⇔⇔⇔⇔
FV1: Financial viability	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	⇔⇔⇔⇔
E1: Relocation of HFEA offices in 2020	Generic risk – whole strategy	**6 – Medium**	Below tolerance	-⇔⇔⇔ New risk in July

* 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 22 July 2019⇨SMT 23 September 2019⇨AGC 8 October 2019⇨SMT 30 October 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**
4	4	16– High	**3**	**3**	**9 – Medium**
Tolerance threshold:					**9 - Medium**
Status: **At tolerance**					

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

Commentary
While planning our 2019/20 budget, we took a prudent approach, utilising our predictive model, planning based on 2% growth on the current budget rather than against the recent trend, which was 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. Increases of 6% have been confirmed to the civil service pension employer contributions, of which we have funded 2.5% within the HFEA budget with the remainder centrally funded. As this was budgeted for it does not pose a particular risk to financial viability, although there is uncertainty about the arrangement for next year and the possible impact of this. The delays in completing the data migration element of the digital projects has increased costs in 2019/20. In May 2019 the Audit and Governance Committee agreed to secure specialist data migration support to complete this work. This has come out of existing budgets and so has had a knock-on effect on other planned work. To ensure that we do not exceed our control totals with DHSC, at the end of Q2 we have reviewed the emerging situation and reprioritised 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 December 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.	Annual budgets are agreed in detail between Finance and Directorates with all planning assumptions noted. Quarterly meetings with Directorates flag any shortfall or further funding requirements. All project business cases are approved through CMG, so any financial consequences of approving work are discussed.	Quarterly meetings (on-going) – Morounke Akingbola Ongoing – Richard Sydee
Additional funds have been required for the completion of the data migration work and this will constrain HFEA finances and may affect other planned and ad hoc work.	The most cost-effective approach was taken to procure external support to reduce costs and the resulting impact. Ongoing monitoring and reporting against control totals to ensure we do not overspend. Where possible, costs have been covered by the IT budget, reducing the impact on key delivery teams and other strategic deliverables. Second quarter budgets were reviewed at CMG, to allow us to consider the impact and reprioritise as appropriate.	Procurement underway – Richard Sydee Ongoing – Richard Sydee October CMG meeting – 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 member present at Programme Board. Periodic review of actual and budgeted spend by Digital Projects Board (formerly IfQ) and monthly budget meetings with finance. Any exceptions to tolerances are discussed at Programme Board and escalated to CMG at monthly meetings, or sooner, via SMT, if the impact is significant or time-critical.	Ongoing – Richard Sydee or Morounke Akingbola Monthly (on-going) – Olaide Kazeem

Failure to comply with Treasury and DHSC spending controls and finance policies and guidance may lead to serious reputational risk and a loss of financial autonomy or goodwill for securing future funding.	The oversight and understanding of the finance team ensures that we do not inadvertently break any rules. The team's professional development is ongoing, and this includes engaging and networking with the wider government finance community. All HFEA finance policies and guidance are compliant with wider government rules. Policies are reviewed annually, or before this if required. Internal oversight of expenditure and approvals provides further assurance (see above mitigations).	Continuous - Richard Sydee Annually and as required – Morounke Akingbola
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC: Legal costs materially exceed annual budget because of unforeseen litigation.	Use of reserves, up to appropriate contingency level available at this point in the financial year. The final contingency for all our financial risks would be to seek additional cash and/or funding from the Department.	Monthly – Morounke Akingbola
DHSC: GIA funding could be reduced due to changes in Government/policy.	A good relationship with DHSC Sponsors, who are well informed about our work and our funding model.	Quarterly accountability 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**
Status: At tolerance.					

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

Commentary
This risk and the controls are focused on business as usual capability, rather than capacity, though there are obviously some linkages between capability and capacity. For 18/19 turnover was 26.8%. 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. In response, we have revised our recruitment strategy using a wider range of national and social media and recruitment agencies to improve the number and quality of applicants. This approach is having some success and we have in recent months attracted several high-quality candidates. We are also taking active steps to improve retention, focussing on things that we can control like learning and development. AGC receive 6-monthly updates on capability risk to consider our ongoing strategies for the handling of these, to allow them to track progress. Looking further ahead, we need to find ways to tackle the issue of development opportunities, to prevent this risk increasing 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.	A new Director has now been appointed and will start in the role in November 2019. In the meantime, other staff are covering elements of this role and work is being re-prioritised as required. There will naturally be a settling in period once the new postholder starts, meaning that there may be a small continuing resource pressure for a time, but given their background in the sector, they will bring valuable capabilities to the role.	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 staff intranet enables regular internal communications. Ongoing CMG discussions about wider staff engagement (including surveys) to enable management responses where there are areas of particular concern.	In place, ongoing – Peter Thompson In place – Jo Triggs In Place – Yvonne Akinmodun
	Policies and benefits are in place that support staff to balance work and life (such as the buying and selling of annual leave policy and PerkBox) promoting staff to feel positive about the wider package offered by the HFEA. This may boost good morale.	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). Work is underway to review our interdependencies matrix, which supports the early identification of interdependencies in projects and other work, to allow for effective planning of resources.	In place – Paula Robinson Matrix relaunching 2019/20 – 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
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.	Small focus groups and all staff awaydays have been utilised to make the most of staff time and involve wider staff in developing proposals. The most recent staff awayday was in July 2019 and we engaged external resources to support work on developing HFEA values and culture.	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 clear and effective onboarding methods including handover process in place.	Ongoing – 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.	See separate E1 risk for full assessment of risk causes and controls.	Early engagement with staff and other organisations underway and ongoing – Richard Sydee
Possible capability benefits of colocation with other organisations, arising out of the office move in 2020, such as the ability to create career pathways and closer working may not be realised.	Active engagement with other organisations early on. We are having wider conversations with other relevant regulators to see what more can be done to create career paths and achieve other benefits of working more closely.	Ongoing – Richard Sydee
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
Government/DHSC The UK leaving the EU may have unexpected operational consequences for the HFEA which divert resource and	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	Communications ongoing – Peter Thompson

threaten our ability to deliver our strategic aims.	earliest opportunity, to limit any impact on patients. We have provided ongoing updates to the sector. Since December 2018, we have run an EU exit project to ensure that we fully consider implications and are able to build enough knowledge and capability to handle the effects of the UK's exit from the EU, 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 exit, to ensure that clinics are adequately prepared in terms of staffing and access to equipment and materials. We continue to engage with the DHSC and clinics to prepare for Brexit. An internal working group attended by the Senior Responsible Officer (SRO) and recently appointed Deputy SRO meet weekly at this point to highlight any current or new issues and concerns and agree actions accordingly. Authority and AGC are also updated at their meetings.	

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**
Status: **At tolerance**					

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
We have undertaken 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 now underway ahead of go-live and AGC will consider the results of this at a special meeting in December. Go-live has been delayed owing to issues with data migration. Options were considered by AGC in May and revised deployment plans have been developed with delivery of the new system in Spring 2020. 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. A cyber security audit in December 2018 gave us a moderate rating 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 Deputy Chair of the Authority is regularly appraised on actual and perceived cyber risks. Recommendations arising from 'moderate' rated internal audit reports on data loss (October 2017) and cyber security (December 2018) have been actioned, with one outstanding recommendation being reported at each AGC meeting. 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 final round of penetration testing is underway 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. Our vision is to have an internal team working in partnership with a third-party software development provider. In May 2018 we awarded a contract for third-party infrastructure and development support. The service is based on the ITIL framework (IT service standard). Our strategy was to recruit to the in-house software development team following a workload review. The workload review has been completed, however during the delay to PRISM and Data Migration work, the funding for the developer post has been used for this ongoing development. Resourcing for the substantive role will be reviewed in autumn.	Approved per the ongoing business plan – Dan Howard Third-party support arrangement in place – Dan Howard Recruitment to internal development team pending – 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, updated information risk training was completed by staff during April / May 2019. Relevant and current policies to support staff in ensuring high standards of information security. 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.	In place – Peter Thompson A review of current IT policies is ongoing – Dan Howard
There is a risk that technical or system weaknesses lead to loss of, or inability to access,	Back-ups of the data held in the warehouse in place to minimise the risk of data loss. Regular	In place – Dan Howard

sensitive data, including the Register.	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. Results of penetration testing have been positive.	The new Register will be deployed once ongoing data migration issue is resolved in spring 2020 – 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 CMG reviewed the plan and agreed revisions in May. 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 System to be completed Spring 2020 – Dan Howard
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**
Status: **Below tolerance**					

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

Commentary
We accept that in a 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 and proactive 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	Ongoing – Catherine Drennan In place – Peter Thompson

	put the HFEA in the best possible position to defend any challenge.	
	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 • Regular email updates to panel to keep them abreast of any changes.	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). Changes made to licensing processes in 2019 to make it more efficient and robust following a 2018 external licensing review.	In place – 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. We have sought to build constructive relationships with legal representatives who practice in the sector and the tone of engagement	In place – Catherine Drennan, Joanne Triggs In place – Peter Thompson, Catherine Drennan

	with them means that challenge is more likely to be focused on matters of law than on the HFEA.	
	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 – Richard Sydee (BIT) / 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 are in place and regularly reviewed, committee decision trees in place. Advice sought through a 2018 Licensing review on specific legal points, and the improvements identified have been implemented where possible.	In place – Paula Robinson In place – 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 a review is planned following the new Director of Compliance and Information

		starting in post – Catherine Drennan
Legal parenthood consent cases are ongoing, and some are the result of more recent failures (the mistakes occurred 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).	The Head of Legal continues to keep all new cases under review, highlighting any new or unresolved compliance issues so that the Compliance team can resolve these with the clinic(s).	In progress and ongoing – Catherine Drennan, Sharon Fensome-Rimmer, Director of Compliance & Information
Storage consent failings at clinics may lead to diversion of legal resource and additional costs for external legal advice. We are aware of endeavours to put some test cases to the courts which may make HFEA involvement more likely.	We took advice from a leading barrister on the possible options for a standard approach for similar cases. Amendments were made to guidance in the Code of Practice dealing with consent to storage and extension of storage, this was launched in January 2019. This guidance will support clinics to be clearer about their statutory responsibilities and thus prevent issues arising in the future. Additional amendments will be made in the 2020 update. Session on storage consent provided at the Annual Conference in June 2019. Storage consent will also be covered in the revision of the PR entry Programme (PREP) in the autumn.	Done in Q1 2018/19 – Catherine Drennan Revised guidance will be provided where appropriate to clinics – Catherine Drennan Underway – Catherine Drennan/ Laura Riley
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**
Status: **Above tolerance**					

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
Data submission work continues although delivery has been delayed as described under risks above. We experienced difficulties with migrating Register data and this has delayed the launch of PRISM and the new Register. Fully developed data migration options went to AGC in May and a plan for deployment was agreed which extended delivery timeframes. These issues obviously cause a delay to accessing improved data and we consequently raised this risk in March 2019. Regular updates on this risk are provided to AGC who have oversight over the final stages of this work.

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 although deployment has been delayed while remaining data migration issues are resolved. Oversight and prioritisation of remaining development work will be through the IT development programme board with oversight from AGC.	Deployment date of data submission system planned for Spring 2020– 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 which is being followed. The migration will not go ahead until agreed data quality thresholds are met.	Deployment date Spring 2020 – Director of Compliance &

	AGC will have final sign off on the migration.	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 2020/21, we plan to establish a review board to manage any ongoing changes.	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. Our IT approach includes some outsourcing of technical second and third line support, to provide greater resilience against unforeseen issues or incidents.	Third-party support contract 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. The inspection team is now at complement although there will be a bedding in period for newer staff.	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 – Sharon Fensome-Rimmer
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 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.	Ongoing - Director of Compliance & Information
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
Since July 2019 there has been a significant increase in the numbers of OTR applications.	There is a dedicated team for responding to OTRs and all processes are documented to ensure information is provided consistently. Since July 2019, increasing demand on the OTR team has been monitored to understand whether this is an ongoing trend.	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**
Status: **At tolerance**					

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
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 the sector in place to help us to underline key campaign messages. Our 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 (although the assessment and certification scheme is being phased out). New providers are in place for the Donor Conceived Register. The executive facilitated a smooth transition of the service to the new supplier to ensure that effective information and support continued to be in place for donor conceived people.	In place and reviewed periodically (last review Jan 2019) – Jo Triggs Ongoing – Nora Cook-O'Dowd In place – Laura Riley, Jo Triggs In place –Jo Triggs Certification in place – Jo Triggs 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 have been 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. Data in CaFC has not been updated for a number of years, due to the continuation of the digital projects. This means that the data provided about success rates on our website is not current.	All staff ensure that public information reflects the latest knowledge held by the organisation. Small working group looking at any minor CaFC issues and CaFC data will be updated in autumn 2019. 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

E1: There is a risk that the HFEA's office relocation in 2020 leads to disruption to operational activities and delivery of our strategic objectives.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	4	16	**2**	**3**	**6 - medium**
Tolerance threshold:					**8 - medium**
Status: **Below tolerance**					

Risk area	Risk owner	Links to which strategic objectives?	Trend
Estates E1: Relocation of HFEA offices in 2020	Richard Sydee Director of Finance and Resources	Whole strategy.	-⇔⇔ New risk in July

Commentary
We have taken an active approach to handling this risk. The Director of Finance and Resources has been involved in discussions with the Department about the office relocation since mid-2018. The physical office build and fit-out is being handled by the British Council and the overall project managing the move of the HFEA and four other organisations is being co-ordinated by the Department of Health and Social Care. An internal project to prepare for the office move was started up in May 2019 to handle the direct impacts of the move on the organisation and ensure that we actively prepare and mitigate associated risks.

Causes / sources	Mitigations	Timescale / owner
The facilities provided in the Stratford office may not fulfil all HFEA requirements and desired benefits, such as ability to host key corporate meetings.	HFEA requirements have been specified up front and feedback given on all proposed designs. We actively engage in all external project meetings. If lower-priority requirements are unable to be fulfilled, conversations will take place about alternative arrangements to ensure HFEA delivery is not adversely affected.	Ongoing – Richard Sydee
We may be unable to recruit staff as they do not see the HFEA as an attractive central London organisation.	We will advertise the move to Stratford in all job adverts, so that applicants are aware. Monitoring of recruitment data will allow us to assess whether we are seeing any impact early on and provide an early warning indicator to enable us to consider whether other mitigations are possible. We will continue to offer desirable staff benefits and policies, such as flexible working, and will	From July 2019 – Yvonne Akinmodun

	evaluate these to ensure that they support staff recruitment and retention. Other civil service and government departments are also being moved out of central London, so this is less likely to impact recruitment of those moving within the public sector.	
Stratford may be a less desirable location for some current staff due to: • Increased commuting costs • Increased commuting times • Preference of staff to continue to work in central London for other reasons, leading to lower morale and lower levels of staff retention as staff choose to leave before the move.	Excess fares policy to be agreed to compensate those who will be paying more following the move to Stratford. Efforts underway to understand the impact on individual staff and discuss their concerns with them via, staff survey, 1:1s with managers and all staff meetings. Conversely, there will be improvements to the commuting times and costs of some staff, which may improve morale for them and balance the overall effect.	By Winter 2019 – Yvonne Akinmodun, Richard Sydee
The Stratford office may cost more than the current office, once all facilities and shared elements are taken into account, leading to opportunity costs.	Costs for Redman Place (the Stratford building) will be allocated on a usage basis which will ensure that we do not pay for more than we need or use. The longer, ten-year lease at Redman Place will provide greater financial stability, allowing us to forecast costs over a longer period and adjust other expenditure, and if necessary fees, accordingly to ensure that our work and running costs are effectively financed. The accommodation at Redman Place should allow us to reduce some other costs, such as the use of external meeting rooms, as we will have access to larger internal conference space not available at Spring Gardens.	Ongoing - Richard Sydee,
The move to a new office will lead to ways of working changes that we may be unprepared for.	Conversations about ways of working are central to the HFEA project, which started up in May 2019. Policies related to ways of working will be agreed and circulated significantly before the move, to ensure that there is time for these to bed in and be accepted ahead of the physical move. Staff will be involved in their development as appropriate. Conversations have been ongoing with the other organisations who are moving to Stratford with us, to ensure that messaging around ways of working is consistent across organisations, while reflecting the individual cultures and requirements of these.	Ongoing - Richard Sydee, Yvonne Akinmodun

Current staff may not feel involved in the conversations about the move, leading to a feeling of being 'done to' and lower morale.	Conversations about ways of working to occur throughout the project, to ensure that the project team and HFEA staff are an active part of the discussions and development of relevant policies and have a chance to raise questions. An open approach is being taken to ensure that information is cascaded effectively and staff are able to voice their views and participate. Staff will be able to visit the site ahead of time so that they feel prepared.	Ongoing – Richard Sydee
The internal move project may be ineffectively managed, leading to oversights, poor dependency management and ineffective use of resources.	Regular reporting to Programme Board and CMG to ensure that effective project processes and approaches are followed. Assurance will be provided by regular reporting to AGC and Authority. The Director of Finance and Resources is Sponsoring the project meaning it has appropriate senior, strategic guidance. A project manager has been allocated from the IT team to ensure there is resource available for day to day management of project tasks. Other key staff such as HR and representatives from other teams involved in the internal HFEA Project Board.	In place – Richard Sydee
Necessary changes to IT systems and operations may not work effectively, leading to disruption to HFEA delivery.	Early discussions with HFEA and other organisations' IT teams underway to determine IT requirements, allowing more time to resolve these. IT upgrades and improvements that were already underway or planned, such as the strategy of moving the IT estate to the cloud where possible, will mean the HFEA should be able to function even if there are IT issues affecting other systems on-site.	Ongoing - Steve Morris, Dan Howard
The physical move may cause short-term disruption to HFEA activities and delivery if necessary resources such as meeting rooms or physical assets are not available to staff.	Careful planning of the move to reduce the likelihood of disruption. Staff would be able to work from home in the short-term if there was disruption to the physical move which would reduce the impact of this.	Ongoing - Richard Sydee
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
British Council – lead on physical build – may not understand or take HFEA needs into account.	DHSC liaising directly with the British Council and managing this relationship on behalf of the other organisations, with feedback through the DHSC project board, on which the Director of Finance and Resources sits.	In place – Richard Sydee, DHSC

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

Reviews and revisions

SMT review – October 2019 (30/10/2019)

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

- C1 – noted the inclusion of a new risk area about inability to capitalise on collocation opportunities as agreed with AGC in October.
- F1 – considered the reallocation of funds and how this would impact the mitigation of legal resourcing risk. SMT noted that this has been done appropriately for the stage of the year; as there is less of the year remaining there is consequently a reduced chance of being involved in significantly resource intensive legal action within the financial year.

AGC review – October 2019 (08/10/2019)

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

- C1 – Members commented on the fact that the office move risks may exacerbate this already high risk and that we therefore needed to consider what other mitigating actions were possible in this shifting situation. This was related to the audit action for the HFEA to consider what contingency actions were possible in relation to the controls for this risk. AGC members commented on the successful appointment of a new Director of Compliance and Information, who would be in post from November.
- LC1 - Members noted that the Executive had discussed legal risk at length and was mindful that the risks in the legal area were not simply about resource diversion, but inherent legal risk was linked to regulatory processes and the risk that the organisation would be challenged on a decision. The Executive would reconsider the framing of the legal risk during the process of composing a new strategic risk register for the 2020-2023 strategy.
- E1 – AGC noted this new risk and asked the Executive to review whether the risk to achieving the benefits of co-location (ie, the opportunity for creating career pathways between organisations and closer working) could be more clearly articulated within the capability risk.

SMT review – September 2019 (23/09/2019)

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

- FV1 – SMT noted that more would be understood about the risk of financial pressures on strategic delivery following the next quarterly financial review and that the risk will be re-considered in the round following that discussion in October.
- LC1 – SMT discussed the legal risk and the ongoing lack of legal challenge. SMT considered that at the time of the next Strategic risk register being drafted (in line with the new 2020-2023 strategy), these risk sources should be reviewed in the round to consider the framing of any legal risk, which at present related to resource diversion. The Chief Executive would discuss this with AGC.
- RE1 – SMT noted that although this risk was above tolerance, due to the delays to the digital projects work, it was being very closely monitored, including with direct reporting to AGC. No further controls were proposed.

SMT review – July 2019 (22/07/2019)

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

- LC1 – SMT considered the comments of AGC and the legal risk score. SMT considered the risk and noted that there continued to be no active legal cases to which we were a party. SMT confirmed that it was happy with the assessment of controls and the rating of the risk.
- E1 – SMT considered the new office relocation risk, reviewing each control and mitigation, including interdependencies and agreed that this was a good assessment of the risk as we currently understood it. SMT noted that before the next AGC meeting in October we would have a more complete view of certain areas of this risk, such as the impact on staff, as a survey of all staff would conclude in early September.

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.

Strategy 2020-2023

Strategic delivery:	☐ Safe, ethical, effective treatment	☐ Consistent outcomes and support	☐ Improving standards through intelligence
Details:			
Meeting	Authority		
Agenda item	8		
Paper number	HFEA (13/11/2019) 933		
Meeting date	13 November 2019		
Author	Paula Robinson, Head of Planning and Governance		
Output:			
For information or decision?	For decision		
Recommendation	The Authority is asked to consider and comment on the first full draft of the HFEA's new strategy for 2020-2023.		
Resource implications	In budget		
Implementation date	1 April 2020 – 31 March 2023		
Communication(s)	The strategy will be published on the HFEA website once final.		
Organisational risk	☒ Low	☐ Medium	☐ High
Annexes	Annex A: Consultation findings Annex B: Strategy 2020-2023		

1. Introduction

1.1. Following earlier Authority discussions and a period of consultation, this paper now presents a full draft of the new HFEA strategy for 2020-2023.

1.2. This covering paper summarises the consultation findings, which are attached at annex A, and outlines the main changes made to the strategy, to reflect the consultation feedback.

1.3. The resulting revised draft of the strategy is attached at annex B. This is not the final design. The Authority's views on this, and on proposed next steps to finalise the document, are now invited.

2. Consultation findings

2.1. The majority of comments on the strategy were very supportive, and included some helpful suggestions about both implementation and drafting. Some of these have been addressed in the fresh draft of the strategy, while others are being considered as we develop our operational delivery plans for the coming three years. A full draft of the business plan for year one (2020/21) will come to January Authority.

2.2. The majority of those responding to our online survey were either fertility clinic staff, others with a professional interest in the sector, or patients. No responses were received from donors, donor-conceived people or partners. We also discussed the outline strategy with stakeholders at our regular meetings with them, and received several written responses from professional bodies.

2.3. The main consultation points that have been addressed in the new draft strategy at annex B are as follows:

- Greater emphasis on the word effective, in relation to treatment
- Recognition of donors, donor-conceived people, surrogates and professionals (as relevant)
- Clearer delineation between the two parts of the 'right information' aim
- Clearer drafting in the 'shaping the future' section to recognise that there may be other legislative changes within the next three years, eg in relation to storage duration; and to broaden the wording of the section about our future operating environment
- Other minor edits to improve wording, flow and clarity in response to queries and observations about our intended approach.

2.4. Our strategic aims were supported, and some additional themes and priorities were raised. On the whole these were either focused on matters beyond our remit, or were already consistent with the existing themes, or were detailed operational suggestions of a one-off nature.

2.5. Access and funding, often raised together, were the only real additional theme(s) that were frequently mentioned. We have previously launched commissioning guidance for fertility treatment, and our website includes a section on costs and funding, with useful links to external resources. In delivering our 'right information' ambitions, we may of course be able to expand the information and signposting in this section of the website, especially in relation to the earliest (pre-treatment) stage. While the HFEA is not directly responsible for the commissioning of services, we do think placing a strategic emphasis on equality of access may be worth considering.

3. Draft strategy and vision

3.1. In our first conversations about the new strategy, we confirmed our belief that our central vision should still be focused on high quality care. The main ideas in this strategy then emerged from further discussions about exactly what this should mean in the future. This has resulted in a draft strategy that has differences in content and focus compared to the current, outgoing strategy.

3.2. It seems appropriate to mark the transition into a new strategy with a fresh and inspiring vision statement. A vision statement should be a central and compelling idea, that is concise and memorable, encapsulating the changes we want to see in the world – how we would like things to be. The vision statement does not need to summarise the whole of the strategy, but rather should clearly signal our overall ambitions.

3.3. The following is proposed as our new vision statement for 2020-2023:

Regulating for excellence: the best fertility care, support and information

4. Recommendation

4.1. The Authority is asked to comment on the new draft of the strategy, including the vision statement.

4.2. In particular:

- Are we being ambitious enough?
- Do we have the right balance between a focus on today, and a focus on the future?
- Should we prioritise the delivery of some areas over others?

4.3. It is proposed that any editorial changes be discussed after the meeting, with a small group of members.

4.4. A final version will then be brought to the January Authority meeting for approval. We will then produce the final, fully designed, document ready for publication in April.

Annex A

HFEA 2020-2023 strategy - Consultation findings

1. Introduction

The consultation ran from mid-May until 2 October 2019. The feedback we received was fundamentally positive - people thought that these were the right areas of focus. Many stakeholders raised ideas for how we could implement things or gave thoughts on the most important work we should do.

This report summarises the findings from the survey, conversations with stakeholder groups and direct responses from organisations, drawing out key points to inform Authority's further discussions.

2. Consultation survey

The aim of the consultation survey was to seek feedback on our strategic aims and the initial work the Authority identified, from the full range of HFEA stakeholders. The survey was kept as short as possible, to maximise completion rates, and answers were mainly free-text so that respondents could provide as much or as little information as they liked.

The survey was published on our website, alongside the draft strategy outline. It was promoted on social media and highlighted to our stakeholders so that they could promote it to their networks.

During the 13 weeks the consultation survey was open we received 96 complete responses.

2.1. Who responded?

Figure 1 – Breakdown of survey respondents by type.

Type of respondent	Percentage	Number
Past, present or future fertility patients	23%	22
Those who have had or will have treatment for reasons other than infertility (eg, to freeze eggs or sperm or have embryo testing)	1%	1
A parent or family member of a donor conceived person	7%	7
Those working in a UK fertility clinic	40%	38
Those working in fertility research (data and/or clinical research)	2%	2
Representatives of a professional organisation	5%	5
Those with a professional interest in the fertility sector	14%	13
Other	8%	8
Total		**96**

Notably, we did not receive any responses from partners, donor conceived people or donors.

Those who described themselves as 'other' included four with a professional interest (such as a member of BICA), two members of HFEA staff and one who did not specify. The Donor Conception Network also responded in this category.

Ratings of strategic themes

The first question was how important the six strategic themes were to respondents personally, we asked them to rank them in order of importance.

Figure 2 – Percentages of respondents who ranked each strategic area as the most and least important to them.

Strategic area	% who ranked this as **most** important	% who ranked this as **least** important
Treatment that is ethically and scientifically robust	**41.67%**	7.29%
Improved recognition of partners' importance in the care process	9.38%	**32.29%**
Improved access to information at the earliest stage of the treatment journey	12.50%	11.46%
Patients, partners, professionals, donors, donor-conceived people, their families and the wider public to have access to high quality information (referenced elsewhere as 'people to have access…')	21.88%	8.33%
Preparing for future legislative and operational changes	9.38%	22.92%
Responding to scientific and social changes, particularly in the fields of genetics and artificial intelligence (AI).	5.21%	17.71%

There was a very strong preference overall for the aim of treatment that is ethically and scientifically robust. Meanwhile, nearly a third of respondents thought that improved recognition of partners' importance in the care process was the least important. However, there was support for all of the themes.

Those 53 individuals who identified as professional respondents (those working in a UK fertility clinic, those working in fertility research (data and/or clinical research) and those with a professional interest) had two strong preferred themes; treatment that is ethically and scientifically robust and people to have access to high quality information. The other themes were broadly ranked as equally important.

On the other hand, the 30 non-professionals had three strong preferences, treatment that is ethically and scientifically robust, improved access to information at the earliest stage of the treatment journey and people to have access to high quality information.

As per the overall rankings, improved recognition of partners' importance in the care process was ranked as the least important theme by both groups, though no partners completed the survey and we did not target them directly. Of course, in any ranking question, one theme has to come last.

What improvements did respondents want to see?

We asked for free text comments about what improvements people wanted to see in the areas most important to them. The comments we received were often general, agreeing that they were important, though we did receive some comments identifying specific improvements. Below is a summary of the types of points raised, along with some direct quotes to illustrate these.

Treatment that is ethically and scientifically robust

As the most important theme for many respondents, we unsurprisingly received many thoughts, with around a third of all respondents giving comments on this area. These ranged from very general, about ensuring the compliance of clinics, to very particular. One recurring theme was people wanting to see more done on add-ons:

> ‘A clear distinction between 'add-ons' that are non invasive and cause no harm and those that are invasive and cause harm (either physically or emotionally through a reduction in success rates)’ **Someone working in a UK fertility clinic**

> ‘No treatments offered unless they 'work' or are in active RCTs to test whether they work. No upfront patient payments for "add ons" or to take part in research.’ **A parent or family member of a donor conceived person**

The importance of scientific evidence and research (such as randomised control trials – RCTs) was stressed by other respondents, such as the following, who work in UK fertility clinics:

> ‘Focus on importance of more robust evidence, RCTs etc. Not just any data to back-up most recent technology.’

> ‘More RCT and high quality evidenced based innovation. Good sound patient information, based on research, given at the appropriate time in the treatment journey’

Several respondents reflected that managing expectations and proper patient support were important aspects of ethical treatment:

> ‘Relatively speaking success rates are fairly low and the information and preparation that patients receive should reflect this and keep a balance between hope and reality so that patients can manage their expectations.’ **A fertility counsellor**

> ‘Improved clinical honesty about fertility treatment and the odds of success. More care and support for patients and their families.’ **A fertility patient**

One respondent reflected on how the regulatory regime might support this theme:

> ‘Sensible regulation - checklist-based inspections by CQC and HFEA need to mature into partnerships to support good patient care’ **A senior NHS professional**

These comments were in line with the thoughts of the Authority and the possible pieces of work already identified under this strategic aim in the strategy outline.

Improved recognition of partners’ importance in the care process

As noted above, this theme was the least preferred and so we had only a handful of free text responses about it, but crucially we did not receive any negative responses. Respondents reflected on the importance of partners supporting patients and the fact that partners themselves needed support.

> ‘Opportunities for partners to discuss all aspects of treatment and to their voice to be heard’ **Someone with a professional interest**

> ‘Most male partners exclude themselves in the treatment journey. It is important that clinics demand spousal support and presence at the beginning of treatment’ **A fertility counsellor**

We received some feedback about what would make a difference, for instance on male fertility:

> ‘Research into the causes of male factor infertility with the aim of sparing some women from unnecessary medical treatment for a condition their partner has.’ **A fertility patient**

> ‘All clinics to ensure full detailed investigation of the male partner PRIOR to any consideration of IVF treatment. […] All partners to be offered counselling individually if required’ **Someone working in a UK fertility clinic**

Improved access to information at the earliest stage of the treatment journey

We didn't have many free text responses specifically related to this theme, the comments we did get supported the view that addressing information gaps about the nature of treatment options at the start would help patients:

> 'Improved access to detailed scientific information from early on - why different clinics have different protocols and what are the differences between these, including short vs long, standard vs mild, different stimulation medication etc.' **A fertility patient**

> 'At the starts [sic] , often you are left coming out of a consultation with more questions than answers. It would be great to create a much clearer, bigger picture of how the treatment is going to look, so we feel informed and in control.' **A fertility patient**

> 'Often people don't know the basics about why things may not work and realities about reproduction. So early access to good information is key.' **A fertility counsellor**

Patients, partners, professionals, donors, donor-conceived people, their families and the wider public to have access to high quality information

This was the theme where we received the most feedback and it came from the full range of stakeholders. Many reflected on the specific information needs of those having treatment:

> 'Accessible language: explanations should be in lay man's term so patients can fully understand them. Managing patients' expectations: making sure that patients have a realistic picture of what to expect from their cycle (especially older patients using their own eggs, either for IVF treatment or fertility preservation)' **Someone working in a UK fertility clinic**

> 'The choose a clinic feature is difficult to access, and is obviously one of the first things that patients will want to investigate. Also patients are thrown straight into 'what is IVF' but might find it useful to have a more simple explanation earlier on, for example, you will attend for tests that look for XYZ, you will discuss those results, and decide what options are right for you.' **Someone working in a UK fertility clinic**

Particular needs were identified for those undertaking or considering donor treatment:

> 'Much better info for people considering donor treatment with more about child's point of view rather than just adults' **A fertility patient**

> 'I would like to see HEFA [sic] take a leading role to advise patients (prospective and current) on the issues facing them at each stage of their journey in the context of choices made to use donors in the UK and globally. There is no overarching group that is pushing out scientific and data driven research. For example I was asked by the fertility clinic to register the birth of a donor conceived child with HEFA. And that was it. I received no acknowledgement from HEFA that this had been done, no information about what happens next, no information about critical choices to be made, no information regarding key critical dates, no information about what HEFA could do or organisations to provide support' **A parent of a donor conceived person**

Some respondents reflected on the wider context of information giving:

> 'Access to high quality information is as much the responsibility of the media as it is individual clinics and yourselves. Could you work to improve how fertility is portrayed in the media and therefore manage the expectations of patients before they even arrive in clinic.' **Someone working in a UK fertility clinic**

Some clinic respondents wanted more to be done about the information available to them, for instance:

> 'Improvements to the clinic portal access to information' **Someone working in a UK fertility clinic**

> ‘A more user friendly website. Clinic alerts based on pregnancy rates per embryo transferred or just per cycle started - seems relevant given per embryo transferred seems to be the Hfea favourite metric’ **Someone working in a UK fertility clinic**
>
> ‘A more formalised process for communication with PRs’ **Someone working in a UK fertility clinic**

Preparing for future legislative and operational changes

The nature of any possible legislative changes in the next strategic period are uncertain but a number of respondents commented on possible areas of change and how they may be handled:

> ‘Preparation for future legislative change should also be high on the agenda, particularly with discussions regarding extension of the 14-day rule on embryo research. However, it is key that any current treatment is ethical and robust- a focus on the future should not detract from a focus on current patients and treatments.’ **Someone with a professional interest**
>
> ‘Improvements in legislation around complex issues like same-sex couples ownership of embryos/donor sperm/surrogacy, particularly preparing for any situations where a relationship may break down.’ **Someone working in a UK fertility clinic**
>
> ‘Better agreement between law in practice and HFEA guidance’ **A clinical scientist**
>
> ‘Responses to, and consequences of, the results of the recent Law Commission report on surrogacy .’ **A parent or family member of a donor conceived person**

No specific comments were made about the handling of future operational changes under this theme.

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

Although, only referred to as ‘social changes’ in the strategic aim, the need to reflect changes in family creation came across in several responses, from addressing the needs of non-heterosexual couples, to those who require donor treatment or surrogacy to start a family.

> ‘Great access to tailored emotional support for all, not just heterosexual couples.’ **TwoDadsUK**
>
> ‘Intended parenthood in corps [sic] border surrogacy arrangements Artificial gametes’ **Someone with a professional interest**

Others reflected that some changes were already having an effect, such as how the availability of DNA testing is shaping the context of donor treatment:

> ‘[…] Self-DNA testing is making anonymity a thing of the past, so better to be open from the start. Most of the donors, recipients and DC children I know now, would prefer this approach.’ **A fertility patient**

Other themes and priorities raised

We asked two further ‘free text’ questions. The first was ‘Are there any other issues that you think we should address, that were not on the list [of strategic themes]?’ 28% of respondents didn’t have anything more to add, suggesting they were happy with what was included. The additional themes identified by others are explained below.

The second question ‘What do you think would make the biggest difference?’ was tailored to specific groups and aimed to get a sense of the most significant changes people wanted.

Not all of the responses to these questions related to things within our remit. For instance one respondent wanted ‘Overarching leadership from a single organisation from pre to post natal’, and others described training that should be offered to certain clinic staff. But the questions gave people the scope to reflect on what from their perspective were the most important improvements. Most of these reflect the same types

of comments described above and largely mapped to the existing strategic themes. But where these differ, they are included below.

Access and funding

Access and funding came up as significant additional themes, with around 20% of all respondents suggesting that this would make the biggest difference to the sector. People mentioned NHS funding, 'fairer access' and the 'postcode lottery' as well as how patients who don't meet access criteria are treated. One respondent asked 'what is the HFEA's strategic intent' regarding lack of funding vs. NICE recommendations.

Suggested HFEA ways of working changes

Several answers were more about how HFEA functions run, such as:

- Expand the Scientific and Clinical Advances Advisory Committee
- Inspection of counselling services in clinics should be more rigorous
- Collaborative approach to continuous improvement
- Updating the IVF success rates every 6 months
- the HFEA should have an ethics committee where decisions on more complex cases can be made away from the financial and social pressures in clinics.

3. Stakeholder groups

While the survey was open we also approached our existing stakeholder groups for feedback. We presented the strategy outline and asked for views from:

- The Association of Fertility Patient Organisations (AFPO)
- The Professional Stakeholder Group (PSG)
- Licensed Centres Panel (LCP)
- The Scientific and Clinical Advances Advisory Committee (SCAAC)

All of the groups had wide ranging and supportive conversations on the strategy content. In every case the discussion centred on how the aims would be achieved or examples of current issues in the area rather than challenging what they were. Overall, the feedback was constructive, and none of the groups disagreed with the themes or any areas of content in the outline strategy. Feedback received is summarised at a high level below.

The best care

- Ensure 'effective' is as prominent as 'ethical'
- Importance of more research and ideas about how we may encourage research to best effect
- Need to be clear that saying 'further research' is needed doesn't mean it will eventually prove treatments are effective
- Partner support, all groups were supportive
- Male infertility – lots of support that this is included and talk about good practice in andrology

The right information

- Supported the need to work collaboratively to produce information (ie, with Royal Colleges). Work done on multiple births is a good example

- Early access to information, lots of support for GP and primary care engagement and ideas for how we could go about collaboratively working to do that
- Importance of conveying facts to older women going through treatment
- Importance of the right information for those considering donor treatment and for the donor children born

Shaping the future

- Lots of interest in possible changes to legislation and the logistics of the parliamentary process for any legislative change
- Implications of access to DNA testing - donor families are reaching out to other genetic half-siblings etc very early on but without any guidance
- Potential for use of artificial intelligence in embryo grading
- Impact of GDPR and more paperless records on practice
- Lots of discussion about Opening the Register changes

4. Other professional and patient organisation responses

We received responses on behalf of seven organisations, some via the survey and others sent directly:

- The British Fertility Society
- The British Infertility Counselling Association
- Chana
- Donor Conception Network
- PROGAR (British Association of Social Workers Project Group on Assisted Reproduction)
- The Progress Educational Trust
- The Royal College of Nursing

These generally welcomed the key themes in the strategy, while in some cases suggesting specific additions or points of difference. These are listed under the headings below:

The best care

- The focus on safety and values and on partners and male fertility were welcomed. The need for emotional support all the way through the process was highlighted.
- One noted more should be done about add-ons to make the traffic lights more enforceable.
- Some specific comments on wording, stressing the need to demonstrate care is ‘values-based’ and the need for treatment to be effective and give a continuing commitment to improving the effectiveness of treatment. Also, that co-parents and known donors should be included and fertility treatment for alternative parenting referenced.

The right information

- Some particularly liked references to information needs at different stages. We had two offers of support to develop and disseminate evidence-based information for specific audiences. The importance of information for patients about the differences between own gamete treatment and donor conception so people can make informed decisions was highlighted.
- A need for clinics recommending treatment overseas to make legal differences clear.

- Comments on the groups of people included and the need to make sure it was clear that surrogates, donors and non-patient groups were important and should not be an afterthought.

Shaping the future

- Some particularly liked the recognition of direct-to-consumer genetic testing. We had a comment about raising awareness with past donors and parents of donor conceived people.
- One organisation suggested that HFEA should not lead debates but instead should facilitate and (where appropriate) engage carefully with them, to maintain the strength of our position as regulator of the fertility sector (gathering intelligence and commissioning public dialogues in the same way we handled mitochondrial donation).
- Comment about the impact of current storage duration regulations on those seeking to preserve their fertility for non-medical reasons and a desire for us to explicitly mention this.
- We had a couple of comments on consent, including a desire for us to do more about documenting consent to legal parenthood for persons using donor sperm and the variation in clinic consent forms.

Human Fertilisation & Embryology Authority

Annex B:

HFEA Strategy

2020-2023

www.hfea.gov.uk

Contents

Vision and overview

Our vision is…

Regulating for excellence: the best fertility care, support and information

The interests of all who use fertility services - patients, their partners, donors, donor-conceived people and surrogates - are at the heart of everything we do. In 2020 to 2023, we are focusing on ensuring they all receive excellent care, support and information.

Our responsibilities also extend to the clinic staff and researchers we work with, regulate, and provide advice and support to.

All users will have different experiences based on their individual circumstances and goals, but our focus will be on the provision of the best possible, most effective care for every individual, ensuring people can access the right information at the right time, and on our own role in shaping and responding to future changes in science and society.

We will achieve our ambitions, summarised in the figure below, by being an effective regulator.

The best care	The right information	Shaping the future
Effective, evidence-based, high quality care	The right information at the right time	Facilitating debates on changes in science, law and society
Ethically and scientifically robust	Improved information at the very beginning	Preparation for future legislative and operational changes
Improved recognition of partners in the care process	Access to useful and impartial information for all	Proactively responding to developments in the fields of genetics and artificial intelligence

Engagement, partnering and collaboration

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

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

Engagement with fertility clinics is about much more than satisfying the requirements of the compliance regime. We know that we achieve our best successes when we involve the sector and the professional bodies working within and around it.

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

Through dialogue and joint working with other bodies, we also want to improve the accessibility and positioning of accurate and timely information about fertility issues and fertility treatment.

Therefore, this will be a key way of working for us in delivering our strategy for 2020-2023.

The best care

Aim: That everyone receives effective and ethical care.		
Objectives	**We want**	**We will**
Treatment that is effective, and both ethically and scientifically robust.	Individualised care that is safe, responsible, consistent and based on clear values.	Regulate effectively and transparently, and provide clinics with more comparative information about performance, to drive improved care. Use our data to explore variations between clinics (eg, for success rates, and levels of compliance) and collaboratively define best practices.
	Clinics that are well led and see compliance as good business and part of high-quality care.	Continue our dialogue with clinic leaders, engaging with a representative cross-section of the sector (NHS and private clinics, including groups).
	A transparent and accurate evidence base, to ensure that patients can make informed choices about their treatment. More research and innovation to improve the evidence base and outcomes.	Work collaboratively to encourage and support more clinical and data research, including the usage of our Register data. Encourage clinics to use add-ons responsibly.
Improved recognition of partners' importance (of the same or opposite sex) in the care process.	Partners to be involved in care and treatment choices throughout the process. Clinics to recognise that partner care is a core part of the service they provide.	Focus strongly on the provision of improved information for, and care of, partners by clinics. Highlight accurate 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 (pre-treatment) stage.	Right-moment information provision from the outset for patients, partners, donors and surrogates.	Create new information flows to support and engage with GPs, practice nurses and patients. Work in partnership with key organisations such as the Royal Colleges to develop or link to materials for primary care professionals to help them access key knowledge to help them guide patients. Develop materials to support people in making early decisions about treatment, donation and surrogacy.
High quality information to support decision-making during and after treatment or donation.	Patients, partners, professionals, surrogates, donors, donor-conceived people and their families all to have access to relevant and impartial information.	Position and promote our information so it is easy to find by everyone including professionals. Publish more information about the evidence-base for treatments and add-ons. Keep our information up to date so that it explains any new treatment options.
	People to be supported all the way through their journey.	Continue to focus on the support patients, partners, donors, donor-conceived people and surrogates receive at all stages of care.

Shaping the future

Aim: To be ready for any changes in law, science and society.		
Objectives	**We want**	**We will**
Preparing for future legislative and operational changes.	To ensure the HFEA and clinics are prepared for future changes in the fertility field, and for any legislative changes.	Prepare to inform any future Parliamentary and public debate and implement any agreed changes. Be responsive to the changing nature of patient and public concerns. Work with the sector to ensure preparedness for ensuing changes.
	To be a modern effective regulator and continue to respond to changes in our operating environment.	Respond to changes such as the growth in donor-conceived people eligible to make 'opening the register' (OTR) requests from 2021 and 2023.
Responding to scientific and social changes, particularly in modern family creation and the fields of genetics and artificial intelligence (AI).	Diverse fertility service users and professionals to have information that is up to date and relevant on developments such as genome research and editing, DNA tests and screening, home genetic testing and AI. To be ready to respond to increasing numbers of complex PGD applications, and potentially more patients without fertility issues being treated in clinics.	Engage with and facilitate debates within the fertility sector on emerging topics, working in partnership with relevant bodies, and providing up-to-date information. Recognise scientific and societal changes, and integrate these into our work and the information we publish.

10 Spring Gardens
London
SW1A 2BU
T 020 7291 8200
E enquiriesteam@hfea.gov.uk

Opening The Register annual report

Strategic delivery:	☐ Safe, ethical, effective treatment	☒ Consistent outcomes and support	☐ Improving standards through intelligence
Details:			
Meeting	Authority		
Agenda item	9		
Paper number	HFEA (13/11/2019) 934		
Meeting date	13 November 2019		
Author	Sumrah Chohan, Donor Information Manager		
Output:			
For information or decision?	For information		
Recommendation	The Authority is asked to note: • the update on OTR activity and performance; • the supportive way in which OTRs are handled by the team; • the level of applications in 2018 and the early indications of further increases received during 2019; and • the planning underway to cope with any potential further increase in applications following donor anonymity changes in 2005		
Resource implications	Within budget at present. Additional budget likely to be required to accommodate future increase in coming years		
Implementation date	OTR service ongoing		
Communication(s)	OTR service on website		
Organisational risk	☐ Low	☒ Medium	☐ High

1. Introduction

1.1. For some years now, we have provided the Authority with an annual report on the number and type of donor information requests (known as Opening the Register (OTR)) and associated counselling support. This paper updates the position to cover activity in 2018.

1.2. Improvements have been made to the OTR service during 2019. This paper provides an overview of those changes and their impact.

1.3. OTR activity has increased in recent months. This paper includes an overview of the increase along with steps taken to manage the increase.

1.4. The law regarding donor anonymity changed in 2005. We believe this will result in an increase in OTRs from early 2022 and 2024, when donor conceived individuals reach 16 and 18. This paper sets out planning underway to estimate how we will support a greater number of applications in the future.

2. Background

2.1. The Human Fertilisation and Embryology Act requires the Authority to keep a Register of information about donors and treatments involving the use of donor gametes and embryos in the UK. It also records the notified births resulting from these treatments.

2.2. Donor-conceived people and donors have a statutory right of access to information held on the Register as follows:

- 16-year-old donor-conceived people can find out:
  - if they are donor-conceived
  - non-identifying information about their donor
  - the number, gender and year of birth of any donor-conceived genetic siblings
  - if their donor has removed their anonymity (since 2005)
  - if they might be related to an intended spouse or partner
- 18-year-old donor-conceived people can find out:
  - identifying information about their donor (if the donor is identifiable)
  - identifying information about their donor-conceived genetic siblings, if both sides consent (via Donor Sibling Link (DSL))
- Donors can:
  - find out the number, gender and year of birth of any children conceived from their donation
  - remove their anonymity - which is relevant to those who donated before the law changed on 1 April 2005

2.3. Parents have no statutory rights to access Register information although in 2004 they were granted discretionary access rights to the following information:

- non-identifying information about their donor
- the number, gender and year of birth of any donor-conceived genetic siblings
- if their donor has removed their anonymity (since 2005)

2.4. As noted above, applications by donor-conceived people, donors and parents for Register information are known as Opening the Register (or OTR). The HFEA has had a process in place for dealing with OTR applications by parents and donors since 2005, and donor-conceived people since 2007 (when the first cohort of donor-conceived people on our Register turned 16). Up until July 2019 the process ran as follows. Applicants submitted the relevant application form with proof of identity and address by post to us. We then returned their identity documents within 5 working days and responded to their application within 20 working days – both by special delivery post. We retained a copy of their identity documents for 5 years to enable applicants who wish to re-apply for updated information at a later date to do so with more ease.

2.5. The OTR service is provided primarily by a small dedicated team (the Donor Information Manager and Donor Information Officer). All OTR staff have completed a 30-hour Introduction to Counselling Skills course. In addition to counselling skills training, the Donor Information Manager regularly attends relevant conferences and has also delivered presentations at various national events to highlight the importance of issues affecting donor conception and to build good working relationships with clinics and the sector.

3. HFEA strategy 2017-2020

3.1. The HFEA strategy 2017-2020, puts patients (including donors and donor-conceived people) and the quality of care and support they receive at the centre of our work. The following elements are relevant to this paper:

Vision: High quality care for everyone affected by fertility treatment

- Improve the emotional experience of care before, during and after treatment or donation
- Donors, parents and donor-conceived people to understand how their information is stored and how they can access it

What we will do:

- Focus efforts on support before, during and after treatment for patients, donors and donor-conceived people
- Make excellent support a core message

3.2. The OTR service is fundamental in the achievement of these strategy objectives. The continued dedication to ensure all OTRs are handled to the highest quality and care contributes further to this aim.

4. Support and intermediary service

4.1. In March 2014, as part of its commitment to providing improvements to the levels of support offered to people affected by donation, the Authority agreed a three-year 'pilot' service to provide enhanced support services at a national level. The contract to do so was awarded to PAC-UK in 2015, an adoption support agency with relevant expertise and suitably qualified staff. The contract with PAC ended in April 2019 and was awarded to Hewitt Fertility Centre as part of the contract to run the Donor Conceived Register (see section 6)

4.2. We currently fund a limited number of 1-hour contact sessions, which can be delivered flexibly, for:

- adult donor-conceived people who have or are considering applying for identifying information about their donor; or are considering joining DSL and making contact with their donor-conceived sibling(s)
- donor-conceived people over the age of 16 who have or are considering applying for non-identifying information about their donor
- donors considering re-registering to be an identifiable donor
- donors who are aware that an adult person conceived from their donation has applied for their identifying information
- we have also offered services to some donor-conceived adults who have found out they are donor-conceived via DNA testing websites and donors who may have accidently been matched with people conceived from their donation
- donor-conceived people and donors considering joining the Donor Conceived Register

4.3. For the duration of the service provided by PAC-UK, 74 referrals (out of which 25 were made in 2018) were made to the support service:

- 30 were for donor-conceived adults who have applied for information about their donor and any donor-conceived siblings
- 10 were for donors considering removing anonymity
- 5 were for donors where their identifying details have been requested by people born as a result of their donation
- 5 referrals were made for a donor-conceived individual who found out they were donor-conceived via a DNA website
- 1 referral was made for a parent who suspected that they had found out the identity of their donor
- 1 referral was made for the donor where the parent had found out their identity
- 9 were made for donor-conceived people who had matches on Donor Sibling Link
- 9 were made for people considering joining Donor Sibling Link
- 4 were made for other reasons where we felt support was needed

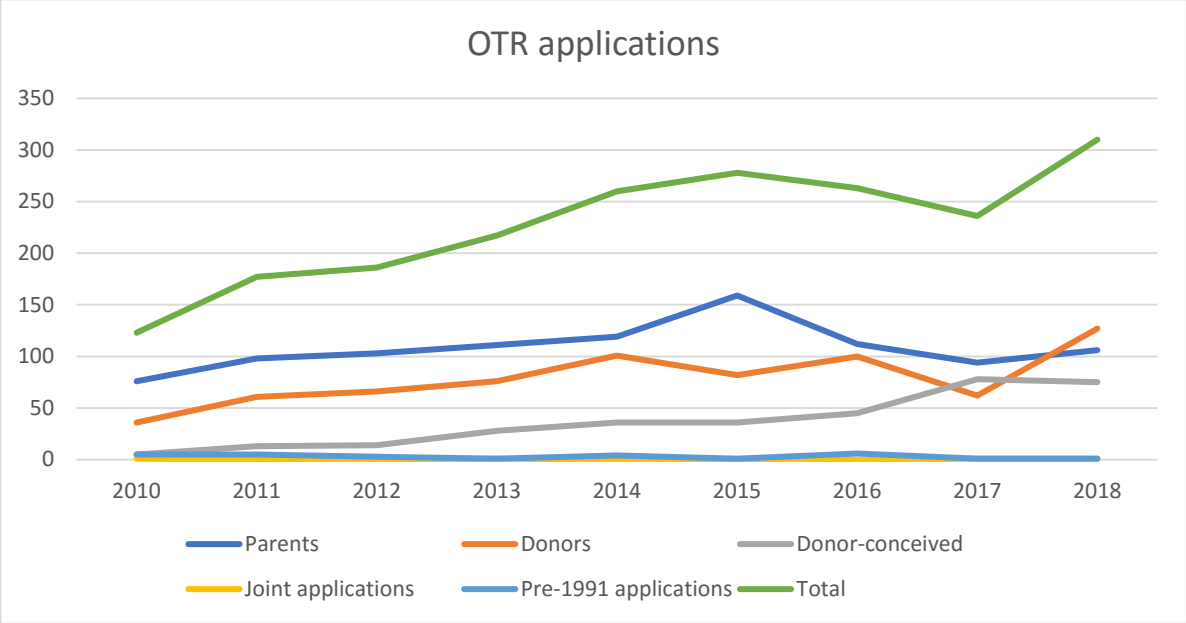
4.4. We surveyed service users as to their experience of the support service. All respondents rated the service as good or excellent, and all had appointments arranged within a week of the service user contacting the support service.

5. Performance

5.1. The number of OTR applications we receive is unpredictable but is driven by two principle factors: the increase in the number of donor treatments over time (which gives rise to more donors and donor conceived people who might wish to use the OTR service) and a greater openness among families (which gives rise to more donor conceived children being aware of their background). The rise in popularity of commercial direct-to-consumer DNA testing websites has also added to the rise in applications (though the number is difficult to quantify because we only have anecdotal evidence from some applicants).

5.2. The table below shows the trend in applications since 2010. That trend was steadily upwards until 2016; there was a slight dip in 2017, however the figures for 2018 show a 30% increase in the number handled compared to that year. This is largely a result of a doubling in applications from donors. Anecdotal information also suggests that there has been an increase in applicants who have used direct-to-consumer DNA testing websites with the aim of understanding genetic backgrounds.

	2010	2011	2012	2013	2014	2015	2016	2017	2018
Parents	76	98	103	111	119	159	112	94	106
Donors	36	61	66	76	101	82	100	62	127
Donor-conceived	5	13	14	28	36	36	45	78	75
Joint applications	1	0	0	1	0	0	0	1	1
Pre-1991 applications	5	5	3	1	4	1	6	1	1
Total	123	177	186	217	260	278	263	236	310



5.3. As of the end of 2018, 193 donor-conceived people had joined Donor Sibling Link, our voluntary contact register where people join to make contact with their donor-conceived genetic siblings. 35 registrants joined in 2018 which is a slight decrease compared to the 41 who joined in 2017, however this is in line with the slight decrease in the number of OTR applications we have received from donor-conceived people. We expect numbers to grow as we approach the 18-year anniversary of the lifting of anonymity in 2023. The first Donor Sibling Link match was made in 2015, with a further four matches in 2016 and four in 2017. Two matches were made in 2018. In each case, support and intermediary assistance is offered.

5.4. As of the end of 2018, 182 applications from donors wishing to remove their anonymity were received. These donors donated after the HFEA was set up and before the change in law in April 2005 whereby all donors would be identifiable to their donor-conceived once they turned 18 years old. We received nine applications from donors to remove their anonymity in 2017 and 11 in 2018. This change will take effect from early 2024 and it may prompt interest from such donors to remove their anonymity. We will be taking this into account when planning for the future.

5.5. The first application for identifying information to be released to an adult donor-conceived child was received in 2013. In total, we have received 14 applications of this kind, with three applications being received in 2018. 11 applicants have proceeded with receiving the identifying information, with the remainder deciding not to proceed with their application. In each case, support and intermediary assistance was offered where desired to the donor and donor-conceived person involved.

6. Recent updates to the OTR service

6.1. In July 2019, in response to feedback from users of the service who had expressed concern at sending in confidential documents in the post, we implemented an easier way to submit OTR and

Donor Sibling Link applications online via DocuSign. DocuSign is a safe online electronic portal for applicants to complete the application and upload supporting identity information securely. It allows a full audit trail, an electronical signature, secure electronic document storage and the ability for individuals to complete an application wherever and whenever they choose. A full privacy impact assessment was conducted ahead of its implementation.

6.2. Applicants are now given a choice of choosing between applying online or sending in a paper application. Online applications are received via email by the team and actioned in the same way as paper applications. The feedback we have received about the new online application system has been very positive.

6.3. Donors wishing to re-register as identifiable are still required to send in their applications via post due to the nature of the applications such as the added handwritten goodwill messages that are submitted.

6.4. To date we have received 70 more OTR applications in 2019 than for the same period in 2018. Whether this is a result of making the application process more accessible and easier is difficult to quantify but since then we have seen the number of applications received increase from around 24 in June 2019 to 52 in September 2019.

6.5. We do not yet have enough information to conclude whether this increase is temporary or the new normal, or indeed whether it will increase further. We will monitor application numbers on a monthly basis over the next 3 months and make any service changes necessary to meet the increase in demand (see section 7).

6.6. As noted above (see section 4), the contract that PAC-UK held to run the support and intermediary service ended in April 2019. To ensure sustainability, the support service contract was included within the Donor Conceived Register (DCR) service. The new three-year contract was awarded to the Hewitt Fertility Centre, a long established HFEA registered organisation providing services to NHS and private patients, in March 2019. (See paper HFEA (13/11/2019) 935 for further details.)

7. The future of the OTR service

7.1. As noted above, the first cohort of adult donor-conceived people whose donors donated after the change in law regarding donor anonymity turn 18 in 2023. This, coupled with the recent increase in the number of OTR and Donor Sibling Link applications referred to above, means that we need to plan for the future. The current OTR team comprises two members of staff. They are presently at full capacity and we need to look seriously how we can manage the workload now and to plan for further increases over the coming years.

7.2. As a first step we have reviewed the current service to see whether there is room to streamline the service without compromising quality

7.3. As per the HFE Act, the Authority is required allow access to information from the Register for donors and donor-conceived people. We have reviewed the current information we provide under our OTR service and we are currently providing the minimum information required.

7.4. Currently, all OTRs have a deadline of 20 working days. As part of the process involves our checking that the information about all the instances in which the donor was used with the fertility clinic that registered the donor, we must allow the clinic a certain amount of time to check this information, and to answer any queries.

7.5. We have considered increasing the deadline, and while this would take some of the pressure of work off at a given time it would not solve the problem as there would simply be more OTRs in process with the same time needed to complete the different stages. Extending the 20 working day deadline could also result in negative feedback from some service users who have in the past expressed concern about the time to wait for information of such a profound nature.

7.6. As a second step, we are looking at training other members of staff to help out in particularly busy time.

7.7. Going forward, with the rise of the increase in people wanting to know more about their genetic makeup via direct-to-consumer DNA testing websites, the accessibility of these services and as we approach 2023, we need to plan to ensure we have enough resource in place.

7.8. During the next 12 months we will review the OTR and DSL process to estimate the time required to complete a typical application. We will then review past, current and expected future OTR activity to better estimate the future demands on the service. Taken together we then expect to be able to make some informed resource decisions about the staffing required to cope with an increase in applications resulting from donor anonymity changes in 2005 and in line with our new 2020-23 strategy.

8. Recommendations

8.1. **The Authority is asked to note:**

- the update on OTR activity and performance
- the supportive way in which OTRs are handled by the team
- the increase in the number of applications received during 2019 and
- potential further increase in applications from 2024 following donor anonymity changes in 2005

9. Recommendations

9.1. The Authority is asked to note:

- the update on OTR activity and performance
- the supportive way in which OTRs are handled by the team
- the increase in the number of applications received during 2019 and
- potential further increase in applications from 2024 following donor anonymity changes in 2005

Donor Conceived Register

Strategic delivery:	☐ Safe, ethical, effective treatment	☒ Consistent outcomes and support	☒ Improving standards through intelligence
Details:			
Meeting	Authority		
Agenda item	10		
Paper number	HFEA (13/11/2019) 935		
Meeting date	13 November 2019		
Author	Dan Howard, Chief Information Officer		
Output:			
For information or decision?	For information		
Recommendation	The Authority is asked to note: • The update on progress to establish a new improved Donor Conceived Register service • The outcome of the tender process and commencement of the new service • The arrangements for monitoring the new service		
Resource implications	None, within budget		
Implementation date	From October 2019		
Communication(s)	Website and social media channels		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	None		

1. Introduction

1.1. Donor Conceived people are important to the HFEA and the Authority received the last update on the development of a new vision and approach for the Donor Conceived Register service in March 2018.

1.2. Our aim was to implement a stable, long term and high-quality service, developed in partnership with the DCR panel. At the time we took the opportunity to review the service and concluded significant improvements could be made regarding quality of DNA testing, turnaround times, availability of support, and data security.

1.3. This paper is for information only and it provides the service outline, details of the tender process followed and describes how the new arrangements are being monitored to ensure it delivers or exceeds improved service standards.

1.4. The DCR enables people conceived through donated sperm or eggs, their donors and siblings to identify each other through DNA matching. Where they wish, they are able to use the contact register to contact each other. The register is intended for use for anyone who donated or who was conceived before August 1991 (i.e. before the HFEA was established). The DCR also includes a small number of those conceived after August 1991 who may have siblings on the register. Around 400 people are registered on the DCR, on-line forum exists via social media and members are invited to meet around twice a year (in practice a meeting might typically involve 10-20 people).

1.5. In April 2017, at the request of the Department of Health, responsibility for the DCR transferred from the DH to the HFEA. At that time the DCR was serviced by the National Gamete Donation Trust under a rolling 12 month contract. That contract ended on 31 March 2019.

1.6. Since the last Authority update in March 2018, we have successfully awarded the contract to the Hewitt Fertility Centre in Liverpool. The tender additionally includes provision for the OTR emotional support and contact-making intermediary service for individuals who wish to access information from the HFEA Register (known as an ‘Opening the Register request’ (OTR).

2. Service outline

2.1. The DCR service comprises of three main parts a) administration, b) DNA testing and matching, and c) counselling.

2.2. Administration includes provision of advice and guidance, co-ordination of DNA test results, maintaining the register, processing results and supporting the DCR registrants’ panel meetings. DNA testing includes sampling to industry standards and holding securely the DNA data associated with this and DNA matching.

2.3. Specialist counselling is provided before, during and after DNA testing and matching, usually by telephone.

2.4. The service operates as follows:

- Registrant joins the DCR and requests the DNA test via the administrative support service. Advice and guidance is provided by the admin service, as is specialist counselling. The administrative support service is responsible for maintaining the register
- The DNA test takes place and the information is checked against the DC register – for example whether a link exists and the quality. The administration service then communicates the outcome, along with the options the registrant has for sharing contact details relating to the link(s). Counselling is offered throughout the process

3. Tender award and performance review/management

3.1. We contacted organisations within the fertility and adoption field to invite expressions of interest. Several organisations expressed an interest and were invited to tender based on their capability to provide the DCR service along with the counselling support service for the DCR and OTR service.

3.2. Following a robust scoring process including telephone interviews we awarded the contract to the Hewitt Fertility Centre. We immediately worked with our specialist legal advisors to support the Hewitt Fertility Centre to put the correct information governance controls in place with respect to consent, data transfer, privacy notices and starting the new service.

3.3. During the transition phase counselling sessions continued to be provided by the post adoption agency ensuring registrants' support needs were met.

3.4. The new contract formally started on 1 October 2019. During the transition phase we have also supported the specialist training of counselling staff.

3.5. Not all aspects of the new service are in place yet and it is our intention for the service to deliver all aspects by the end of November 2019. The contract will deliver many improvements over the previous service, namely the quality of DNA testing, turnaround times, availability of support, and data security. The registrants' panel continue to be kept updated on progress.

3.6. We will regularly monitor service performance and customer satisfaction to ensure the new service delivers the service standards we are seeking and exceeds its vision of a stable, long term and high-quality service.

4. Recommendation

4.1. The Authority is asked to note:

- The update on progress to establish a new improved Donor Conceived Register service
- The outcome of the tender process and commencement of the new service
- The arrangements for monitoring the new service

Update on Storage Consent

Strategic delivery:	☒ Safe, ethical, effective treatment	☒ Consistent outcomes and support	☐ Improving standards through intelligence
Details:			
Meeting	Authority		
Agenda item	11		
Paper number	HFEA (13/11/2019) 936		
Meeting date	13 November 2019		
Author	Catherine Drennan, Head of Legal		
Output:			
For information or decision?	For decision		
Recommendation	Approve		
Resource implications	Ongoing resource to support application of Regulations and improve sector awareness		
Implementation date			
Communication(s)			
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: Name Annex 2: Name		

1. Background

1.1. The Human Fertilisation and Embryology Act 1990 (as amended) ('the Act') requires that gametes and embryos can only be stored for a specified period and with the patient's consent. When that consent lapses, for some patients the decision to let embryos perish is one that they are comfortable with; for others it causes great upset. Over the last few years the HFEA has received an increasing number of enquiries from clinics that have gametes or embryos in storage in relation to which there is no longer valid consent for storage.

1.2. What do we mean when we say, 'no longer valid consent for storage'? This refers to one of two scenarios. The first scenario is where a patient has given consent to storage of his or her gametes or embryos for any period less than the statutory maximum of ten years, but that consent period has lapsed. The second scenario is where the patient has given consent to storage for the statutory storage period of ten years, but that ten-year period has lapsed.

1.3. In both scenarios, clinics have stored gametes or embryos after consent has lapsed i.e. there has been a gap when consent was not in place, yet in most cases, patients wish to continue storing. This gives rise to several complex questions including whether storage can lawfully continue in the UK after a period of unlawful storage and questions around compliance with the regulations that allow for storage beyond 10 years.

1.4. Most of the cases in which the HFEA has been approached for assistance have been capable of resolution, some more readily than others and some with considerable cooperation from clinics, though not always. The commonality in all these cases is their complexity and the need for very considered analysis of the facts and careful application of the law.

1.5. As members of the Statutory Approvals Committee will be aware, those cases in which a resolution has not been possible such that storage could continue in the UK, clinics have made application for a Special Direction to export the gametes or embryos. Clearly this is not a desirable outcome for patients but in some cases, it presents the only opportunity for ongoing storage and potential use.

1.6. In addition to the growing number of clinic enquiries about storage consent, the focus on wider consent practices during inspection over recent years has revealed clinics storing gametes or embryos, in the absence of consent. In such cases we have worked with those clinics to resolve the issue.

1.7. The HFEA has provided some guidance on consent to storage yet the fact that clinics continue to approach us directly for assistance and that cases emerge through the inspection process, suggest that we should try to address the problem in a more rounded way.

1.8. Through all of the work that has been done by the Executive, it has become clear that the problems on the whole stem from a lack of understanding of the law on consent and the regulations which allow for extended storage.

1.9. With this in mind, and of course in the desire to prevent patients having to face the upset and anguish that these cases cause, we have taken active steps to inform the sector of the Authority's approach to these cases, together with training to try to improve clinic understanding of the issues to try prevent cases arising in the first place. This paper summarises the actions taken thus far

and seeks Authority approval for the approach that the Executive has adopted to resolving certain cases.

2. Summary of the legal framework

2.1. The legal framework sets out strict parameters for the storage and use of gametes and embryos in the UK and every clinic that is licensed by the HFEA is mandated to comply with those requirements. It goes without saying that the HFEA has a statutory duty to uphold and promote compliance with the legal framework.

2.2. The framework requires that gametes and embryos are not be stored unless there is effective consent in place, and they must be stored in accordance with that consent. The statutory storage limit for all gametes and embryos is currently 10 years, although Regulations make provision to extend storage in some cases where certain conditions are met.

2.3. It is a condition of every licence that no gametes or embryos are kept in storage for longer than the statutory storage period and, if stored at the end of that period the law dictates 'they shall be allowed to perish'.

2.4. It is a condition of every licence granted by the HFEA that the consent provisions set out in Schedule 3 of the Act, are complied with. In addition, unlawful storage of gametes or embryos is a criminal offence under section 41 of the Act.

2.5. Quite apart from causing huge distress for patients, clinics storing gametes or embryos in the absence of consent are in breach of the law and their licence conditions. This is a significant regulatory concern for the HFEA and something that should be a concern for clinics.

2.6. To date, a solution has been found to every storage consent case without recourse to the courts, but that may not be possible in every case and clinics that fail to get on top of this issue may run the risk of legal challenge and may have to support patients in seeking a declaration in relation to ongoing storage.

3. Why do these cases arise?

3.1. In our experience, these cases usually arise, although not exclusively, because of failings in consent practices at clinics. The law in this areas is complex and although there is guidance set out in the Code, some clinic staff do struggle. This raises a question of whether we can do more to assist.

3.2. For example, the clinic might not take the necessary steps within the original consent period to get the patient to consent to storage for a further period of storage (where the original period consented to was less than 10 years and the patient therefore still has the option to consent for a further period up to the statutory maximum of 10 years).

3.3. In other cases where the statutory storage period has lapsed, clinics have failed to establish whether it is possible to comply with the relevant provisions of the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 ('the 2009 Regulations') which allow for storage for up to 55 years, or do not understand these Regulations

and how they apply, so they are unable to ensure eligible patients satisfy the requirements at the right time.

4. Actions

4.1. Against this backdrop, a range of steps have been taken to address what is clearly a significant issue both for patients and clinics. We began by taking legal advice to see whether there is any flexibility in the interpretation of the law, particularly in difficult cases. We then looked to see how we could best train HFEA inspectors and provide guidance for clinics to bridge any gaps in their understanding of the law and its practical application. 'The next step is to update our Code of Practice guidance. We then need to assess whether all clinics' have the knowledge and confidence to handle storage consent to a consistently high standard. Having established a new baseline of knowledge in this difficult area we will then update our Code of Practice guidance. The remainder of this section sets out those actions in turn.

Legal Advice

4.2. Counsel's advice was sought to clarify our understanding of the 2009 Regulations and their practical application. It is not rehearsed here for obvious reason; however, it is possible to take a generous interpretation in both of the scenarios set out at 1.2 above.

4.3. That is, in cases where patients are still within the statutory storage period of 10 years but there has been a gap in consent, it is possible to continue storing up to the statutory limit provided there is *currently* consent in place. And in cases where patients wish to store for longer than 10 years but there has been a gap in consent, again, provided there is currently consent and there are no other issues with compliance with the extension regulations, the HFEA would not expect the gametes or embryos to be removed from storage.

4.4. This is a generous interpretation adopted to enable clinics to resolve these cases in favour of patients who wish to continue storing their gametes or embryos, and who find themselves in this position through no fault of their own. However, the fact that we are able to take a generous view to try to ensure that patients wishes are not needlessly overridden, does not mean that clinics that have storage consent cases will not face regulatory action.

4.5. When HFEA inspectors become aware of these cases, clinics are required to explain what actions they have taken and why. Inspectors will check that clinics understand the law and can apply it correctly, and importantly, that measures are being taken to ensure that gaps in consent do not recur.

4.6. We believe this strikes a fair balance between supporting patients and taking a patient-centric regulatory approach, but at the same time upholding the HFEA's responsibilities as a regulator to uphold and promote compliance with the law.

Inspector Training

4.7. Having taken counsel's advice and settled on an approach in these cases, formal training has been undertaken with inspectors to ensure a clear understanding of the law, how the HFEA applies the law in such cases and the HFEA's approach to resolving these cases. Inspectors also

have ongoing one to one support from the Head of Legal as they assist clinics with these cases and have subsequently had a further briefing on storage consent.

Sector Engagement

4.8. The next stage was to engage with clinic staff. We have of course long provided guidance on storage consent generally, however the complexity of the law and the fact specific nature of these cases has meant that it has been difficult to draft a public position that is applicable in all circumstances where clinics have not got it right.

4.9. With this in mind, we started a dialogue with the sector with the workshop at the 2019 Annual Conference, titled 'Extending storage beyond 10 years - are you getting consent right', delivered by Catherine Callaghan QC, who advised the HFEA on storage consent.

4.10. The workshops were very well received, with standing room only during the last session and feedback from the sector has been overwhelmingly positive. There was extensive engagement during the case studies and Q&A session at the end of each workshop which illustrates just how significant this issue is for the sector. That said, we will look at how we can continue to engage with the sector on this.

4.11. This week the Progress Educational Trust held an event titled 'Trouble in Store? How Not to Break the Law when Storing Embryos and Gametes' at which the HFEA spoke. We will take other opportunities as they arise to speak to the sector.

New PR Entry Programme

4.12. To further aid clinic understanding we are preparing a module on storage consent for the new Person Responsible Entry Programme ('the PREP') and learning tool, which is currently under development.

4.13. The new learning module will help promote understanding of consent, in particular storage consent, and will include both visual and written material. The visual element is a training video, a first for the HFEA, which covers similar ground to that which was covered in the workshop at the Annual Conference. This is followed by written material and references to various other resources that are available and ends with a few scenario-based questions on the topic.

4.14. This new PREP will be rolled out in the coming months and will form an integral part of how we promote understanding of what is a complex area of law and practice. It will be open to other members of clinic staff besides just the PR and as it is modular, we will be able to develop or add to it in response to trends in the sector or particularly concerning areas of poor practice.

4.15. For example, where a clinic has a number of storage consent cases and where it is evident that there is a lack of understanding of the law and the applicable Regulations, inspectors will be able to recommend that the PR and perhaps other relevant staff, complete the PREP module on storage consent. In other words, the vision is that as well as clearly being an important and necessary step in assessing the competence of anyone who wishes to be appointed as a PR for the first time, the new PREP learning tool has a much broader application beyond just PRs and is something that can be used in addition to the Code, to promote better understanding of important areas of law and practice and thus ultimately drive up good practice across the sector.

Code of Practice

4.16. Looking ahead, we will update the Code of Practice at the next opportunity to provide further guidance and embed our position on consent to storage.

5. In summary

5.1. The Authority is invited to endorse:

- the approach to storage consent as set out at paragraphs 4.2 to 4.5
- the multi-pronged approach to raising awareness of the issue and improving understanding of a complex area of law.

5.2. The Authority is asked to note that the new PREP learning tool will be launched early in the New Year.

5.3. The proposed new Code of Practice guidance on storage consent to be included in the next iteration of the Code which will as usual, come to the Authority for sign-off.

Register Research Panel annual report

Strategic delivery:	☒ Safe, ethical, effective treatment	☐ Consistent outcomes and support	☐ Improving standards through intelligence
Details:			
Meeting	Authority		
Agenda item	12		
Paper number	HFEA (13/11/2019) 937		
Meeting date	13 November 2019		
Author	Nora Cooke O'Dowd, Head of Research and Intelligence		
Output:			
For information or decision?	For decision		
Recommendation			
Resource implications			
Implementation date	01 April 2020		
Communication(s)			
Organisational risk	☒ Low	☐ Medium	☐ High
Annexes	Annex A: Research projects using identifiable Register data approved since 2010 Annex B: HFE Disclosure of Information for Research Purposes Regulations 2010, Section 13: Fee in relation to the disclosure of information		

1. Background to Register Research Panel

1.1. The HFEA holds probably the largest register of data on assisted reproduction treatments in the world. Until 2010, it was prohibited by law to use that data for research. Since then, however, we have been able to make identifiable register data available to researchers under strict conditions and we have also published an anonymised dataset. This paper sets out research activity in 2019 using HFEA data (section 2 and annex A) and the improvements we have made to our systems to ensure that we can better serve the increasing number of researchers that are interested in accessing the data we hold (sections 3 and 4). Lastly, the paper sets out a proposal to charge for access to HFEA register data (section 5).

1.2. The Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 states that the Authority may grant authorisation to a research establishment for the processing of disclosable protected information for the Register.

1.3. The Authority delegates to the Register Research Panel, the power to: a) authorise access to Register data for the purposes of medical or non-medical research, and b) deny, suspend, revoke, vary or impose conditions upon authorisation to access Register data.

1.4. One of the aims of our 2017-20 strategy has been to engender high quality research and responsible innovation in clinics. As a result of promoting this aim, interest in undertaking research with Register data has been increasing in recent years.

1.5. Since 2010, 16 projects have been approved in total, with a maximum of one or two projects approved each year (Annex A). In 2018, there was an increase in interest, when seven projects were approved in a single year.

1.6. The level of interest has increased again in 2019 with 26 expressions of interest from separate research projects, although this has yet to translate into formal applications to the Register Research Panel.

2. Register Research Panel activity 2019

2.1. The last annual report on the Register Research Panel to authority was on 30 January 2019. Due to staff turnover in the intelligence team and on the panel, applications to the Register Research Panel were suspended between February and August 2019 whilst new members were embedded.

2.2. During the period in which formal applications were suspended, we continued to engage with researchers and advise them on their future applications. Since the end of January, we engaged with researchers from 26 different research projects who expressed an interest in applying for Register data. These came from:

- 19 academic institutions,
- four commercial companies,
- two clinics,
- one government agency.

2.3. Staff turnover over the last year resulted in the loss of organisational memory and it became clear that we need to strengthen our existing processes to ensure they are transparent and well documented.

2.4. In order to make our processes more robust, we have reached out to other public bodies to emulate best practice around application processes and information governance.

2.5. We have compiled a single internal log of project approvals including approval, amendment and expiry dates and researchers have been contacted where expiry periods have come to an end.

2.6. We have also engaged a lawyer to consult on contract issues around data linkages, which prove to be complex and lengthy.

2.7. The Register Research Panel is now scheduled to meet every second month. The newly appointed Information Governance and Records Manager now also provides advice to the panel.

2.8. The Register Research Panel met in July to approve the new applications forms, based on the open licence forms used by Public Health England. These have now been shared with researchers – the first application on this form is expected in November 2019.

3. Challenges

3.1. Whilst it was possible to easily track one or two applications per year, more robust processes are now required to manage the increased volume of interest, applications and renewals and our resources to support this work may need to change over time. For example, there is a considerable amount of administration and liaison work in reviewing forms, liaising with researchers, and providing guidance on research methodology. The increased number of projects also means the Data Analyst has an increased burden in processing and disclosing data and keeping up to date with consents etc.

3.2. The external data protection landscape has developed considerably since 2010. Where authorisation alone has been sufficient in the past, there is now an expectation to have additional data sharing agreements in place and standard terms and conditions for accessing Register data.

3.3. A number of potential applicants intend to conduct data linkage studies, which adds to the length and complexity of the application process. This requires legal advice to ensure the appropriate data flows and legal arrangements are in place to protect our data.

3.4. Data linkage studies also require the Head of Research and Intelligence to liaise with multiple institutions and legal advisors e.g. one proposed research project includes four databases and data processors, and each processor is likely to require a separate agreement.

4. Work to be done into 2020

4.1. An aim of our new strategy 2020-23 is to encourage more research and innovation to improve outcomes. As part of this, we will actively encourage researchers to apply for and use Register data. This is likely to further increase the number of researchers expressing interest and applying for Register data and we must ensure we are prepared for this.

4.2. To this end, we will update the website to provide researchers with information outlining the application process and addressing frequently asked questions. A data release register of all information that is released under the regulations, including a lay summary, will be made available

for transparency and to encourage collaboration between researchers with similar research interests.

4.3. In addition, we will further develop in-depth standard terms and conditions which will be attached to all authorisations.

4.4. We also aim to improve the quality of the data extracts we produce for researchers and the Government Statistical Service will deliver a Quality in Statistics workshop to promote principles of data quality in the production and disclosure of data extracts, including a two-analyst quality assurance process.

4.5. A Research Engagement Day is to be held on 18 May 2020 at the Francis Crick Institute, to promote quality research and engage researchers across the field of fertility research, particularly those using – or with potential uses for – HFEA Register data and those involved or interested in commencing research with human embryos.

4.6. We will become members of the UK Health Data Research Alliance, which aims to establish best practice for the ethical use of UK health data for research. This includes providing information that describes the data held in our Register to make it more easily discoverable and searchable for potential researchers.

5. Charging a fee

5.1. When the Authority first set out its policy in this area following the publication of the 2010 Regulations, it was decided not to routinely charge applicants a fee in respect of the disclosure of protected information even though the regulations state that the Authority **should** charge such a fee (see Annex B). Given the challenges set out above, we now the think it is time we charged for this service as set out below to recover costs.

5.2. There is a maximum of £5,000 per application set out in the regulations. The fee is based on the time taken to locate, assemble and prepare the information. If the time taken to undertake the work is likely to be in excess of 10 days, the application can be rejected due to the substantial resources that would be required from the HFEA to complete the request.

5.3. There is no minimum period for which the authorisation could be approved per application, meaning a renewal fee could be charged where yearly data extracts are required.

5.4. The full amount (£5,000) would not be charged for every project. A charging scheme will be developed based on the amount of time taken to prepare the data, given the complexity of the request, the type of data to be released and the frequency of release.

5.5. If all 26 research projects that expressed interest in receiving information this year had applied and been successful, the income generated would have been approximately £55,000. Each project would be charged at a minimum £250 to a maximum £5,000 for full data linkage.

5.6. If the fee were charged, it could cover the cost of required external legal advice and partially cover the staff costs of processing, quality assuring and disclosing Register data with the current staff. The income would form part of overall HFEA income and the risk centrally managed.

Potential risk of charging a fee

5.7. There is a potential risk that researchers may be discouraged from applying for Register data because of the fee. However, we have discussed this with researchers who generally expect to be charged to access data and build provision for this into funding proposals and thus the risk seems minimal.

5.8. It is worth noting that other public bodies who disclose health data, such as Public Health England and NHS Digital, aim to run a full cost recovery model and charge for data disclosures.

5.9. For comparison:

- The charge to access the NHS Digital Hospital Episode Statistics Online Portal is £12,130 for one user for three years access (New application £1030, £3200 per user per year, £500 annual renewal fee).
- Since September 2016, the Office for Data Release at Public Health England charge for the cost of the time it takes to assess applications, produce data extracts and to run the service at a charge of £378 per hour plus VAT.
- Clinical Practice Research Datalink (GP data) provide patient level datasets for individual studies and have different pricing for non-commercial (£15,000) and commercial datasets (up to £60,000).

5.10. Anonymised data will still be available free of charge on our website and is updated annually. Also, as standard practice, we now publish underlying data tables alongside all of our data-related publications.

6. Recommendation

6.1. It is recommended that the Authority approves the introduction of the RRP fee effective from 1 April 2020.

Annex A

Research projects using identifiable Register data approved since 2010

	Lead organisation	Research project description
1	University of Aberdeen	Validation of prediction model: Predicting the chances of a live birth after one or more complete cycles of in-vitro fertilisation
2	University of Aberdeen	Investigation of whether there is any difference in perinatal outcomes following either a fresh or a frozen-thawed embryo transfer and following either a cleavage stage or blastocyst stage embryo transfer.
3	University of Cambridge	Development of a prediction model using Machine Learning to estimate the chances of live birth over multiple cycles of IVF based on embryo and outcome data from prior failed treatments to improve the prediction of live birth in subsequent treatments.
4	Teranalytics LLC	Development of machine learning algorithms to help doctors and patients make better decisions during IVF procedures (increasing the probabilities of life birth, optimizing drug dosage, etc)
5	University of Edinburgh	To examine whether exposure to environmental characteristics (ambient outdoor air pollution and solar Ultraviolet Radiation) is associated with outcomes of IVF fertility treatment.
6	University of Oxford	The aims of the PEARL study to: find out the effect of fertility problems and treatment on the health and development of children from birth to adolescence; look at the impact of successful fertility treatment on the health and wellbeing of women; estimate any additional costs to the NHS of caring for women and their children after successful fertility treatment
7	Leeds Teaching Hospitals NHS Trust	Investigation of ethnic variation in fresh and frozen embryo transfer outcomes
8	University of Aberdeen	To estimate the benefit of in vitro fertilisation compared to expectant management in couples with unexplained infertility
9	University College London	The study aims to address the question of whether children born after ART are at a higher risk of developing learning or behavioural problems.
10	University College London	To conduct a retrospective UK population-based cohort study to investigate hospital admissions and diagnoses made in children born after assisted reproduction.
11	University College London	To assess the cancer risk among children born after assisted reproduction.
12	University College London	To assess the risk of cancer and death in women who have undergone hormonal therapy as part of assisted reproduction therapy.
13	University College London	To investigate whether children born after assisted reproduction have a higher mortality than those born after spontaneous conception
14	University of Nottingham	To determine the effects of ethnic background on the outcome of assisted reproduction treatment
15	University of Aberdeen	Development and validation of statistical models to predict pregnancy outcomes following in-vitro fertilization (IVF) treatment
16	Central Manchester University Hospitals NHS Foundation Trust	The EpiHealth Outcomes study investigates the impact of ART on neonatal health, including congenital abnormalities, low birth weight and the potential for longer term health issues such as hypertension, and provide comparative data for conventionally-conceived babies

Annex B

HFE Disclosure of Information for Research Purposes Regulations 2010, Section 13: Fee in relation to the disclosure of information

(1) The Authority shall charge the applicant under these Regulations a fee in respect of the disclosure to the applicant of disclosable protected information.

(2) The fee shall be in respect of the time taken by the Authority to--

(a) locate the information;

(b) assemble the information; and

(c) prepare the information for disclosure.

(3) Subject to paragraph (4), the fee shall be--

(a) £250, if the time taken by the Authority is not more than half a day;

(b) £500, if the time taken by the Authority is more than half a day but not more than one day; or

(c) where the time taken by the Authority is more than one day--

(i) £500; and

(ii) £250 for every additional half a day or less.

(4) Where the fee calculated in accordance with paragraph (3)(c) is greater than £5000, the fee shall be £5000.

(5) In paragraph (3), a reference to "one day" is to a period of 7 hours and 30 minutes; and "half a day" shall be construed accordingly.

(6) In calculating the time taken by the Authority, the time of any individual involved in the disclosure shall be recorded separately and then the time of all the individuals involved shall be added together to reach the total number of hours taken by the Authority.

(7) The time taken by the Authority may include the time of a person providing services to the Authority (or an individual employed by such a person).

(8) The applicant must pay the fee to the Authority specified in the Authority's notice to the applicant requiring payment.

(9) The Authority may refuse to disclose the disclosable protected information until it has received the fee.