

Authority meeting - agenda

30 January 2019, Church House, Deans Yard Westminster, London SW1P 3NZ

Agenda item	Time
1. Welcome, apologies and declaration of interests	12.45pm
2. Minutes of 14 November 2018 Authority meeting HFEA (30/01/2019) 900 For decision	12.50pm
3. Chair's report (verbal)	12.55pm
4. Chief Executive's report (verbal)	1.05pm
5. Committee chairs' reports (verbal)	1.15pm
6. Performance report HFEA (30/01/2019) 901 For information	1.25pm
7. Standing Orders HFEA (30/01/2019) 902 For decision	1:45pm
8. EU exit preparations HFEA (30/01/2019) 903 For information	2:05pm
Break	2:20pm
9. Communication strategy HFEA (30/01/2019) 904 For information	2:35pm
10. The register research panel (RRP) and data research HFEA (30/01/2019) 905 For information	3:15pm
11. Estates update HFEA (30/01/2019) 906 For information	3:35pm
12. Any other business	3:55pm
13. Close	4:00pm

Minutes of Authority meeting 14 November 2018

Strategic delivery:

Safe, ethical
effective
treatment

Consistent
outcomes and
support

Improving standards
through intelligence

Details:

Meeting

Authority

Agenda item

2

Paper number

HFEA (30/01/19) 900

Meeting date

30 January 2019

Author

Catherine Burwood, Senior Governance Manager

Output:

For information or
decision?

For decision

Recommendation

Members are asked to confirm the minutes as a true and accurate record of the meeting.

Resource implications

Implementation date

Communication(s)

Organisational risk

Low

Medium

High

Annexes

Minutes of the Authority meeting on 14 November 2018 held at Church House, Deans Yard, Westminster, London SW1P 3NZ

Members present	Sally Cheshire Margaret Gilmore Andy Greenfield Anthony Rutherford Bobbie Farsides Emma Cave	Gudrun Moore Kate Brian Rachel Cutting Ruth Wilde Yacoub Khalaf
Apologies	Anne Lampe Anita Bharucha Jonathan Herring	
Observers	Steve Pugh (Department of Health and Social Care)	
Staff in attendance	Peter Thompson Clare Ettinghausen Nick Jones Richard Sydee Catherine Drennan	Helen Crutcher Joanne Anton Laura Riley Lisa Whiting
Other attendees	Gavin Ellison (YouGov) Melanie Nicholls (YouGov)	

Members

There were 11 members at the meeting; seven lay members and four professional members.

1. Welcome, apologies and declarations of interest

- 1.1. The Deputy Chair opened the meeting by welcoming Authority members and members of the public to the sixth meeting of 2018. As with previous meetings, it was audio-recorded, and the recording would be made available on our website to enable interested members of the public who could not attend the meeting to listen to our deliberations.
- 1.2. Apologies were received from Anne Lampe, Anita Bharucha and Jonathan Herring.
- 1.3. Declarations of interest were made by:
 - Anthony Rutherford (Clinician at a licensed centre)
 - Rachel Cutting (Clinician at a licensed centre)
 - Yacoub Khalaf (Clinician at a licensed centre)

2. Minutes of Authority meeting held on 12 September 2018

- 2.1. Members agreed the minutes of the meeting held on 12 September 2018 for signature by the Chair of the meeting.

3. Chair's report

- 3.1. The Chair welcomed new Authority member, Professor Emma Cave, who joined the HFEA on 1 October 2018. The Chair explained that recruitment for a member from a faith background was being undertaken and it was hoped there would be an appointment agreed early in the new year. As usual the appointment process was being led by the Department of Health and Social Care (DHSC).
- 3.2. The Chair reminded members that this was the last Authority meeting for Dr Andy Greenfield, who joined the Authority in 2009 and whose term of appointment would end on 31 December 2018. The Chair thanked Dr Greenfield for his contributions to the Authority, the Licence Committee, which he chaired, and the Scientific and Clinical Advances Advisory Committee (SCAAC).
- 3.3. On 19 September the Chair attended the first Royal Institution Trustee Supper Club to participate in an event on establishment of new technologies.
- 3.4. On 31 October the Chair attended a networking lunch with members of the Association of Fertility Patient Organisations (AFPO) and the Professional Organisations Stakeholder Group (PSG).
- 3.5. The Chair advised members that on 7 November the HFEA held the first of two leadership event for PRs, in London. Another event would take place in Manchester next week. Over 60 PRs attended and feedback suggests that the event was a great success.

4. Chief Executive's report

- 4.1. The Chief Executive and Senior Management team attended the Department of Health and Social CARE (DHSC) and HFEA quarterly accountability meeting on 21 September.
- 4.2. On 1 October, together with the Director of Strategy and Corporate Affairs, the Chief Executive met the joint chairs of the Fertility Fairness campaign, Sarah Norcross and Aileen Feeney.
- 4.3. On 3 October the Chief Executive met representatives from other non-economic regulators to discuss whether there would be merit in working more closely together on common issues, such as good regulatory practice or talent management.
- 4.4. The Chief Executive attended the London leadership event for PRs on 7 November.

Press Coverage

- 4.5. The Chief Executive covered some of the main topics of enquiry and interest for this period:
Daily Mail reporting of some clinics offering sex selection
- 4.6. Following a report by the Daily Mail the HFEA were looking into this matter. The Director of Compliance would provide an update on the progress of investigations into the allegations later in the meeting.

Treatment add-ons

- 4.7.** The Chief Executive provided information about an article in the Guardian which had been written about the draft consensus statement on treatment add-ons.

5. Committee Chairs' reports

Licence Committee

- 5.1.** The Chair of the Licence Committee provided the members with an update on the 6 September meeting, now that the minutes were finalised.
- 5.2.** At this meeting the committee approved two research renewal applications and two treatment and storage licence renewal applications. The committee also considered and noted two executive updates and one grade A incident report.
- 5.3.** The Chair of the Licence Committee reported that the committee had last met on 8 November.
- 5.4.** The committee considered 11 items: six research renewal applications; one treatment and storage licence renewal application; one application to vary premises; one application to vary the PR; one application to vary the licence holder; and one executive update. The minutes were not signed yet so the Chair of the committee could not provide details of the decisions made.

Statutory Approvals Committee

- 5.5.** The Chair of the Statutory Approvals Committee (SAC) reported that the committee met on 27 September and 25 October.
- 5.6.** In September the committee considered seven items: two mitochondrial donation applications and five pre-implantation genetic diagnosis (PGD) applications. All applications were approved.
- 5.7.** In October the committee considered eight items: three mitochondrial donation applications and five PGD applications. The minutes were not signed yet so the Chair of SAC could not provide details of the decisions made.
- 5.8.** At this meeting the committee also considered a paper regarding the outcome of the recently completed PGD review. The Chair of SAC provided the members with the background around this piece of work and the outcomes of it.

Executive Licensing Panel

- 5.9.** The Chair of the Executive Licensing Panel (ELP) advised members that the Panel had met five times since the last Authority meeting, on: 11 September, 26 September, 10 October, 24 October and 8 November.
- 5.10.** The panel considered 21 items in total: two initial treatment and storage licence applications; four licence renewal applications; five interim inspection reports; eight licence variation application; one executive update; and one application for special directions. 20 applications were approved, and the executive update was noted.

- 5.11.** The Chair of ELP reported that the Licensing Officer had considered 68 items: 65 importing tissue establishment (ITE) certificate applications and three applications to change licence holder.

Audit and Governance Committee

- 5.12.** The Deputy Chair of the Audit and Governance Committee (AGC) reported that the committee had met on 9 October 2018.
- 5.13.** Aside from the usual standing items and updates from internal and external audit, the committee received reports on: General Data Protection Regulation; a Digital Programme update; resilience, business continuity management and cyber security; an estates update; the risk policy; the strategic risk register; Brexit; legal risks; whistle blowing and fraud; and contracts and procurement.
- 5.14.** The Chief Executive reported that more information about Brexit would be reported in January 2019.

Scientific and Clinical Advances Advisory Committee

- 5.15.** The Chair of the Scientific and Clinical Advances Advisory Committee (SCAAC) reported that the committee had met on 15 October 2018.
- 5.16.** The committee considered items on the following topics: intrauterine culture; treatment add-ons; and alternative methods to derive embryonic and embryonic-like stem cells.

6. Performance report

- 6.1.** The Chief Executive began by providing members with an update about staffing and resources, stating that the number of leavers was still higher than wished. The staff survey had recently been completed and the results would be considered at the upcoming staff away day in December.
- 6.2.** The Director of Compliance and Information provided the members with an update about the sex selection investigation being undertaken in response to a Daily Mail article. The members heard that it had been determined that there had been no breach of law in the UK, but that the HFEA was exploring UK clinics' and clinicians' associations with clinics abroad.
- 6.3.** The Director of Compliance and Information also provided an update about the data submission system (PRISM) and data migration to support this.
- 6.4.** The Director of Strategy and Corporate Affairs provided members with information about the implementation of the next version of the Code of Practice, which was still with the DHSC for approval from the Secretary of State.
- 6.5.** The Director of Strategy and Corporate Affairs also provided information about the State of the Sector report; two private members bills that were going through Parliament; and Fertility Awareness Week, which ran from 29 October to 4 November.
- 6.6.** In relation to Fertility Awareness Week, the Chair expressed concerns over some of the exhibitors present at the London Fertility Show. An alternative fertility day which would

be held at the Royal College of Obstetricians and Gynaecologists (RCOG) would take place in March 2019 and the Chair urged patients to take note of this.

- 6.7.** The Director of Finance and Resources provided members with information on the financial forecast. Members heard that the HFEA had a larger than anticipated surplus, and that we were also ahead of our full-year forecast. The members heard that the HFEA will look to utilise this emerging position in a practical way.
- 6.8.** The Director of Finance and Resources also reported that, following meetings with the DHSC in November, further news regarding estates should be available in the new year.

Decision

- 6.9.** The members noted the latest performance report.

7. National Patient Survey

- 7.1.** The Chair welcomed two representatives from YouGov, Gavin Ellison and Melanie Nicholls, to the meeting, following which the Director of Strategy and Corporate Affairs introduced this item regarding the recently completed National Fertility Patient Survey.
- 7.2.** The Research Manager provided the members with background about why the Executive decided to conduct this work and the subsequent approach that was taken.
- 7.3.** Following a competitive tender process, YouGov were appointed to conduct the survey. They delivered the project overseen by an internal working group, which included two Authority members.
- 7.4.** The YouGov representatives explained the methodology used for the survey. Qualitative research was conducted via focus groups and in-depth interviews, which fed in to the development of the quantitative survey. This was carried out between 3 September and 2 October 2018. 1,017 patients or partners responded.
- 7.5.** The YouGov representatives outlined the findings of the survey. This included information on the following topics: routes to finding treatment; the patient experience of treatment; treatment add-ons and transparency of costs; overall experience; and familiarity with the HFEA.
- 7.6.** The key findings found related to the following areas:
- The role of GPs
 - The detail of treatment planning
 - Feeling comfortable asking questions and the desire for doctors' notes/audio recording of consultations.
 - Interest shown to patients and partners "as a person"
 - The role of counselling in impacting overall experiences
 - Small changes that could positively impact dignity and respect for patients
 - The coordination of administration of treatment

7.7. The Research Manager outlined the next steps, including the publication of the report and using the findings to feed into future HFEA work.

7.8. The Authority was asked to:

- Note the results of the national patient survey
- Comment on the strategic implications for the Authority

Decision

7.9. The members noted and discussed the results of the survey.

7.10. The members raised questions and discussed areas including assessing the quality of counselling and non-medical treatment add-ons, such as acupuncture. The members heard that it would be possible to interrogate the survey data further to determine areas the HFEA could look into and to drive future strategic planning.

8. Business plan 2019/20 – full draft

8.1. The Risk and Business Planning Manager introduced this item and reminded members that the Authority approved an outline of the business plan for 2019-2020 in September.

8.2. Members were presented with the full draft of the business plan, in readiness for submission to the DHSC.

8.3. The draft business plan set out key activities for 2019/20, which would take the HFEA to the end of its current strategy period. The Risk and Business Planning Manager explained that some sections of the business plan would be written later in the business year for practical reasons, so the document would continue to be a work in progress.

8.4. The members were asked to approve the draft business plan for 2019/20, for submission to the DHSC and for further development.

8.5. The members were also advised that a near-final version of the business plan would be presented at the March 2019 Authority for sign-off, prior to publication.

Decision

8.6. The members agreed to approve the current draft of the 2019/20 business plan.

9. Donor conceived register

9.1. The Chief Executive introduced this item which outlined several deliverable options that had been identified to provide a new service for the donor conceived register (DCR) and new counselling/support services in relation to opening the register (OTR) requests. The Chief Executive advised the members that the options presented did not indicate the limit of possibilities available for this work.

9.2. The Policy Manager explained that four distinct approaches had been identified and provided details of the key considerations that had been taken into account when doing so.

9.3. The Policy Manager described the possible options, stating that option 3 had received the highest score when assessing the service qualities of each possible approach.

- 9.4.** The Authority was asked to consider the four approaches and agree a preferred approach, to be implemented by March 2019 when the current service would end.

Option 1

- 9.5.** Option 1 was to work with direct to consumer DNA testing and matching websites, with counselling provision delivered by the HFEA.
- 9.6.** This option presented the greatest likelihood of donors and donor conceived people finding genetic matches and was the lowest resource option for the HFEA.
- 9.7.** However, this option would risk disclosing the identity of a donor or donor conceived person without consent.

Option 2

- 9.8.** Option 2 was for the DCR and counselling provision to be delivered by the HFEA.
- 9.9.** This option was favoured by some DCR registrants who trust the HFEA to provide a high quality service. However, we do not have the necessary skill set or structure in place to deliver this. Similarly, the HFEA has no experience in dealing with genetic test results.
- 9.10.** This was also the most expensive option.

Option 3

- 9.11.** Option 3 was for the end-to-end service to be provided by an external provider (GeneHealthUK; The National Fertility Service; the Hewitt Fertility Centre's counselling team; or Rafan House).
- 9.12.** Most of these providers would have infrastructure already in place and were open to recruiting additional staff where necessary. Some also have relationships with genetic laboratories, and experience of providing test results or telephone helplines.

Option 4

- 9.13.** Option 4 was a mixed model, with the DCR run by an external provider and counselling provision overseen by the HFEA.
- 9.14.** Whilst this option would overcome the challenge of using an agency without direct experience of specialist counselling, the Policy Manager explained that it may not be as user friendly, as it would require people to potentially contact two organisations for support.

Decision

- 9.15.** Members noted the importance of these services, but recognised that the counselling service would potentially only be required for very small numbers of people.
- 9.16.** Members also noted concern about the March 2019 deadline, although it was not possible to extend this.
- 9.17.** It was agreed that the executive should explore all options further, taking note of the suggestions and points raised by members.

10. Strategic risk register

- 10.1.** The Risk and Business Planning Manager presented the latest edition of the strategic risk register.
- 10.2.** The strategic risk register was last reviewed by AGC on 9 October and by the Senior Management Team (SMT) on 29 October.
- 10.3.** The Risk and Business Planning Manager reported that currently one risk was rated as high (capability), and one risk (cyber security) was above tolerance.
- 10.4.** The Risk and Business Planning Manager explained that the HFEA defines risk appetite as the general level of risk that we are willing to accept, as opposed to risk tolerance, which is the particular level we are willing to accept in relation to specific risks. The members heard that the statement on risk appetite had not been reviewed by the Authority for some time. It was good practice to confirm this periodically.
- 10.5.** The Authority was asked to:
- Note and comment on the latest edition of the strategic risk register.
 - Discuss and agree the current appetite of the Authority to risk, as outlined at section 2.3 of the risk policy.

Decision

- 10.6.** Following discussion, the members confirmed the current low appetite of the Authority to risk as outlined at section 2.3 of the risk policy.

11. Consensus statement on treatment add-ons

- 11.1.** The Head of Regulatory Policy presented a paper on innovative treatments used in fertility, explaining that the responsible use of such treatment add-ons had been an issue of concern to the HFEA and many in the fertility sector for some time.
- 11.2.** In September 2017 it was agreed that a working group composed mainly of professional and patient organisations would be set up to develop a consensus statement on the responsible use of treatment add-ons.
- 11.3.** The working group met for the first time in March 2018, and agreed that the HFEA should put together a first draft of the statement.
- 11.4.** The first draft was circulated in August 2018 and, based on feedback, a second draft was developed. The second draft was discussed at a further working group meeting in October 2018. No substantive changes were made and final comments were agreed via email.
- 11.5.** The Head of Regulatory Policy provided information about plans for dissemination and publication of the final statement, as agreed at the October working group meeting. This included publication on all signatories' websites, conveying necessary messages at the HFEA's Leadership events in November 2018 and discussion at the HFEA's 2019 annual conference.

- 11.6.** Future HFEA inspections will also include a checklist seeking information from clinics about what add-ons they offer and how these are presented to patients. This will be supported by workshops for clinics, being held in 2019, around the key consensus statement principles.
- 11.7.** The Head of Regulatory Policy explained that it was hoped that agreement on the final text of the consensus statement would be reached by the end of November 2018. Members had received a draft version of the text in their papers.
- 11.8.** The Authority was asked to note:
- that the consensus statement aims to support partnership working by signatories towards the responsible use of treatment add-ons in fertility services.
 - that the HFEA will continue to monitor the use of add-ons in use in clinics via inspection and other methods and that the consensus statement is likely to inform future work by the HFEA towards supporting the aims of the statement.
 - the plans for dissemination and publication of the consensus statement.

Decision

- 11.9.** The members noted the above points, and positively acknowledged the progress that had been made to date.

12. Any other business

- 12.1.** There was no further business discussed.

13. Chair's signature

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

Signature

Chair

Date

Performance report

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

Details:

Meeting	Authority
Agenda item	6
Paper number	HFEA (30/1/2019) 901
Meeting date	30 January 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)	<p>The Senior Management Team (SMT) reviews performance in advance of each Authority meeting, and their comments are incorporated into this Authority paper.</p> <p>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.</p> <p>The Department of Health and Social Care reviews our performance at each DHSC quarterly accountability meeting (based on the SMT paper).</p>

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 November 2018, with finance data until end December 2018.
- 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 the November performance data at its 7 January 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 – November data

Overall performance – RAG status (all indicators)



People – capacity

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

↓
Leavers: 2
(25.3%)

Engagement – Website traffic

Website sessions this month
Arrow tracks performance since last month

↑
50,832

Licensing end-to-end

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

★
50 working days

Money – budget

Summary Financial Position - 31 December 2018

	Year to Date			Full Year		
	Actual £'000	Budget £'000	Variance £'000	Forecast £'000	Budget £'000	Variance £'000
Income	4,968	4,916	(53)	6,852	6,490	(361)
Expenditure	4,722	4,679	(44)	6,568	6,270	(298)
TOTAL Surplus / (Deficit)	246	237	9	284	221	63

Commentary

The position at the end of December is a surplus of £246k, broadly in line with our YTD budgeted position. Expenditure is slightly higher than anticipated but offset by additional income over the same period.

The full year forecast is a surplus of £284k, £63k higher than the full year budget position. This position has been arrived at following in-depth discussions with Directorates as to their final quarter plans and makes provision for key projects relating to our IT systems and telecoms. The forecast also takes account of ongoing temporary staff costs which have increased due to the work required to ensure data used within PRISM is clean and reliable.

Overall performance – November 2018

SMT reviewed the overall performance picture on 7 January. There were 5 red indicators. Overall, November performance was generally good.

SMT has discussed the ongoing PGD trends and is looking at the efficiency of the process end to end. However, PGD applications continue to increase in complexity and it may soon be sensible to consider a more radical analysis of the sustainability of the approval process.

We continue to consider options for addressing staff turnover and more detailed information about our people plans, and how we are addressing the current challenges, was considered by AGC in December.

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

- Staff sickness absence rate (%) per month. Our target is for sickness to remain under 2.5%. Performance in November was 3.65% which was due in a large part to two members of staff on long-term sick leave.
- Establishment ('unplanned') leavers per month. Our target is to remain within 5 - 15% headcount turnover for the year. Performance in November was 25.3%. The overall planned and unplanned leavers for the year is 31.7%.

Licensing decisions approved and finalised

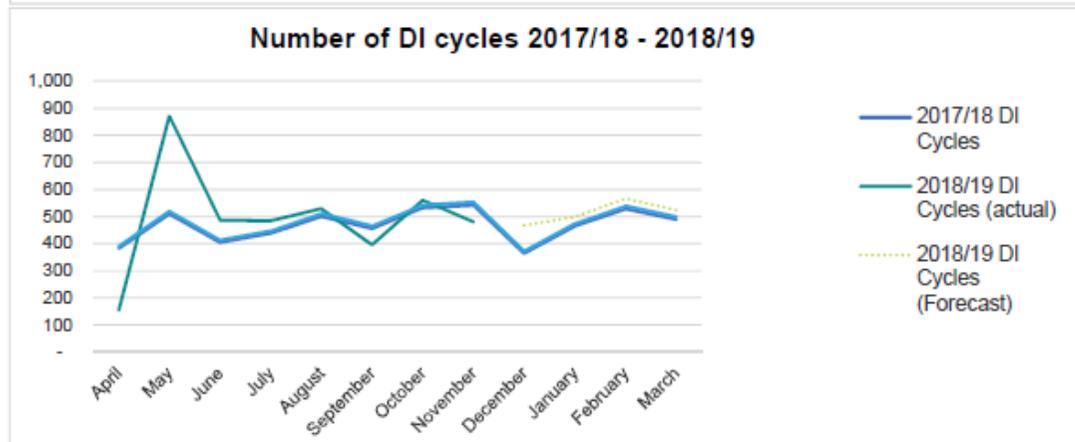
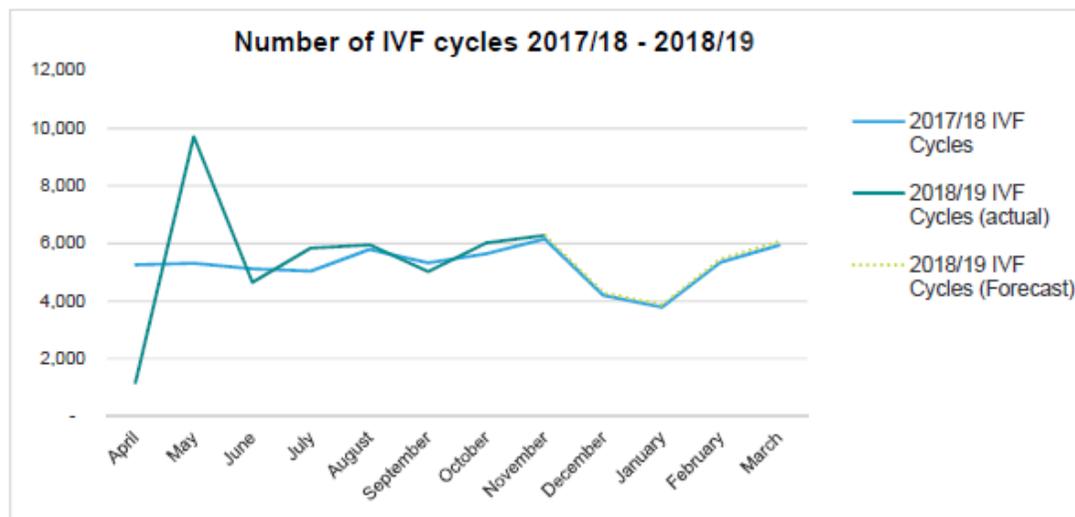
- Average number of working days between SAC date and minutes being finalised (signed by the Chair). The target for SAC minutes is 100% in 20 working days but in November average performance was 23 working days with none of the items finalised within the 20 working day target. Increasingly complex SAC items are adding to delays in finalising these minutes

PGD processing

- Percentage of PGD applications processed within three months. Our target is 100%, but in November none of the four applications due to be completed, was done in this timeframe.
- 3 month rolling average figure – Percentage of all PGD applications processed within 3 months for the three months to date. Our target is 100% within 66 working days, but in the three months to November this dropped to 0% (0/10) with an average processing time for those that had been completed of 87 working days.

Budget status – December data

2018/19 Income



IVF Cycles

	YTD		YE / Forecast	
	Volume	£	Volume	£
2017/18 IVF Cycles	47,883	3,830,640	62,969	5,037,520
2018/19 IVF Cycles	49,570	3,965,600	64,353	5,148,232
Variance	1,687	134,960	1,384	110,712

The year to date position shows an increase of 3.5% in IVF activity over the same period last year, this has increased since we reported at the end of Q2 due primarily to a 17% increase in December 2018 when compared to December 2017. As our budget for 2018/19 anticipated a 2% increase on 2017/18 volumes, current volumes would suggest full year income of from IVF fees of £5,215k - £77k higher than budgeted and £177k higher than 2017/18

We will continue to review our income forecast monthly over the last quarter and consider the impact of this level of increased activity as we prepare 2019/20 budgets

DI Cycles

	YTD		YE / Forecast	
	Volume	£	Volume	£
2017/18 DI Cycles	4,126	154,725	5,607	210,263
2018/19 DI Cycles	4,425	165,938	6,013	225,488
Variance	299	11,213	406	15,225

Year to date, the volume of DI treatment cycles reported is 7% higher than for the same period in 2017/18. As reported above for IVF treatments, December DI activity is significantly higher than in 2017/18.

Our year end position anticipates current activity levels remaining broadly constant and would result in c £15k of additional income this financial year.

HFEA Income & Expenditure

Dec-2018

	Year to Date			Full Year			Management commentary
	Actual £'000	Budget £'000	Variance £'000	Forecast £'000	Budget £'000	Variance £'000	
Income							Income. Year to date income is £50k higher than budgeted for due to increased activity in both IVF and DI treatments. Our full year forecast position includes a small increase in our full year licence fee income and the additional Ring Fenced funding we have received from DHSC relating to our depreciation costs
Grant-in-aid	700	700	-	934	934	-	Expenditure. Year to date expenditure is above our budget by £44k (1%). Below are details of our material variances:
Licence Fees	4,153	4,110	(43)	5,430	5,416	(14)	Staff costs including Temporary staff - £170k above budget - a result of overspends on agency staff (£384k) offset by underspends in salary and on-costs (national insurance and pension).
Other Income	11	-	(11)	11	-	(11)	Facilities including non-cash - £17k above budget - additional desks space was rented for the first half of the year to provide space for IT contractors - this ceased in September. The overspend will remain but is offset by reduced depreciation charges as we are yet to incur the full depreciation costs relating to PRISM.
Seconded Salary reimbursed	105	105	1	477	141	(337)	IT Costs - £91k over budget - due to significant overspends within IT Consultancy (£35k) and Consumables (£27k) which is the result of recent necessary pieces of work agreed by SMT.
Total Income	4,968	4,916	(53)	6,852	6,490	(361)	Legal/Professional fees - £156k under budget - the core legal budget is overspent by £58k, due to the write back of accrued costs award from a previous case (£40k). The overall underspend in this area relates to the litigation contingency funds that were held to meet a Court of Appeal hearing. This has since not materialised, and the funds have been redeployed.
Revenue Costs							Authority and Other Costs £30k - underspends relate to costs budgeted for external advisers which have not materialised.
Salaries (excluding Authority)	3,103	2,933	(170)	4,058	3,911	(147)	Other Costs - £11k - underspends are within the Strategy directorate totalling (£14k) offset by a nil variance within Compliance. The most significant area under budget remains within Patient Survey (£12k) which is due to timing of billing.
Staff Travel & Subsistence	102	123	21	160	162	2	Forecast Outturn. Overall, we are forecasting a surplus £284k against budget of £221k - a decrease of £63k. So far, our forecast expenditure takes account additional support costs for IT and Consultancy and revenue cost of the new Document Management System (DMS). As part of wider discussions between DHSC and all ALBs we have agreed to deliver this underspend in order to help alleviate wider financial pressures on the Department.
Other Staff Costs	79	94	15	121	126	5	
Authority & Other Committees costs	183	213	30	264	280	16	
Facilities Costs incl non-cash	529	512	(17)	715	710	(5)	
IT Costs	253	162	(91)	549	211	(338)	
Legal / Professional Fees	267	424	156	396	585	189	
Other Costs	207	218	11	305	285	(20)	
Total Revenue Costs	4,722	4,679	(44)	6,568	6,270	(298)	
TOTAL Surplus / (Deficit)	246	237	9	284	221	63	

People – key performance and volume indicators

Indicator	Score	RAG	Recent trend ¹	Notes																		
Current headcount by month Staff in post/headcount	63/66	↔	<p>Headcount vs establishment</p> <table border="1"> <caption>Headcount vs establishment data</caption> <thead> <tr> <th>Month</th> <th>Establishment</th> <th>Headcount</th> </tr> </thead> <tbody> <tr> <td>Jul</td> <td>~65</td> <td>~62</td> </tr> <tr> <td>Aug</td> <td>~65</td> <td>~61</td> </tr> <tr> <td>Sep</td> <td>~65</td> <td>~61</td> </tr> <tr> <td>Oct</td> <td>~65</td> <td>~60</td> </tr> <tr> <td>Nov</td> <td>~65</td> <td>~62</td> </tr> </tbody> </table>	Month	Establishment	Headcount	Jul	~65	~62	Aug	~65	~61	Sep	~65	~61	Oct	~65	~60	Nov	~65	~62	Overall volume (capacity) indicator.
Month	Establishment	Headcount																				
Jul	~65	~62																				
Aug	~65	~61																				
Sep	~65	~61																				
Oct	~65	~60																				
Nov	~65	~62																				
Turnover: Establishment ('unplanned') leavers (% establishment turnover for the year). This is done monthly for the rolling year to date.	25.3%	↑	<p>Turnover vs target range (5-15%)</p> <table border="1"> <caption>Turnover vs target range data</caption> <thead> <tr> <th>Month</th> <th>Turnover (%)</th> </tr> </thead> <tbody> <tr> <td>Jul</td> <td>19.1%</td> </tr> <tr> <td>Aug</td> <td>22.1%</td> </tr> <tr> <td>Sep</td> <td>22.1%</td> </tr> <tr> <td>Oct</td> <td>23.8%</td> </tr> <tr> <td>Nov</td> <td>25.3%</td> </tr> </tbody> </table>	Month	Turnover (%)	Jul	19.1%	Aug	22.1%	Sep	22.1%	Oct	23.8%	Nov	25.3%	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.						
Month	Turnover (%)																					
Jul	19.1%																					
Aug	22.1%																					
Sep	22.1%																					
Oct	23.8%																					
Nov	25.3%																					

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 ¹	Notes												
Staff sickness absence rate (%) per month.	2.65%	↑	<p style="text-align: center;">Sickness absence</p> <table border="1"> <caption>Sickness absence rate (%)</caption> <thead> <tr> <th>Month</th> <th>Rate (%)</th> </tr> </thead> <tbody> <tr> <td>Jul</td> <td>0.93%</td> </tr> <tr> <td>Aug</td> <td>0.13%</td> </tr> <tr> <td>Sep</td> <td>1.10%</td> </tr> <tr> <td>Oct</td> <td>2.53%</td> </tr> <tr> <td>Nov</td> <td>2.65%</td> </tr> </tbody> </table>	Month	Rate (%)	Jul	0.93%	Aug	0.13%	Sep	1.10%	Oct	2.53%	Nov	2.65%	<p>KPI: Absence rate of ≤ 2.5%.</p> <p>Average rate of public sector sickness absence is 2.9% versus 1.7% for the private sector.</p> <p>(Source: ONS data 2016)</p>
Month	Rate (%)															
Jul	0.93%															
Aug	0.13%															
Sep	1.10%															
Oct	2.53%															
Nov	2.65%															

Information – key performance and volume indicators

Indicator	Score	RAG	Recent trend	Notes																		
Number of emailed public enquiries received (compared with same month last year)	172	↓	<table border="1"> <caption>Number of emailed public enquiries received</caption> <thead> <tr> <th>Month</th> <th>This year</th> <th>Last year</th> </tr> </thead> <tbody> <tr> <td>Jul</td> <td>143</td> <td>156</td> </tr> <tr> <td>Aug</td> <td>169</td> <td>143</td> </tr> <tr> <td>Sep</td> <td>146</td> <td>165</td> </tr> <tr> <td>Oct</td> <td>218</td> <td>166</td> </tr> <tr> <td>Nov</td> <td>172</td> <td>172</td> </tr> </tbody> </table>	Month	This year	Last year	Jul	143	156	Aug	169	143	Sep	146	165	Oct	218	166	Nov	172	172	Volume indicator.
Month	This year	Last year																				
Jul	143	156																				
Aug	169	143																				
Sep	146	165																				
Oct	218	166																				
Nov	172	172																				
Percentage of Opening the Register requests responded to within 20 working days	100%	★	<table border="1"> <caption>Opening the Register requests</caption> <thead> <tr> <th>Month</th> <th>Number of requests</th> <th>% within 20 days</th> </tr> </thead> <tbody> <tr> <td>Jul-18</td> <td>31</td> <td>100%</td> </tr> <tr> <td>Aug-18</td> <td>26</td> <td>100%</td> </tr> <tr> <td>Sep-18</td> <td>36</td> <td>100%</td> </tr> <tr> <td>Oct-18</td> <td>33</td> <td>100%</td> </tr> <tr> <td>Nov-18</td> <td>27</td> <td>100%</td> </tr> </tbody> </table>	Month	Number of requests	% within 20 days	Jul-18	31	100%	Aug-18	26	100%	Sep-18	36	100%	Oct-18	33	100%	Nov-18	27	100%	<p>KPI: 100% of complete OTR requests to be responded to within 20 working days (excluding counselling time)</p>
Month	Number of requests	% within 20 days																				
Jul-18	31	100%																				
Aug-18	26	100%																				
Sep-18	36	100%																				
Oct-18	33	100%																				
Nov-18	27	100%																				

Indicator	Score	RAG	Recent trend	Notes
Number of requests for contributions to Parliamentary questions	11	↓		Volume indicator. We received a spike of applications in October.
Number of Freedom of Information (FOI) requests	6	↑		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)	50	★		KPI: Less than or equal to 70 working days.

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												
Monthly percentage of PGD applications processed within three months (66 working days).	0% (0/4)	↔	<table border="1"> <caption>Monthly Performance Percentage</caption> <thead> <tr><th>Month</th><th>Performance (%)</th></tr> </thead> <tbody> <tr><td>Jul</td><td>29%</td></tr> <tr><td>Aug</td><td>0%</td></tr> <tr><td>Sep</td><td>0%</td></tr> <tr><td>Oct</td><td>0%</td></tr> <tr><td>Nov</td><td>0%</td></tr> </tbody> </table>	Month	Performance (%)	Jul	29%	Aug	0%	Sep	0%	Oct	0%	Nov	0%	KPI: 100% processed (i.e. considered by SAC) within three months (66 working days) of receipt of completed application.
Month	Performance (%)															
Jul	29%															
Aug	0%															
Sep	0%															
Oct	0%															
Nov	0%															
Average number of working days taken (in the month).	78	↓	<table border="1"> <caption>Average Number of Working Days (Monthly)</caption> <thead> <tr><th>Month</th><th>Working days</th></tr> </thead> <tbody> <tr><td>Jul</td><td>70</td></tr> <tr><td>Aug</td><td>93</td></tr> <tr><td>Sep</td><td>102</td></tr> <tr><td>Oct</td><td>84</td></tr> <tr><td>Nov</td><td>78</td></tr> </tbody> </table>	Month	Working days	Jul	70	Aug	93	Sep	102	Oct	84	Nov	78	
Month	Working days															
Jul	70															
Aug	93															
Sep	102															
Oct	84															
Nov	78															
Cumulative 3 month (rolling average) percentage of PGD applications processed within three month KPI (66 working days)	0% (0/10)	↔	<table border="1"> <caption>Cumulative 3-month Performance Percentage</caption> <thead> <tr><th>Month</th><th>Performance (%)</th></tr> </thead> <tbody> <tr><td>Jul</td><td>50%</td></tr> <tr><td>Aug</td><td>33%</td></tr> <tr><td>Sep</td><td>17%</td></tr> <tr><td>Oct</td><td>0%</td></tr> <tr><td>Nov</td><td>0%</td></tr> </tbody> </table>	Month	Performance (%)	Jul	50%	Aug	33%	Sep	17%	Oct	0%	Nov	0%	KPI: As above.
Month	Performance (%)															
Jul	50%															
Aug	33%															
Sep	17%															
Oct	0%															
Nov	0%															
Average number of working days taken (cumulative 3 month picture).	87	↓	<table border="1"> <caption>Average Number of Working Days (Cumulative 3-month picture)</caption> <thead> <tr><th>Month</th><th>Working days</th></tr> </thead> <tbody> <tr><td>Jul</td><td>69</td></tr> <tr><td>Aug</td><td>77</td></tr> <tr><td>Sep</td><td>84</td></tr> <tr><td>Oct</td><td>92</td></tr> <tr><td>Nov</td><td>87</td></tr> </tbody> </table>	Month	Working days	Jul	69	Aug	77	Sep	84	Oct	92	Nov	87	
Month	Working days															
Jul	69															
Aug	77															
Sep	84															
Oct	92															
Nov	87															

Standing Orders

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

Details:

Meeting Authority

Agenda item 7

Paper number HFEA (30/01/2019) 902

Meeting date 30 January 2019

Author Paula Robinson, Head of Planning and Governance

Output:

For information or decision? For decision (formal vote required)

Recommendation The Authority is asked to approve minor revisions to Standing Orders.

Resource implications None.

Implementation date 31 January 2019

Communication(s) Replacement Standing Orders will be published on our website and reissued to all members. Our standard pack for licensing meetings is also updated whenever a new version is agreed.

Organisational risk Low Medium High

Annexes Annex 1: revised sections of Standing Orders

1. Background

- 1.1. Our standing orders are the instrument governing how we run the Authority and our meetings. The standing orders set out the role of members and employees, and the way we run our formal meetings. Terms of reference are included for our committees.
- 1.2. We typically review our standing orders annually, at the March meeting, but can revise them at any point in the year. On this occasion, there are minor changes to the memberships of SCAAC (our Scientific and Clinical Advances Advisory Committee) and SAC (our Statutory Approvals Committee), following on from recent Authority appointments. These require small revisions now to the terms of reference of both committees, for practical reasons.
- 1.3. Revisions require a notice of motion to be sent to members in advance. This was circulated on 15 January 2019. Accepting revised standing orders also requires:
 - Two thirds of members to be present at the meeting
 - A majority vote of those present. The wording of the requirement states ‘at least half must vote in favour’.

2. Proposed revisions

- 2.1. There are three proposed revisions, all to committee or panel terms of reference in Annex A to the standing orders. The proposed revisions are attached for reference in Annex 1 to this paper.

SAC terms of reference

- 2.2. In order to include new Authority members in decision making, and in recognition of the growing workload of the Committee, we plan to operate SAC from a rotating pool of seven members. In accordance with current standing orders, the committee will continue to sit with a maximum of six members at each meeting, so that (up to) six out of the seven possible members will be assigned in advance. A rota of attendance has been established, in anticipation, for all meetings in 2019, including the meeting to be held the day after the Authority meeting (31 January). Expressing this new arrangement in standing orders is good practice, for clarity, and can be dealt with by a simple wording change.
- 2.3. The practical operation of this model is straightforward, and we will continue to ensure that, as now, there is always a lay/professional balance for every meeting. This is assisted by the Chair and Deputy Chair (who continue in their existing roles) and are both lay members.
- 2.4. The authorisation of mitochondrial donation treatment has also been added to the list of decision types at paragraph 3.10 in the terms of reference, where voting arrangements are described.

SCAAC terms of reference

- 2.5. The membership of SCAAC has been revised to reflect recent turnover in Authority membership (this requires no changes to standing orders). The Chair took this opportunity also to review the current expert adviser appointments on the committee, in light of upcoming areas of work.
- 2.6. As a result of the review, it is proposed that paragraph 6.4 be amended to increase the number of external expert advisers appointed to the committee from eight to eleven.

- 2.7.** This reflects an identified need for further expertise to complement the expertise of the existing SCAAC membership in developmental biology genetics and embryo research, clinical ‘big data’ and andrology.

Register research panel terms of reference

- 2.8.** The proposal for RRP is to extend its role and function to include making decisions for access to ‘safeguarded’ data requests, such as additional fields added to the anonymised Register, which is available publicly on our website. This additional scope has been introduced through a Data Research Project which aims to provide more useful and timely data to researchers, where this can deliver public benefit.
- 2.9.** The membership of RRP needs to be revised to reflect recent turnover in HFEA staff, and to recognise the new expertise we have in the organisation, following the organisational restructure (including the Head of Research and Intelligence and Research Managers).
- 2.10.** To ensure that appropriate independence is retained when making decisions, while recognising that the risk and impact of decisions taken at RRP can vary significantly, we propose to amend the membership considerations to include “due consideration to the balance of membership to ensure a fair and robust appraisal of any research applications and decisions.”
- 2.11.** We also propose to make explicit the requirement for the Chair of the panel to sign off all decisions and minutes.

3. Recommendation

- 3.1.** The Authority is asked to approve the three amendments to Committee terms of reference set out in Annex 1 to this paper, by formal vote.
- 3.2.** If agreed, the changes will take effect from 31 January 2019.

Annex 1 (Revised terms of reference – from Annex A of standing orders)

3. The Statutory Approvals Committee

Purpose of the committee

- 3.1.** The purpose of the Statutory Approvals Committee is to keep under review and to authorise the use of embryo testing; to authorise the use of mitochondrial donation treatment; to issue special directions for the import/export of gametes; and to authorise the use of novel processes in licensed activities.

Delegated powers and functions of the Statutory Approvals Committee

- 3.2.** The Authority delegates to the Statutory Approvals Committee the following powers:
- a) the authorisation of the use of embryo testing for conditions not previously authorised by the Authority (under schedule 2, paragraph 1ZA(1)(a), (b) and (c) of the Act)
 - b) the authorisation of the use of embryo testing to establish whether the tissue of any resulting child would be compatible with that of a sibling that suffers from a serious medical condition (under schedule 2, paragraph 1ZA(1)(d))
 - c) the authorisation of the use of embryo testing to establish whether an embryo is one of those whose creation was brought about by using the gametes of a particular person (under schedule 2, paragraph 1ZA(1)(e))
 - d) the authorisation of the use of maternal spindle transfer (MST) and/or pronuclear transfer (PNT) for a named patient (under The Human Fertilisation and Embryology (mitochondrial donation) regulations 2015)
 - e) the issuing of special directions for the import/export of gametes or embryos (under section 24(4AA) of the Act), and
 - f) the authorisation of the use of novel processes in licensed activities.
- 3.3.** The functions of the Statutory Approvals Committee shall include:
- g) keeping under review the genetic conditions authorised by the Authority for embryo testing.

Membership of the Statutory Approvals Committee

- 3.4.** The Statutory Approvals Committee shall operate from a pool of members, sitting for each meeting consist of with no more than six members, ~~which~~ The membership shall include:
- a) a Committee Chair (who shall be a lay Authority member)
 - b) a Deputy Committee Chair (who shall be a lay Authority member)

c) up to ~~four~~five other Authority members.

3.5. The Chair of the HFEA shall appoint the members of the Statutory Approvals Committee.

3.6. Members of the Statutory Approvals Committee shall usually be appointed for a term of three years.

Meetings of the Statutory Approvals Committee

3.7. The quorum for a meeting of the Statutory Approvals Committee shall be three including the Committee Chair or Deputy Committee Chair and two other members.

3.8. The Statutory Approvals Committee shall usually meet 12 times per year. At the discretion of the Chair, the committee may meet additionally at short notice (and, if necessary, by telephone- or video-conference) if the Chair considers there is an item (or items) which cannot be delayed until the next meeting.

3.9. No member of the Statutory Approvals Committee present at a meeting shall abstain from voting.

3.10. Decisions of the Statutory Approvals Committee to authorise embryo testing, mitochondrial donation treatment or novel processes, or to issue special directions, require a simple majority (and in the event of a tie, the Committee Chair shall have a casting vote).

Attendance at meetings of the Statutory Approvals Committee

3.11. In addition to members of the Statutory Approvals Committee, the following persons shall usually attend its meetings:

- d) a legal adviser
- e) a specialist adviser
- f) the Senior Governance Manager or the Head of Planning and Governance
- g) the Committee Secretary.

3.12. The Committee Chair may invite such other persons (including employees) as he/she considers appropriate, to attend the meetings of the Statutory Approvals Committee and/or to provide advice to inform the deliberations of the Statutory Approvals Committee.

3.13. The Committee Chair may determine when and whether it is necessary or desirable for any non-members of the committee to withdraw from the meeting to enable the committee to deliberate in private.

6. The Scientific and Clinical Advances Advisory Committee

Purpose of the committee

- 6.1.** The purpose of the Scientific and Clinical Advances Advisory Committee is to advise the Authority on scientific and clinical developments (including research) in assisted conception, embryo research and related areas.

Functions of the Scientific and Clinical Advances Advisory Committee

- 6.2.** The functions of the Scientific and Clinical Advances Advisory Committee shall be to:
- a) make recommendations to the Authority on the safety and efficacy of scientific and clinical developments (including research) in assisted conception, embryo research and related areas
 - b) make recommendations to the Authority on patient information relating to those scientific and clinical developments
 - c) advise the Authority on significant implications for licensing and regulation arising out of such developments, and
 - d) where required, work with the Authority members to consider the social, ethical and legal implications arising out of such developments.

Membership of the Scientific and Clinical Advances Advisory Committee

- 6.3.** The Scientific and Clinical Advances Advisory Committee shall consist of five Authority members, which shall include:
- a) a Committee Chair (who shall be an Authority member)
 - b) a Deputy Committee Chair (who shall be an Authority member), and
 - c) three other Authority members.
- 6.4.** In addition, up to ~~eight~~ eleven other persons, who shall not be Authority members, shall be appointed as expert advisers to the committee. Such persons shall not be entitled to vote.
- 6.5.** At least one of the Authority members of the Scientific and Clinical Advances Advisory Committee shall have clinical or scientific expertise.
- 6.6.** The Chair of the HFEA shall appoint the members of the Scientific and Clinical Advances Advisory Committee.
- 6.7.** Members of the Scientific and Clinical Advances Advisory Committee shall usually be appointed for a term of three years. Expert advisers may be appointed for a period of one, two or three years.

Meetings of the Scientific and Clinical Advances Advisory Committee

- 6.8.** The quorum for a meeting of the Scientific and Clinical Advances Advisory Committee shall be three including the Committee Chair or Deputy Committee Chair of the committee.
- 6.9.** The Scientific and Clinical Advances Advisory Committee shall usually meet three times each year.

Attendance at meetings of the Scientific and Clinical Advances Advisory Committee

- 6.10.** The Committee Chair may invite such other persons (including employees) as he/she considers appropriate, to attend the meetings of the Scientific and Clinical Advances Advisory Committee and/or to provide expert advice to inform the deliberations of the committee.
- 6.11.** The Committee Chair may determine when and whether it is necessary or desirable for any non-members of the Scientific and Clinical Advances Advisory Committee to withdraw from the meeting to enable the committee to deliberate in private.

8. Executive Panels concerned with Disclosure of Information for Research Purposes

Register Research Panel

Purpose of the Register Research Panel

- 8.1.** The purpose of the Register Research Panel is to consider applications made under the Human Fertilisation and Embryology (disclosure of information for research purposes) regulations 2010 ('the 2010 regulations') and requests for additional fields on the anonymised register ("safeguarded" data).

Delegated powers and functions of the Register Research Panel

- 8.2.** 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.
- 8.3.** The functions of the Register Research Panel shall be to:
- a) consider requests for the provision of data for research purposes, including safeguarded and identifiable data
 - b) comply with the requirements of the 2010 regulations
 - c) review annual reports submitted by research establishments
 - d) publish lay summaries of research projects involving the use of Authority Register data
 - e) submit a report to the Authority's Oversight Committee about the work of the Register Research Panel not less than once a year
 - f) refer appeals against the decisions of the Register Research Panel to the Register Research Review Panel, and
 - g) liaise and collaborate with any appropriate bodies in the UK with an interest in the safeguarding of personal data and the oversight of research studies involving the linkage of complex datasets.

Membership of the Register Research Panel

- 8.4.** The Register Research Panel shall consist of:
- a) an HFEA Director, who will act as the Chair of the Register Research Panel
 - ~~a) the Director of Compliance and Information, who will act as the Chair of the Register Research Panel~~
 - b) the Authority's Caldicott Guardian
 - ~~b) the Authority's Caldicott Guardian (the Head of Intelligence), and~~

- a) the Head of Research and Intelligence
- b) the Chief Information Officer
- c) the Register Information Manager
- d) the Data Analyst
- e) a Policy team member
- a)f) the Research Manager responsible for Register Research, who will act as secretary

Meetings of the Register Research Panel

- 8.5.** The quorum for a meeting of the Register Research Panel shall be three, and there shall be due consideration to the balance of membership to ensure a fair and robust appraisal of any research applications and decisions. All decisions and minutes must be signed off by the Chair.
- 8.6.** Meetings of the Register Research Panel will be scheduled as required and in accordance with any memorandum of understanding between the Authority and bodies responsible for national information governance.
- 8.7.** Meetings of the Register Research Panel will be private.

Attendance at meetings of the Register Research Panel

- 8.8.** In addition to the Chair and members of the Register Research Panel, such other employees as the Chair considers necessary may attend the meetings of the Register Research Panel.
- 8.9.** The Chair of the Register Research Panel may invite such other persons (including non-Authority members and representatives from the Department of Health and Social Care) as the Chair considers appropriate, to attend the meetings of that panel and/or to provide expert advice to inform the deliberations of the panel.

EU exit preparations

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

Details:

Meeting	Authority
Agenda item	8
Paper number	HFEA (30/01/2019) 903
Meeting date	30 January 2019
Author	Peter Thompson, Chief Executive and Nick Jones, Director of Compliance and Information

Output:

For information or decision?	For information
Recommendation	Comment and approve arrangements relating to the Authority's preparedness for EU exit
Resource implications	
Implementation date	
Communication(s)	
Organisational risk	<input type="checkbox"/> Low <input type="checkbox"/> Medium <input checked="" type="checkbox"/> High
Annexes	Annex A: HFEA EU exit preparedness for a 'no deal'

1. Background

- 1.1.** This paper sets the challenges of EU Exit for the HFEA. Although we do not have a direct operational delivery role, our approach to this issue is to try to ensure continuity of service for fertility patients and staff where we can.
- 1.2.** Our membership of the EU affects the provision of assisted reproduction and research involving human embryos in the UK in two principal areas:
- Legal – several pieces of EU law, which have been incorporated into our national legislation already, are relevant to the responsibilities of the HFEA;
 - Operational – EU rules set the framework for the movement of gametes and embryos across European borders; as one of the 28 Competent Authorities we share information about the quality and safety of gametes and embryos across the UK; many drugs and medical devices are imported into the UK from elsewhere in the EU; and many EU nationals work in UK fertility clinics and laboratories.
- 1.3.** The UK government recently reached a withdrawal agreement with the EU. However, at the time of writing (23 January 2019) the UK Parliament has not yet approved that agreement. Delivering the deal remains the government's top priority and is the best 'no deal' mitigation. The Department of Health and Social Care (DHSC) is leading and co-ordinating planning across the health and social care sector and all its 15 arms-length bodies (ALBs) have been asked to play their part.
- 1.4.** Like other parts of the public sector we have been working to mitigate the impact of EU Exit for some time. Elements of that work have been considered by our Audit and Governance Committee on several occasions in 2018 but this is the first full Board level consideration of our EU Exit preparedness. As members will be aware, the political position is obviously fluid and it may be that some of the actions set out here will have been overtaken by events by the time the Authority meet.

2. Legal readiness

- 2.1.** There are five pieces of EU law that are relevant to the responsibilities of the HFEA:
- The EU Tissues and Cells Directive (2004/23/EC)
 - The First Technical Directive (2006/17/EC)
 - The Second Technical Directive (2006/86/EC)
 - The Coding Directive (EC/2015/565)
 - The Import Directive (EC/2015/566)
- 2.2.** All five of these Directives have been transposed into domestic UK law with the effect that regardless of what happens with EU Exit, including a 'no deal' exit, licensed fertility clinics in the UK will continue to meet – at least in the immediate period post exit - EU standards of quality and safety regardless of the EU Exit outcome.
- 2.3.** The only outstanding legal issue concerns the draft Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019 which were laid in Parliament in November 2018.

These draft regulations are technical in nature and are designed to ensure that the references to the EU Directives that exist in the HFE Act(s) are changed to reflect the UK's exit. These Regulations have been approved by the House of Commons and are due to be debated in the House of Lords. The Regulations come into force on exit day and allow for a six-month transitional period to enable time for UK clinics to put appropriate arrangements in place to reflect their new third country status. The aim is therefore that the Regulations are made before the UK's exit from the EU and the HFEA will continue to provide advice and guidance to clinics and patients in preparing for exit day. Depending on the outcome of the negotiations, the Regulations can be revoked or amended as required.

3. Operational readiness: the sector

- 3.1** We first surveyed licensed clinics in May 2018 with the aim of establishing whether EU Exit was having an impact on their operations, with a particular focus on the consequences on staffing given the numbers of EU nationals working in clinics. The feedback received largely indicated that the sector was not facing serious problems.
- 3.2.** In August 2018 the government released a 'technical notice' on the quality and safety of organs, tissues and cells in the event of a 'no deal' EU Exit (one of 25 technical notices issued that day). The aim of this notice was to set out the actions that organisations and businesses should consider taking, to ensure continued access to and use of organs, tissues and cells, including reproductive tissues and cells, in this scenario. The notice sets out two key points (discussed above):
- That in a 'no deal' exit tissues and cells from the UK would meet the current EU safety and quality standards;
 - That after exit day, the UK and EU countries would consider each other as third countries, and that written agreements would need to be made to import and export tissues and cells for human use between EU countries and the UK.
- 3.3.** We circulated that technical notice to all licensed clinics in Clinic Focus in September 2018.
- 3.4.** On 7 December 2018, the Secretary of State wrote a letter to the health and care system detailing the government's preparations for a March 2019 'no deal' scenario.
- 3.5.** We highlighted this letter to licensed clinics through Clinic Focus that same month. We highlighted the government's advice that clinics should be prepared for the possibility and impact of delays at the UK border and in relation to medicines and medical devices. We also urged clinics to review their business continuity plan (BCP) and adopt a 'reasonable worst case' mindset in doing so. To that end we asked clinics to:
- assess the risks to the supply of all essential supplies – medicines, gases, consumables, equipment parts in the event of failure – in relation to the safety of patients, gametes and embryos, and staff;
 - develop an awareness of the supply routes of their essential supplies.
- 3.6.** The actions clinics need to take will in part depend on whether they are within the NHS or independent sector.

- 3.7.** The January 2019 Clinic Focus will reinforce this advice and our inspectors will follow-up each clinic to ensure that they are undertaking an assessment and to deal with queries and any issues that arise.

4. Operational readiness: the HFEA

- 4.1.** It is important to note that some larger ALBs have a delivery focus that differs significantly from our functions. For example, NHS England/Improvement; Public Health England; NHS Blood and Transplant and MHRA are all engaged in the support of front-line services – which is qualitatively different from our primarily regulatory obligations.
- 4.2.** Like all DHSC delivery partners, we have been asked to implement our ‘no deal’ plans of which this paper is a part. To that end, we have appointed a SRO (senior responsible officer) for EU Exit and are participating in the various regular official level meetings with the wider health and care system and the DHSC. The DHSC, with the support of NHS England and Improvement, and Public Health England, has set up a national Operational Response Centre. This will lead on responding to any disruption to the delivery of health and care services in England, that may be caused or affected by EU Exit. The Operational Response Centre will co-ordinate EU Exit-related information flows and reporting across the health and care system.
- 4.3.** The DHSC have produced a framework to help organisations assess their readiness and our initial assessment of the HFEA is attached at Annex A. This framework is also be a useful guide for clinics in the sector and we will circulate it to them as part of Clinic Focus this month.

5. Next steps

- 5.1** In terms of next steps we are focused on:
- Being able to respond appropriately within DHSC operational readiness arrangements
 - Ensuring that our BCP arrangements are fit for purpose in what may be a fast-moving set of circumstances
 - Continuing to communicate with clinics, respond to their queries and check they are making contingency arrangements
 - Developing a script for enquiries team, for requests for information and assistance for both patients and clinics

6. Recommendation

The Authority is asked to:

Comment on and approve arrangements relating to the Authority’s preparedness for EU exit.

Annex A

HFEA EU exit preparedness for a 'no deal'

Things	<p>What, if anything, needs to be manufactured, developed or purchased and tested in order for the organisation to be ready to deal with any disruption? Have you factored in potential delays in the event of disruption at the border in a no deal scenario?</p> <p>We do not rely on imports of goods or services to undertake any aspect of our work</p>
Services	<p>Have you identified any EU Exit impacts on the services that you deliver, including any disruption at the border? Is your organisation affected by changes to legislation or the implementation of new regulations? Does your organisation have a full understanding of any process changes that might be needed to be ready to do business after exit day? Does your organisation need to update existing systems or implement new ones?</p> <p>See impact of legislation notably European Directive in relation to imports and exports of gametes and traceability, in paragraph 2 above.</p>
Workforce	<p>Have you publicised the EU Settlement Scheme to the EU citizens in your organisation? Have you considered paying the costs of the scheme for EU citizens in your organisation (£65 per adult)?</p> <p>Our capacity is not affected as we have few EU nationals in our workforce.</p>
Data flows	<p>All health and care organisations should follow DCMS and the ICO's guidance on data protection in a 'no deal' scenario, which can be viewed on gov.uk and the ICO website. Have you considered your organisation's data arrangements? Have you fed into DHSC's work on data so far?</p> <p>All of our data flows are within the UK</p>
Policies and procedures	<p>What needs to be in place for your organisation to be ready for exit day in all scenarios? How will your organisation measure, monitor and report on the impact of EU Exit, and what governance arrangements are in place? Have EU Exit impacts been discussed at your Audit and Risk Committee, and at your Board?</p> <p>Our EU exit planning, and reporting to AGC, started some time ago and aside from the uncertainty we are confident that we have assessed our own risks and readiness, and are working collaboratively with DHSC and clinics to mitigate apparent risks.</p> <p>Further, we are starting a body of work to test our attitude to enforcing compliance where exit has impacted upon a clinic's ability to comply – for example in the supply of equipment and materials. There may be compelling arguments for accepting mitigating arguments in such areas; at the same time we will wish to carefully consider the health and safety implications of doing so.</p>

People	<p>Will staff, customers, users, third party suppliers and delivery partners be ready? Have any organisational changes be communicated to them?</p> <p>We update clinics on a regular basis and will be enhancing the mechanisms for feedback over the next few weeks. We are preparing communication lines for patients and the public on how EU exit may affect them.</p>
Contracts	<p>Have you engaged with DHSC's work to identify contracts that may be impacted by potential changes to trading relations with the EU? Have you developed mitigations?</p> <p>We currently have no contracts that are impacted by EU exit.</p>
Funding	<p>Have you identified any funding implications on your organisation caused or affected by EU Exit? Have you considered factors such as: the direct and indirect cost of tariffs on goods and services that you buy; foreign exchange movements that could increase costs on goods and services; and higher vacancy rates and upward pay pressure if EU citizens in your workforce leave. Have you identified any loss of EU research funding? Have you identified all the potential costs of EU Exit on your organisation?</p> <p>We have identified no funding issues over the short to medium term.</p>

Communications strategy update 2017-2020

Strategic delivery:	<input checked="" type="checkbox"/> Safe, ethical, effective treatment	<input checked="" type="checkbox"/> Consistent outcomes and support	<input checked="" type="checkbox"/> Improving standards through intelligence
Meeting	Authority		
Agenda item	9		
Paper number	HFEA (30/01/2019) 904		
Meeting date	30 January 2019		
Author	Jo Triggs, Head of Engagement		
Output:			
For information or decision?	For information		
Recommendations	<ul style="list-style-type: none"> To review activities against the communications strategy. To consider the plans for future work. 		
Resource implications	Underpins all our corporate communications activities		
Implementation date	1 February 2019		
Communication(s)			
Organisational risk	<input type="checkbox"/> Low	<input checked="" type="checkbox"/> Medium	<input type="checkbox"/> High
Annexes	Communications strategy update		

1. Introduction

- 1.1. The HFEA was set up as a bargain by policy makers between science, medicine and society. Our communications work must always be reflective of this delicate balance between providing information on cutting edge scientific developments; considering the impact of our regulatory work; and providing information to patients.
- 1.2. We have achieved many of the objectives we set out in the two years since the 2017-2020 communications strategy was approved by the Authority. This update looks at what we want to further build on and what we will deliver in the final year of the strategy.
- 1.3. The communications strategy is closely aligned to our strategic objectives of equipping patients with information to make informed choices about their care and raising the quality of care by engaging with patients to encourage them to give feedback on their treatment. Our communications work also focuses on engagement with the media, social media and clinic staff.
- 1.4. When the strategy was considered by Authority in 2017, our focus was on communication to patients as it coincided with the launch of our (then) new website. We set out with the new website to be the first place that patients go for information about fertility treatment and factual information about clinics across the UK.
- 1.5. Our position as the fertility sector regulator provides both communication opportunities and constraints. We want to be a provider of information to patients, but we are not a campaign group and our work must reach lots of different audiences – not only patients.
- 1.6. As the regulator, we also need to maintain a level of separation from specific medical advice and remember we are not a direct deliverer of fertility services. However, we can regularly be an advocate, an intermediary between patients and complex information; and between the media and the public, we can support as well as regulate clinic activity and be the ‘moral touchstone’ that we were set up to provide.
- 1.7. This paper sets out some key aspects for discussion and further background information in terms of an update on our 2017-2020 communications strategy can be found in Annex 1.
- 1.8. The Authority is asked to consider what we have achieved against the objectives in the communications strategy and to review the proposed approach for the next 12 months.

2. Where are we now

- 2.1. We have done a lot in the last two years to establish good foundations to further build on and exciting new tools to use and develop. We have:

- implemented the new patient-focused website and evaluated its effectiveness as an information source for patients.
- introduced rich media to provide another visual element to our communications including patient videos and a video animation.
- increased our social media activity, including launching a new Facebook page and using infographics to increase our reach and get our messages across
- run more campaigns (used in the sense of linked communications over time on a given policy topic or theme) – examples include the 40th anniversary of IVF in 2018 and most recently treatment add-ons
- redesigned our clinic communications including the Clinic Focus newsletter and the knowledge base of the Clinic Portal
- considered our approach to the media to manage our reputation as a robust regulator but also to show we are knowledgeable and insightful of the sector we regulate. We are now building a more proactive approach to the media.

3. How successful have we been

- 3.1.** During 2018 we have had access to more metrics and feedback to give us a greater insight into the performance of our communications activities.
- 3.2.** These have included the national patient survey, in-page patient ratings on the website, and the patient ratings on choose a fertility clinic and google analytics.
- 3.3.** These tell us:
- 71% of patients who answered the patient survey are aware of the HFEA.
 - The new website is performing well with over 430,000 UK visitors in one year and a more engaged audience than the old website had.
 - We have exceeded our KPIs for social media engagement by putting out an average of 30 tweets each month and our followers growing on average by 20% each month.
 - Using ‘paid for’ social media advertising is a cost-effective way of getting our message across to a large audience within the limited resources we have.
 - The ‘only you’ campaign to promote the patient ratings on CaFC has gathered over 1500 patient ratings in the first year.
 - Over 900 clinic staff accessing the knowledge base areas of the Clinic Portal per month.

4. What we will do next and what are the challenges

- 4.1.** We have come a long way with our communications and engagement but there is still more to do to deliver the strategy.

- 4.2.** We know we are reaching patients through our social media and digital work and that we should continue this approach as it is a cost effective way of reaching a large audience when we have limited resources. There will always be challenges in this area, given the number of different groups and types of social media that exist. We will continue to evaluate our work here, including use of twitter, Facebook, looking into Instagram and further activities like informal Facebook groups.
- 4.3.** Our approach to media management has been to continue to use the media to manage our reputation as a robust regulator but also to show we are knowledgeable and insightful of the sector we regulate. As noted above, being the regulator does shape and constrain some of our communications. While we don't want to be part of every debate about fertility treatment we do want to speak proactively and boldly about topics that matter to us. We need to work harder with the media to create more opportunities to do this.
- 4.4.** This approach could bring us some challenges. If we are bolder with our messages it could open us up for some criticism, so we must be able to defend our stance. There will be some experts within the fertility sector who may challenge our opinions, so we must be prepared to enter debates and respond quickly to any criticism where necessary. This can be on social media or via statements to the press or broadcast media.
- 4.5.** Over the next 12 months we will channel our resources into different external communications opportunities to get our core messages across proactively to our stakeholders. These include:
- continuing our communications to inform patients about treatment add-ons
 - identifying core topics that we want to champion and seeking proactive media opportunities to do this
 - increasing our social media presence by identifying messaging for our channels and making more use of infographics
 - adapting a more proactive approach to media management and approaching journalists about the subjects we want to talk about and making our data more accessible to journalists.
 - seeking more external speaking opportunities to provide us with a public stage to get our core messages across
 - identifying credible spokespeople in the sector for the media to approach for unbiased views on specific topics
 - using case studies, where appropriate, to enforce our messages and provide a more 'human side' to the Regulator
 - improving our clinic communications as clinic staff are an audience in themselves, as well as an information channel to help us get messages across to patients

- developing our public affairs strategy to ensure we have effective communications with policy makers and professional bodies and other relevant groups across the UK.

5. How will we know if we are successful?

- 5.1.** We have developed a set of KPIs for our communication activities that we will use to monitor their success during the year.
- 5.2.** We report on the performance of our communications for our media, website and social media activity at the monthly corporate management group meetings.
- 5.3.** We will use other measures such as the staff and any future patient surveys to evaluate the performance of our communications
- 5.4.** We will carry out user testing on our website during 2019 which will give us qualitative feedback from patients on the design and content of the site.

The register research panel (RRP) and data research

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

Details:

Meeting Authority

Agenda item 10

Paper number HFEA (30/01/2019) 905

Meeting date 30 January 2019

Author Caylin Joski-Jethi, Head of Research and Intelligence

Output:

For information or decision? For information

Recommendation The Authority should note:

- the activity conducted by the RRP in 2018 (Annex A)
- the steps we have taken towards improving data research
- the process in place for accessing data held by the HFEA in the future

Resource implications

Implementation date Ongoing

Communication(s) None

Organisational risk Low Medium High

Annexes Annex 1: An overview of the delegated activity carried out

1. Background

- 1.1.** In its 2017-2020 strategy the HFEA committed to 'improve the quality of treatment, by encouraging world class research and clinical trials'. Particularly relevant to this paper are the commitments to:
 - Develop a larger, higher quality evidence base to lead to improved outcomes
 - Patients to be aware of research they could take part in, and to understand the benefits of research
- 1.2.** The HFEA holds a vital and central position supporting research into fertility treatment: we hold the largest register of fertility treatment data in the world, with experience of world class research being carried out using our data, either alone or, since 2010, by linking to other datasets.
- 1.3.** There are two main types of data which can be used in research, and there are different rules about how each can be accessed:
 - Anonymised data - where no identifiers are present and some of the information may be banded, or obscured, to protect patient privacy. This does not require patient consent to release.
 - Patient-identifying data - where the data may be very detailed, or contain actual identifiers (such as name, and date of birth) allowing the records to be linked to another database. This requires patient consent to release, and, for the years when consent was not collected on the Register (prior to October 2009), falls under the scope of the Human Fertilisation and Embryology (disclosure of information for research purposes) regulations 2010 ('the 2010 regulations').
- 1.4.** Since October 2009, patients who register for fertility treatment have been asked to consent to their information being included in studies where patient 'identifiers' are needed.
- 1.5.** However, in 2009 some clinics did not always recognise the importance of collecting consent to research and therefore, the overall consent rate for some years (2009-2012) is quite low (around 50%). This means the Register has reduced utility for these years, as research which requires identifiable data is less high powered. Over time, we have been able to work with clinics to improve the status of data research and consent rates are now around 70%, and we are continuing to look at ways to improve consent rates, and particularly, to improve consistency in consent rates across clinics.
- 1.6.** To ensure that information collected and held by the HFEA prior to 2009 (when as noted above consent to research was not collected) could be made available for high quality research, Parliament introduced the 2010 regulations, allowing the release of this data in some circumstances under strict ethical oversight.
- 1.7.** The remit of the Register Research Panel (RRP) under the 2010 regulations is to consider and, where appropriate, authorise access for research studies which require identifiable data. Such identifiable data can only be released through a RRP determination (with due regard to the regulations) and for patients who have consented to the use of their data being used in research.
- 1.8.** To enable the Authority (the 'Oversight Committee' under the 2010 regulations) to discharge its functions, it considers an overview report submitted by the RRP on an annual basis. The previous overview report of this type (January 2017) also set out the ways in which the profile of the RRP

could be increased following the establishment of the intelligence team and the ambitions set out in the HFEA's 2017-2020 organisational strategy.

1.9. This paper has three related aims:

- To provide an overview of the work conducted in 2018 which falls under the RRP's delegated functions (see Annex A)
- To provide an update on the steps we have taken so far towards improving data research
- To provide a summary of the data access process in the future

2. The benefits of register research

2.1. Large scale linkage studies (those using identifiable data) can deliver significant value to the understanding of the safety and efficacy of assisted reproductive treatments with a focus on the long term health effects on woman, child, donor or partner; and factors which might affect success rates, or the risks of treatments.

2.2. Recently, three studies were published using linked data from our Register. The summaries below are excerpts from the research paper abstracts.

Cancer risk in children born after donor ART¹

- This is the first study to investigate cancer risk in children born after donor ART. Although based on small numbers, results are reassuring for families and clinicians. The small but significant increased risk of hepatoblastoma detected was associated with low birthweight, a known risk factor for this tumour type. It should be emphasized that the absolute risks are very small. However, on-going investigation with a longer follow-up is needed.

Risks of ovarian, breast, and corpus uteri cancer in women treated with assisted reproductive technology in Great Britain, 1991-2010: data linkage study including 2.2 million person years of observation²

- No increased risk of corpus uteri or invasive breast cancer was detected in women who had had assisted reproduction, but increased risks of in situ breast cancer and invasive and borderline ovarian tumours were found in this study. Our results suggest that ovarian tumour risks could be due to patient characteristics, rather than assisted reproduction itself, although both surveillance bias and the effect of treatment are also possibilities. Ongoing monitoring of this population is essential.

The growth of assisted reproductive treatment-conceived children from birth to 5 years: a national cohort study³

- ART babies born from fresh embryo transfer grow more slowly in utero and in the first few weeks of life, but then show postnatal catch up growth by school age, compared to NC and

¹ C L Williams, K J Bunch, M F G Murphy, C A Stiller, B J Botting, W H Wallace, M C Davies, A G Sutcliffe; Cancer risk in children born after donor ART, *Human Reproduction*, Volume 33, Issue 1, 1 January 2018, Pages 140–146, <https://doi.org/10.1093/humrep/dex333>

² Williams Carrie L, Jones Michael E, Swerdlow Anthony J, Botting Beverley J, Davies Melanie C, Jacobs Ian et al. Risks of ovarian, breast, and corpus uteri cancer in women treated with assisted reproductive technology in Great Britain, 1991-2010: data linkage study including 2.2 million person years of observation *BMJ* 2018; 362 :k2644

³ Hann, Mark, Stephen A. Roberts, Stephen W. D'Souza, Peter Clayton, Nick Macklon, and Daniel R. Brison. "The growth of assisted reproductive treatment-conceived children from birth to 5 years: a national cohort study." *BMC medicine* 16, no. 1 (2018): 224.

FET babies. As low birth weight and postnatal catch-up are independent risk factors for cardiometabolic disease over the life-course, we suggest that further studies in this area are now warranted.

- 2.3.** Research using anonymised Register data can also produce high quality insight and knowledge. Previous studies have shown, for example:
- The age of the sperm donor (up to 45 years) does not influence live birth outcome in assisted reproduction⁴
 - There is a higher-risk of preterm birth and low birth weight after oocyte donation IVF⁵
 - That although most couples in the UK still do not receive three complete IVF cycles; assuming no barriers to continuation of IVF treatment, around 83% of women receiving IVF would achieve a live birth by the eighth complete cycle, similar to the natural live birth rate in a non-contraception practising population⁶
- 2.4.** These studies raise important questions about how the HFEA builds on the knowledge gained from research and use this to inform our understanding of risks and success factors, and influence how we provide clear, unbiased and trusted information for patients, donors, and donor conceived people. With the expected completion of our information systems renewal project, this is the type of evidence-based approach to regulation we will be pursuing in our current work and strategies in the future.
- 2.5.** We will share these thoughts with SCAAC and explore how to ensure close links between RRP and SCAAC as our work to improve engagement with data researchers increases its pace.

3. Facilitating high quality and ethical data research

- 3.1.** We have made some significant changes in the past year to improve the way we work with researchers and initiate a process to ensure research can deliver the benefits we aim to deliver through our strategy.
- 3.2.** Since the last report to Authority we have:
- Held a workshop with a selection of researchers in January 2018. This workshop identified key areas of improvement, as well as developing the data access process
 - Developed and published a new anonymised Register, with clear and accessible guidance on the variables included
 - Developed an 'Our data' area of the website which provides information on the data we hold, how to apply to access our data, and a summary of some studies to date. We intend to develop this further to provide updated guidance on how researchers can access Register data, , more information on ongoing research, and more information on published studies.

⁴ N.K. Ghuman, E. Mair, K. Pearce, M. Choudhary; Does age of the sperm donor influence live birth outcome in assisted reproduction?, Human Reproduction, Volume 31, Issue 3, 1 March 2016, Pages 582–590, <https://doi.org/10.1093/humrep/dev331>

⁵ Kamath, M.S., Antonisamy, B., Mascarenhas, M. and Sunkara, S.K., 2017. High-risk of preterm birth and low birth weight after oocyte donation IVF: analysis of 133,785 live births. Reproductive biomedicine online, 35(3), pp.318-324.

⁶ McLernon, D.J., Maheshwari, A., Lee, A.J. and Bhattacharya, S., 2016. Cumulative live birth rates after one or more complete cycles of IVF: a population-based study of linked cycle data from 178 898 women. Human Reproduction, 31(3), pp.572-581.

- Published expanded underlying datasets for each of our publications, offering more scope for researchers and policy makers to explore the questions that are relevant to them
- Set up an 'Intelligence inbox' through which we liaise regularly with researchers and address ad hoc queries about the data we hold
- Developed a new tiered data access request service, which incorporates a clear requirement for impact to be evidenced through the evaluation process (detailed in section 4)
- Developed an intelligence strategy which ensures sufficient capacity is allocated to improving data research
- Reviewed all our data research policies, processes and MoUs with significant external organisations
- Designed a new data sharing contract to ensure we are meeting our obligations under GDPR

4. Accessing Register data for research

- 4.1.** In addition to fulfilling its delegated statutory role to oversee access to identifying patient data for use in research, the HFEA publishes anonymised, very low risk, Register data on its website, known as the anonymised Register. This is appropriate for many kinds of research which can still provide high quality and valuable knowledge.
- 4.2.** However, there are some limitations to providing anonymised data only in the existing anonymised Register format. By banding so many variables, and only providing a limited subset of the Register, not all research questions can be answered with this data source, such as those about cumulative success rates, or those looking at variables not included in this anonymised dataset.
- 4.3.** The existing RRP process for accessing identifiable data is a barrier to researchers wanting to conduct research using anonymised data (that with a very low risk of identifiability), and the process is very involved and time consuming.
- 4.4.** Therefore we determined that, in order to ensure that cost-effective and high quality research could take place, the HFEA needed to establish a new data access process, to enable researchers to access variations of our anonymised Register dataset that does not risk identifying patients.
- 4.5.** To help inform the structure of our new data access service, we held a workshop with researchers in January 2018. Feedback from this identified strong support for an intermediary level of data access for data which has a low risk of identification, but may contain more, or different Register data fields.
- 4.6.** Subsequently we developed a three-tiered approach to processing requests for Register data. This approach will enable us to meet our strategic objectives to make best use of our Register and engender high quality research, while ensuring the security and confidentiality of patient data.
- 4.7.** The tiered access process incorporates the following levels:
- Open – this is published online and can be provided to anyone on request. The anonymised Register is updated on an annual basis and is published here: <https://www.hfea.gov.uk/about-us/our-data/>

- Safeguarded – data which presents very low privacy risks, and is an adapted version of our anonymised Register published online. RRP determines that the potential benefits of providing dataset outweigh any potential privacy risks and the resource implications for the HFEA in making this available. In order to eliminate any privacy risks, we limit access to the dataset using a licence process as part of our safeguarded access terms and conditions of use.
- Full RRP data access – datasets which present high privacy risks where the benefits are judged to outweigh the potential privacy risks, and where the full conditions of the 2010 regulations are met. In order to reduce, manage and monitor the privacy risk whilst enabling the benefits to be realised, the formal RRP data access and oversight mechanisms will be used.

4.8. This new data access process offers many benefits as:

- The data request can be assessed to ensure it protects patient confidentiality and is useful for scientific research.
- It recognises that zero risk data provision is not possible, if we want to achieve some benefit. However, it puts in place a framework to mitigate that risk (such as setting restrictions on use) and gives the Authority assurance.
- The measures put in place to manage this risk are proportionate to the risk associated with the dataset.
- This supports us to engage in regular dialogue with researchers.
- It ensures more research can take place using the full set of Register data (rather than only those who consented to the use of their data in research from 2009 onwards, which, due to low consent rates in 2009-2012 could reduce the validity of the study).

5. Incorporating the patient perspective into our data access process

- ### **5.1.** The patient perspective is important when considering data that is released under open or safeguarded terms and conditions, because while this data is anonymised, we want to ensure that we put patients at the heart of high quality care in fertility clinics. This means understanding their perspectives before making a change to how we work, even where there is very low risk.
- ### **5.2.** Existing research into public attitudes about health data shows that, in general, people are happy for their personal data to be used for research. Research by the Wellcome Trust⁷ showed that a strong case for public benefit is the most important factor for many patients: without it, data use by any organisation (public or commercial) is rarely acceptable.
- ### **5.3.** Patients tended to apply four tests to their decision-making process:
- Why? Is it for a particular public benefit and not just private profit?
 - Who? Can the people using data be trusted to produce a public health benefit?
 - What? Is this data sensitive? Could it be linked back to me?
 - How? Are there safeguards in place to keep data private and secure?

⁷ <https://wellcome.ac.uk/sites/default/files/public-attitudes-to-commercial-access-to-health-data-summary-wellcome-mar16.pdf>

- 5.4.** We want to make sure that our data access processes are in line with research into how patients feel about their data being used for research, and, where patient data is used, it's managed safely and securely, and patient confidentiality is respected.
- 5.5.** In delivering our new data access service, and updating our policies and processes as part of the data research project, we incorporated what we know from research into how patients want their data to be used by:
- Incorporating a focus on 'public benefit' into the application process and decision-making process
 - Taking a risk-based approach to the release of data, with 'safeguarded data access' terms and conditions to manage the very low risk to patient confidentiality
 - Considering the background of the organisation requesting the data in our decisions about whether to approve safeguarded data requests
 - Plan to continue to develop the 'Our data' section of the website so that patients can receive up to date information on the research that is taking place and be fully informed

6. Recommendations

- 6.1.** This work is underway, as part of the 2018/19 and 2019/20 workstreams, and we continue to strengthen our work with the research community.
- 6.2.** The Authority are asked to note:
- the activity conducted by the RRP in 2018 (Annex A)
 - the steps we have taken towards improving data research
 - the process in place for accessing data held by the HFEA in the future

1. Annex 1: An overview of the delegated activity carried out

New applications

- 1.1.** There was one new application approved during 2017. The researcher's summary of the project is provided below.

Environmental Determinants of IVF, University of Edinburgh, Dr Tom Clemens

- 1.2.** The main aim of this project is to examine whether exposure to environmental characteristics (ambient outdoor air pollution and solar Ultraviolet Radiation) is associated with outcomes of IVF fertility treatment. There is good evidence that characteristics of the physical environment influence fertility, pregnancy and the long term health of children. Research has shown that ambient air pollution exposure is associated with low birth weight and an increased risk of preterm birth.

- 1.3.** This study will involve a linkage between the HFEA's Register data and Scottish environmental data via the National Records of Scotland (NRS) who have a linkage service working in partnership with NHS National Services Scotland (NSS) and the Administrative Data Research Centre (ADRC), funded by the Economic and Social Research Council (ESRC). This collaboration is part of the Scottish Informatics and Linkage Collaboration (SILC).

- 1.4.** This was approved for a period of 2 years from November 2017.

Engagement in previously approved research projects

- 1.5.** There was one project which required engagement from the Register research panel in order to progress their application through the next stage of the data linkage process. The researchers' summary of the project is provided below.

Prolonged effects of assisted reproductive technologies on the health of women and their children: a record linkage study for England (PEARL), University of Oxford, Dr Claire Carson

- 1.6.** In general, most children born after the use of fertility treatment (such as IVF) are healthy. However, there is a slight increase in the number of children who are born early, have a low birthweight, with health or developmental problems. Less is known about the health of children born after fertility treatment as they grow up, as long-term follow-up studies are costly and time consuming. As a result, many studies are not big enough to detect small differences between the groups – which is important because the effects of fertility treatment on health may be subtle. More evidence is also needed about the long-term wellbeing of women accessing fertility treatment.

- 1.7.** This study will link data from the HFEA Register to health records from GP practices across England held by the Clinical Practice Research Datalink (CPRD) and records of hospital care, from Hospital Episode Statistics already linked to CPRD data. The linkage will be conducted by NHS Digital and requires approval of all the relevant legal bases, data sharing agreements and contracts between all parties, and the assurance that appropriate security and access policies are in place.

- 1.8.** The NHS's Data Access Request Service and CPRD required significant engagement to agree the best way to present the legal basis, security information and data sharing contracts. This

project's RRP approval is due to expire on 12 January 2018 and we will need to consider if this should be extended on 12 January 2020.

Estates update

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

Details:

Meeting Authority

Agenda item 11

Paper number HFEA (30/01/2019) 906

Meeting date 30 January 2019

Author Richard Sydee, Director of Finance & Resources

Output:

For information or decision? For information

Recommendation The Authority is asked to note the progress with the DHSC programme and the recommendation that Stratford is the preferred future location for the HFEA.

Resource implications

Implementation date November 2020

Communication(s)

Organisational risk Low Medium High

Annexes -

1. Background

- 1.1.** The HFEA have a lease on their current office space, at 10 Spring Gardens, that runs until November 2020. The main tenant of the building, the British Council, have secured new premises and have offered all other tenants of 10 Spring Gardens (ourselves and NICE) the opportunity of relocating with them to new offices in Stratford, East London. We have been involved in those discussions since spring 2018.
- 1.2.** In mid-2018 DHSC launched a wider programme of work looking at the current and future accommodation needs of all its ALBs with a London presence. The Authority will recall that all Whitehall Departments have been actively reducing their office accommodation within central London, limiting space only to those who need regular access to Parliament and Ministers. The DHSC programme was initiated to consider the future requirement for central London and the possibility of accommodating more staff outside London and the South East.
- 1.3.** This programme has now absorbed our requirement in to their overarching programme and the ongoing negotiations with regard to a future location for the HEA rest therein.
- 1.4.** In December 2018 the DHSC Project Steering Group approved the recommendations paper for the future DHSC London Estate; this confirmed the preferred location for HFEA as Stratford alongside a number of other ALBs. The Stratford option is preferred predominantly for its ability to deliver appropriate accommodation space at the start of the programme and in line with our need to vacate Spring Gardens by November 2020 and as it aligns with the wider programme aims of accommodating the majority of London based ALB staff in either Stratford or Canary Wharf.

2. Next steps

- 2.1.** Now this first stage of the process has been completed there are a number of further approvals and permissions that must be sorted before contracts can be signed.
 - The Steering Group recommendations must be approved by David Williams, Director General Finance and Group Operations at DHSC.
 - The recommendations must then be cleared by the Cabinet Office “Places for Growth” Directorate, who own the wider Government initiative to move more Government organisations and jobs outside of London and the South East.
 - A full business case for the overarching programme will then be prepared and approved by the steering group and DHSC board.
 - Individual Board approval for each organisation to the programme recommendations.
- 2.2.** It is hoped that the first three points in this process will be complete by 31 March 2019, at which point organisation level business cases will be prepared to be ratified by ALB boards. We anticipate bringing a decision paper to the Authority, including the HFEA business case for relocation, to the May Authority meeting, this will be dependant on the speed at which decisions will need to be made regarding contract commitments to facilitate our move.
- 2.3.** Although no contracts will be signed until the full business case has been approved discussions continue with the British Council and the lease owner to develop plans for the Stratford site to

ensure that the new accommodation is available for HFEA in line with the required exit date from Spring Gardens in November 2020.

- 2.4.** As well as managing the programme and logistical elements of the move we will soon be initiating an in-house project group to look in more detail at both the physical requirements of our new office space and how the organisation can adopt new technologies and ways of working. We are keen to ensure that the move of office support our wider cultural transformation work, to ensure the physical environment suits our working practices and requirements and allows staff to be fully engaged with the organisation regardless of the frequency in which they attend our offices.

3. Recommendation

- 3.1** The Authority are asked to note the progress with the DHSC programme and the recommendation that Stratford is the preferred future location for the HFEA.