

Authority meeting held by teleconference

Date and – Wednesday, 27 January 2021

Time - 1.15pm to 3.00pm

Venue - online

Agenda items	Time
1. Welcome, apologies and declarations of interest	1.15pm
2. Minutes of the meeting held 11 November 2020 For decision	1.20pm
3. Chair's report For information	1.25pm
4. Chief Executive's report For information	1.40pm
5. Performance report For information	1.50pm
6. Covid-19 update For information	2.10pm
7. PRISM update For information	2.35pm
8. The register research panel (RRP) annual report For information	2.45pm
9. Any other business	3.00pm

Minutes of Authority meeting 11 November 2020

Details:

Area(s) of strategy this paper relates to:	<p>The best care – effective and ethical care for everyone</p> <p>The right information – to ensure that people can access the right information at the right time</p> <p>Shaping the future – to embrace and engage with changes in the law, science and society</p>
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Agenda item	2
Meeting date	27 January 2021
Author	Debbie Okutubo, Governance Manager

Output:

For information or decision?	For decision
Recommendation	Members are asked to confirm the minutes of the Authority meeting held on 11 November 2020 as a true record of the meeting

Resource implications

Implementation date

Communication(s)

Organisational risk Low Medium High

Annexes

Minutes of the Authority meeting on 11 November 2020 held via teleconference

Members present	Sally Cheshire Margaret Gilmore Anita Bharucha Anthony Rutherford Emma Cave Anne Lampe	Jonathan Herring Gudrun Moore Ruth Wilde Yacoub Khalaf Ermal Kirby Kate Brian
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Apologies

Observers	Marina Pappa Steve Pugh (Department of Health and Social Care - DHSC)
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Staff in attendance	Peter Thompson Richard Sydee Rachel Cutting Catherine Drennan Dan Howard Andrew Leonard	Paula Robinson Debbie Okutubo Dina Halai Helen Crutcher Emily Tiemann
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Members

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

1. Welcome, apologies and declarations of interest

- 1.1. The Chair opened the meeting by welcoming Authority members, the public and staff present online. She stated that the meeting was audio recorded in line with previous meetings and the recording would be made available on our website to allow members of the public who were not able to listen in during our deliberations to hear it afterwards.
- 1.2. There was one staff apology for absence from Clare Ettinghausen, Director of Strategy and Corporate Affairs.
- 1.3. Declarations of interest were made by:
 - Yacoub Khalaf (PR at a licensed clinic)
 - Anthony Rutherford (clinician at a licensed clinic)
 - Ruth Wilde (counsellor at licensed clinics)
 - Kate Brian (working at Fertility Network UK).

2. Minutes of the last meeting

- 2.1. Members agreed that the minutes of the meeting held on 16 September 2020 were a true record of the meeting and could be signed by the Chair.

3. Performance report and strategic risk register

- 3.1. The performance report, covering data up to September 2020 was presented to the Authority. It was noted that there were three indicators classed as red, F1 - debt collection; F3 - prompt payment; and R1 - register errors.
- 3.2. The Chief Executive (CE) commented that overall performance was good. Sickness absence was very low with only eight days in total. The majority of staff had adapted well to working from home, but staff wellbeing remained a concern and will continue to be kept under review.
- 3.3. In response to a question, it was noted that staff were encouraged to take annual leave to avoid burn out, even though it was appreciated that people were unable to travel anywhere due to the current lockdown and the pandemic. It was noted that this information was cascaded to staff through a number of avenues including the all-staff meetings, team meetings and during one to ones.
- 3.4. The Chair commented that HFEA staff were doing incredible work even though we were not regarded as frontline staff. At the persons responsible (PR) virtual event held recently, it was noted how stressful clinic staff were finding working during this pandemic and the effect it was having on morale and efficiency.
- 3.5. The CE elaborated on this and explained that we hosted the annual PR event with identical morning and afternoon sessions. They were very well attended and the agenda was varied. The Chair opened the meeting at both sessions and among other topics, the challenges posed by Covid-19 were discussed.
- 3.6. Today, in the absence of the Director of Strategy and Corporate Affairs, the CE informed members that the Competition and Markets Authority (CMA) had launched their draft guidance for the fertility sector about clinics' consumer law obligations. The guidance has been issued for consultation and would be finalised next March. After a period of 'bedding in', enforcement action could be taken by the CMA if they found that UK consumer protection law was not being adhered to by clinics. The HFEA have been closely involved in developing this work and are fully supportive of it. It will be very helpful for patients to ensure costs and terms of treatment are fully transparent and more easily comparable between clinics.
- 3.7. The week commencing 2 November 2020 was National Fertility Awareness week and the HFEA had supported it through online activity and a video message from the Chair. Staff were thanked for all their work on this.
- 3.8. The State of the Sector report, our annual review of compliance, would be published later in the month. As we now published quarterly non-compliance reports via Clinic Focus, this would be a shorter report than in previous years.
- 3.9. It was reported that progress had been made on the patient forum to ensure a regular flow of feedback between the HFEA and patients. This would be via virtual and online activity and more information would be given at the next Authority meeting.
- 3.10. The Chair commented that she spoke at a Wellbeing of Women webinar on egg freezing where the HFEA website was being signposted as an excellent source of independent information and advice.

- 3.11.** The Director of Compliance and Information presented to the Authority. Members were advised that the paused opening the register (OTR) service was re-opened on 20 October. The OTR team had processed the earlier backlog of applications. Due to the service being closed for six months there has now been a significant influx of new applications which would take longer to process.
- 3.12.** Members asked what the timeliness risk was in turning around the backlog in OTR requests. The Director of Compliance and Information responded that the previous backlog had already been cleared, and that it was the increased influx of requests since the service had re-opened which were the issue. The OTR team are working through them and applicants are being told that there may be a delay but the team will do their very best to expedite requests as soon as possible. The new Register Information Team Application (RITA) was being developed and it would support the register. It was noted that the website states that requests would be responded to as soon as possible.
- 3.13.** It was noted that the Choose a Fertility Clinic (CaFC) verification exercise in preparation for the forthcoming update was progressing well.
- 3.14.** The Director of Finance presented on HFEA finances and reiterated that debt collection was in the red. He commented that this indicator had been affected by Covid-19 impacting the sector, but we had started to see improvements in recent weeks' and we expect the collection rate to continue to improve over time.
- 3.15.** Members were advised that we were forecasting an underspend in expenditure against the budget.
- 3.16.** Regarding the office move to Redman Place, Stratford E20, the premises would be ready by 18 November and we will change our address officially on 1 December 2020. Staff will potentially be able to go into an office setting subject to government guidance from January 2021.

Strategic risk register

- 3.17.** The strategic risk register was noted. The Chair commented on board appointments and hoped that it should be resolved shortly via our sponsor team at the DHSC. Also, although the rating of this risk had been reduced earlier due to progress made on recruitment, as time passed we may wish to raise this higher than a medium (amber) rating as we still do not have clarity on when new members will be appointed.

Decision

- 3.18.** Members noted the performance report and the strategic risk register.

4. Covid-19 updates

- 4.1.** The Director of Compliance and Information presented the Covid-19 updates, and it was noted that regular catch-ups were held with NHS England alongside the two progress meetings held directly with the Secretary of State for Health and NHSE to assess progress in reopening the fertility sector to patients.
- 4.2.** The CE issued a position statement following the announcement of the second lockdown which was well received by clinic staff and patients. In the statement, it was acknowledged that clinics had robust procedures in place to be Covid-19 secure; and that there was an expectation for

clinics to promptly review their policies and procedures and to demonstrate how their service would be safely maintained.

- 4.3. The statement went on to inform clinics that we would closely monitor the situation and requested that referrals for necessary urgent or emergency treatment made by licensed clinics to an NHS facility other than their own clinic be reported through the HFEA incident reporting system. Lastly it was not envisaged that a further national closure of clinics would be necessary.
- 4.4. Members were reminded that they had approved inspections to recommence in November and currently government restrictions during this second lockdown were not as severe as the lockdown which happened in March 2020 since travelling for work purposes was currently allowed. Clinics remained open and inspections would be undertaken wherever possible.
- 4.5. Members were informed that virtual inspections would be conducted if a centre has had a visit within the last 2 years. Risk assessments were conducted on centres and inspectors had been provided with PPE by the DHSC.
- 4.6. In response to a question, it was noted that, although there has not been a further national closure of clinics, local circumstances such as staff being redeployed may mean that individual clinics will have to close or restrict appointments. It was also noted that some patients had reported that they had found the period of closure very hard and some clinics had not communicated well with patients during the pandemic.
- 4.7. Members advised that clinics need to keep reporting on the good work they have been doing and translating this back to patients, whilst updating their Patient Support policies.
- 4.8. The Chair commented that at the PR event some clinics said they were short staffed, some due to ill health or self-isolation. At the PR event they agreed that there should be another event in three months' time to specifically discuss best practice and share experiences with respect to the pandemic.
- 4.9. Members commented that the current national situation was having a huge impact on patients in terms of what it meant for their treatment and mental health, which could not be ignored. Best practice needed to be shared.
- 4.10. The Chair thanked the inspection team for responding to the sector in an agile manner.

Decision

- 4.11. The Covid-19 update was noted.

5. PRISM update

- 5.1. The Chief Information Officer (CIO) presented the PRISM update to the Authority. Members were advised of the progress made and the remaining steps of the launch process.
- 5.2. It was noted that the PRISM release candidate was launched on 13 October. Clinic engagement sessions and a refresh of the data in choose a fertility clinic (CaFC) had also started. The reprofiling of the PRISM launch and the CaFC verification exercise was allowing clinics to spend more time ensuring their 2020 data was as accurate as possible. The legacy EDI system migration was also completed in early November.
- 5.3. Members were advised that the steps to the PRISM launch process that were still outstanding included:

- Data quality improvement work and essential PRISM functionality for staff in December 2020
 - Launch of live release candidate, integrated testing and cutover and system suppliers' updates in January 2021.
- 5.4.** The CIO stated that PRISM was planned to go live on 25 January 2021 and would be embedded by 31 March 2021.
- 5.5.** Members asked what would happen to patients' data during the cutover period, and the CIO responded that the EDI system would be switched off so no data would then be transferred until PRISM went live.
- 5.6.** The Chair of the Audit and Governance Committee (AGC) congratulated the team both past and present on the launch of the release candidate and the progress made, and advised members that AGC continued to have monthly meetings to ensure oversight of PRISM.
- 5.7.** It was noted that AGC would continue to have oversight on staff maintaining the timetable, cost and the integrity of data.
- 5.8.** The Deputy Chair of AGC commented that the risk remained of the reliance on a small number of key staff and asked the CIO if there was a difference between private and NHS clinics' take up of PRISM. The CIO responded that they had not seen a major difference.
- 5.9.** A member commented that clinics needed to be given time to allow them to transfer from the legacy EDI system to PRISM as this would be in addition to clinics' business as usual activity and extra work associated with being Covid-19 compliant.
- 5.10.** Clinics were thanked for their engagement with PRISM.

Decision

- 5.11.** Members noted the PRISM progress to date, timetable to launch and go live date.

6. Business planning 2021/22

- 6.1.** The Risk and Business Planning Manager presented the business plan for 2021/22 to the Authority. Members were advised that the DHSC had recently signed off the six-month business plan for the remainder of 2020/21, approved at the last Authority meeting, so this would now be published on our website.
- 6.2.** Members were reminded that the three-year plan which was presented in November 2019 had been refined in the light of the impact of Covid-19 and following earlier Authority discussions about priorities.
- 6.3.** The business plan for 2021/22 would cover the first full year of delivery of our 2020 - 2024 strategy.
- 6.4.** The Chair asked if members felt that the right things had been focused on and if they were achievable.
- 6.5.** Members responded that it felt like a good business plan and thanked everyone who had worked on it.
- 6.6.** Members asked whether the HFEA would need to undertake tasks relating to surrogacy and the linkages between surrogacy and some of our processes.

- 6.7.** The Chief Executive (CE) responded that there is a Law Commission review on surrogacy that has not yet been completed and it would therefore be advisable to wait for the outcome of this work before making a decision on what HFEA actions may be needed.
- 6.8.** In response to a question, it was noted that work was ongoing to analyse areas of our Act in anticipation of a future review of legislation, and that we continued meanwhile to do other beneficial strategic work on aspects of treatment not directly covered by the Act, for instance on treatment add-ons and leadership.
- 6.9.** Members cautioned about staff resources and suggested that this looked like an ambitious plan. It was therefore imperative to know that there were sufficient resources to implement it, bearing in mind the small size of the organisation.
- 6.10.** Members commented that the right things were contained within the plan as these had emerged out of conversations about the strategy over recent months. In addition, it would be worth considering how further partnership working could be helpful in some areas of work.
- 6.11.** The Risk and Business Planning Manager responded that work was underway on more detailed planning and consideration of resources, as service delivery planning and resource allocation was discussed in teams. These would be aligned with the business plan and considered together in upcoming management conversations. Members' comments will be taken on board.
- 6.12.** The CE advised that he would feed back to the Authority once the business plan and service delivery plans have been reviewed at CMG.
- 6.13.** The Chair asked that communication plans for different stakeholder groups be included in our planning, so as to share our plans and engage with relevant groups, such as researchers.
- 6.14.** The Chair thanked all involved.

Decision

- 6.15.** The next steps were explained and agreed.
- 6.16.** The business plan would be re-presented at a future meeting.

7. Treatment add-ons progress report 2020

- 7.1.** The Scientific Policy Manager presented to the Authority and commented that our work on add-ons is a key feature of our new strategy and that as far as we knew, we were the first regulatory body to attempt to tackle issues around unevidenced fertility treatment add-ons.
- 7.2.** Treatment add-ons were described as 'extra' to routine fertility treatment and often claimed to improve patients' chances of having a baby. We have provided a traffic light assessment of the state of the evidence base for a number of the most widely available treatment add-ons on the HFEA website.
- 7.3.** The Authority were asked to consider our approach to providing information about the use of holistic/alternative therapies during fertility treatment. It was noted that some fertility patients choose to use holistic/alternative therapies, but they are not a licensable activity and are often not offered in a licensed fertility clinic. However, occasionally patients do come to us for advice and there is therefore an argument that it would be appropriate for us to publish information about them on our website.

- 7.4.** The Authority agreed that holistic/alternative therapies should be featured as additional treatments that were sometimes offered during fertility treatment, especially in light of the new CMA guidance which mentions complementary therapies.
- 7.5.** The Authority were then asked to consider the best approach to providing information about green rated add-ons. It was explained that a green add-on would be where there was more than one good quality randomised controlled trial (RCT) which showed that the procedure was effective at improving live birth rates and was shown to be safe for patients to use. Currently, none of the add-ons reviewed by the HFEA were rated green. And it could be argued that if an add-on was green for all patient types, it should be part of standard treatment, and not an optional add-on.
- 7.6.** Members commented that RCTs remained the only evidence which was sufficient to change a red or amber traffic light rating to green.
- 7.7.** In discussion, Members commented that this was a complex issue, where it was important that patients were presented with information on whether a proposed add-on was optional with no proven benefit or strongly recommended with some proven benefit of increasing the chance of a live birth. It was noted that some patients found it difficult to opt out of any additional treatments offered, for fear that it might reduce their chances of having a child.
- 7.8.** The Chair commented that add-ons needed to be put in a wider context of 'routine' treatment. She suggested that we should:
- clarify what a 'routine IVF treatment' cycle involved for most patients
 - clarify which add-ons could be green for some types of patients (while perhaps being amber or red for other patients)
 - clarify which treatment add-ons have limited evidence and therefore would fall into the amber or red categories.
- 7.9.** Members stated that the information we publish on our website should make it clear for patients that it is their own choice to opt for a treatment add-on which is over and above the routine IVF cycle, and that they should bear in mind that it would cost extra, and there may be no robust evidence base to suggest that it would have any benefit.
- 7.10.** The Chair of the Scientific and Clinical Advances Advisory Committee (SCAAC) commented that the work of the committee to review the evidence base for add-ons will continue. It was their role to look at evidence impartially and independently and information relating to holistic/alternative treatments needed to be communicated well to patients.

Decision

- 7.11.** Members agreed that information on holistic/alternative therapies should be featured on our website as a separate item to the treatment add-ons list and that it need not be traffic light rated.
- 7.12.** Members agreed that we should publish information about what a routine IVF cycle involves, and which add-ons may be appropriately offered to some patients.
- 7.13.** This information should make it clear that treatment add-ons and holistic/alternative therapies were in addition to IVF cycles and could be expensive.
- 7.14.** The CE commented that a broader framework would be worked on and brought back to a future Authority meeting.

- 7.15. The Chair concluded that we had made huge progress in this area and thanked everyone involved.

8. Compliance & enforcement policy pre-consultation

- 8.1. The Director of Compliance and Information presented the revised draft compliance and enforcement policy to the Authority.
- 8.2. It was noted that the current policy was approved in 2016. The new policy incorporates several improvements to
- ensure the escalation of concerns is undertaken through a process which is managed consistently, fairly, and transparently
 - define the process inspectors follow when deciding what recommendations to make to Licence Committee
 - mitigate the risk of centres feeling they have been treated unfairly or disproportionately
 - provide a robust framework when we are faced with legal challenge, setting out when and how regulatory action will be taken.
- 8.3. Members commented that the updated policy would help avoid potential inconsistencies.
- 8.4. The CE responded that what has been set out is a framework which leaves room for individual clinic circumstances and balanced judgements to avoid it becoming a tick box exercise. The policy includes examples of mitigating and aggravating factors but it is not an exhaustive list.
- 8.5. In response to a question it was noted that this policy would not affect the licensing representations and appeals processes.

Decision

- 8.6. Members approved the revised draft version of the Compliance and Enforcement Policy to go out for consultation for a four-week period in January 2021.

9. HFEA preparations for the end of the EU exit transition period

- 9.1. The Chief Executive presented this item and thanked staff directly involved in the development of this piece of work.
- 9.2. The 2020 Regulations provided for a six-month transition period.
- 9.3. After the transition period the HFEA will remain the Competent Authority for Northern Ireland (CA-NI) and we will continue to regulate licensed clinics and embryo research in NI, in line with the requirements of the HFE Act 1990 (as amended) and to reflect the provisions of the NI protocol.

Decision

- 9.4. Members noted the arrangements relating to the Authority's preparedness for the end of the transition period.
- 9.5. Members agreed to delegate to the Chair the power to make any decisions necessary to give effect to the 2020 Regulations and the application thereof.

10. Any other business

- 10.1.** The Chair commented that this was going to be the last meeting for Anthony Rutherford who had been an Authority member since 2014. Members thanked him for his hard work and expertise on the board and valuable contribution during his time on the Authority and the committees that he sat on.
- 10.2.** Mr Rutherford thanked everyone for their kind words and the privilege of working on the HFEA's board.
- 10.3.** The Chair commented that Mr Rutherford had agreed to advise the HFEA in the future as an external expert when required, particularly if professional expertise was needed before the appointment of the HFEA's new Board members is approved by Ministers.
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Chair's signature

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

Signature

Chair: Sally Cheshire

Date: 27 January 2021

Performance report

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	5
Meeting date:	27 January 2021
Author:	Helen Crutcher, Risk and Business Planning Manager
Annexes	Annex 1: Performance scorecard Annex 2: Financial management information Annex 3: High level KPIs

Output from this paper

For information or decision?	For information
Recommendation:	Authority is asked to note and comment on the latest performance report
Resource implications:	In budget
Implementation date:	Ongoing
Communication(s):	<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:	Medium

1. Latest review

- 1.1. The attached report is for performance up until November 2020.

2. Key trends

- 2.1. In November performance was generally good, seeing an improvement from last month. There were no red indicators.
- 2.2. The annexes to this paper provide a scorecard giving a performance overview, high-level financial information including the monthly management accounts and more detailed information on KPIs.

Annex 1 HFEA Performance scorecard and management commentary – November 2020 data

Breakdown of total Red, Amber, Green and Neutral Indicators



Figure 1 - Fewer red indicators this month

RAG	Area	Trend and key data
Green – On target	People - Employee turnover Target: between 5%-15%	13.5 % Turnover 1 leaver
Green – On target	Regulatory efficiency - Time for end-to-end inspection and licensing process Target: 100% in 70 working days or less	100% within target. Average of 55wds (items beginning with an inspection, including desk-based analysis)
No target	Engagement - HFEA website sessions	71,805 sessions (56,471 in same month last year)

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

Type	Actual in YTD £'000s	Budget YTD £'000s	Variance Actual vs Budget £'000s	Forecast for 2020/21 £'000s	Budget for 2020/21 £'000s	Variance Budget vs Forecast £'000s
Income	4,180	4,764	(584)	7,465	7,211	254
Expenditure	4,331	4,762	431	7,143	7,211	68
Total Surplus/(Deficit)	(151)	2	(153)	322	0	322

Commentary on financial performance to end November

The Year-to-date position is a deficit against budget of £152k which is an improvement on previous periods. The effect of the COVID-19 pandemic has started to abate and is reflected in the increase in our income month on month. Looking ahead to the 4th quarter of the business year, the third wave of the pandemic may cause treatment numbers to decline once more reducing our expected income. Our expenditure is below budget with an underspend of £431k, which is due to reduced activity levels in the early part of the year because of the COVID-19 pandemic.

We are forecasting a surplus against budget of £322k that relates mainly to the net non-cash funding element (£221k) provided by DHSC to cover depreciation and amortisation charge, which we cannot use for other operational purposes. This position is likely to change post the January 2021 review.

Management commentary

In November, performance was generally good. We had no red indicators.

November's good performance and lack of red indicators highlights the hard work put in by staff across the organisation to continue to deliver well, while working remotely.

The positive state of Inspection and Licensing Indicators demonstrates that we have delivered out core statutory duties within our target delivery timescales, despite increased workload associated with our revised inspection strategy (for delivering inspections during the Covid-19 pandemic).

The Opening the Register (OTR) service has reopened, as reported at Authority in November 2020 and we have received an extraordinary number of applications since then, which reflects pent up demand. We are actively taking steps to increase our staffing in order to alleviate this backlog. We are taking a 'best endeavours' approach during this difficult period and are now tracking applications in this report, before we can commit to reporting against a new KPI. We have actively communicated with all applicants awaiting a response and updated the information on our website to manage expectations.

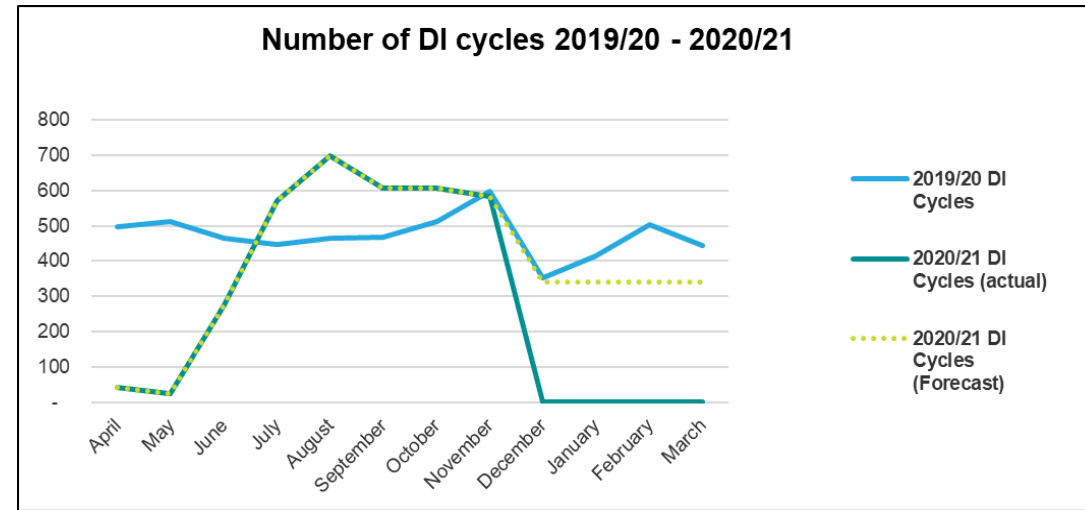
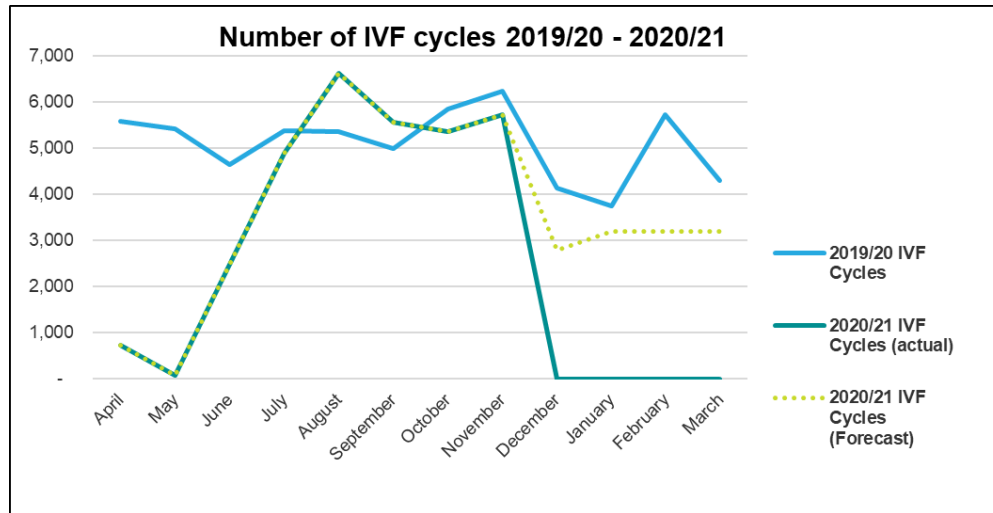
Positively, we can see that the finance indicators which were previously red rated are now returning to normal levels. Two of these are now green and the one amber indicator F1, Debt Collection, is very close to target (83% compared with a target of 85%). We will continue to monitor our finance performance very carefully over the coming months.

At the time of writing in early 2021, we are in the process of having management discussions in the light of the new national lockdown, including consideration of our inspection approach and whether any of our planned work will need to be reprioritised. A discussion will be held with the Authority to understand the implications of these discussions, priorities, and agree a way forward for delivery in the remainder of the 2020/2021 business year and into 2021/2022.

In a couple of areas, we have found that technical changes associated with necessary preparatory work for launching PRISM has meant we are no longer able to report against the current KPIs. For instance, we cannot access the current Register data performance metrics and the IT statistics for EDI tickets will cease being pertinent in 2021 as clinics stop using this system, prior to the launch of PRISM. We do not believe this will present a challenge to ongoing management, as the Register team continues to monitor individual clinic submissions closely. Discussions are ongoing about developing metrics for the new system.

For the period of September-November 2020 the count for public enquiries received by the HFEA has been revised following an internal check which revealed a counting error. This has now been rectified and logging and reporting processes are being reviewed with staff who handle Enquiries at all stages up to reporting point, working across several internal teams, to ensure these are clear and there is no such reoccurrence.

Annex 2 Financial management information



The graph illustrates reduction in IVF treatment cycles (28%) compared to the same period (eight months ended 30 November). Our forecast reflects a somewhat prudent view that volumes will increase slowly. A review and decision as to whether we amend our monthly forecast was made in December.

DI treatments do not follow IVF activity patterns exactly and we continue to experience lower volumes compared to 2019/20 (down 14%). We are forecasting modest increases in activity to the end of the financial year. As with IVF volumes, we reviewed our forecast in December. This will be reflected in reporting for December.

Management Accounts

HFEA Income & Expenditure

Nov-20

	Year to Date				Full Year		
	Actual £'000	Budget £'000	Variance £'000	Variance YTD %	Forecast £'000	Budget £'000	Variance £'000
Income							
Grant-in-aid	1,108	619	(489)	(79)	2,993	1,238	1,755
Non-cash (Ring-fenced RDEL)	340	340	-	0	510	510	-
Grant-in-aid - PCSPS contribution	67	67	0	0	100	100	-
Licence Fees	2,570	3,661	1,091	30	3,707	5,209	(1,502)
Interest received	1	5	4	82	10	10	-
Seconded and other income	95	72	(23)	-32	144	144	-
Total Income	4,180	4,764	583	12	7,465	7,211	253
Revenue Costs							
Salaries (excluding Authority)	3,135	3,194	59	(2)	4,731	4,629	(102)
Staff Travel & Subsistence	4	69	65		48	161	113
Other Staff Costs	59	61	2	(3)	99	121	22
Authority & Other Committees costs	129	183	54	(30)	226	284	58
Facilities Costs incl non-cash	480	615	134	(22)	804	928	124
IT Costs	334	342	8	(2)	551	517	(33)
Legal / Professional Fees	142	205	63	(31)	406	388	(18)
Other Costs	42	94	52	(56)	209	183	(24)
Other Project Costs	6	-	(6)	#DIV/0!	70	-	(70)
Total Revenue Costs	4,331	4,762	431	(9)	7,143	7,211	67
TOTAL Surplus / (Deficit)	(151)	2	(152)		322	(0)	322
Adjusted for non-cash income/costs	(350)	(83)	(266)		101	(0)	100

Management commentary

Income.

For the eight months ended 30 November 2020, treatment fees are under budget by £1.09m (£58k drop from October). The IVF volumes are slowly increasing with November increasing by 6.9% above October. The DI volumes have remained largely the same.

Expenditure by exception. Year to date we are underspent by £431k.

Salary costs - currently running under budget by £59k (down by £49k from October) which is due to some vacancies being filled.

Staff Travel and Subsistence - underspending by £65k due to low inspection activity..

Authority & Other Committee costs - underspent of £54k represented by £10k within Members' fees where we are carrying vacancies, £16k and £11k within T&S and Venue Hire, where meetings are held virtually. Other areas such as Members training and non-committee costs have small underspends..

Facilities costs - underspent by £134k and include our non-cash costs of depreciation/amortisation (£188k). The underspend here is due to the timing of the capitalisation of IfQ and PRISM. These costs are covered by Ring-fenced RDEL received from the DHSC. Also costs associated with COVID-19 (£5k) not budgeted for.

Legal/Professional Fees - under budget by £63k represented by underspend in Legal Fees of £13k and underspend of £50k in audit fees and contingency.

Other costs - underspent by £52k. significant overspends are within Donor Information/Other costs £7k and Library and Subscriptions £7k, offset by underspends within Stakeholder events £17k, Media monitoring £8k and within Compliance £14k (Licence Centre Panel and Compliance Other costs).

Other Project costs - this line represents the costs incurred for EU Transition which is funded by Grant in aid of £70k.

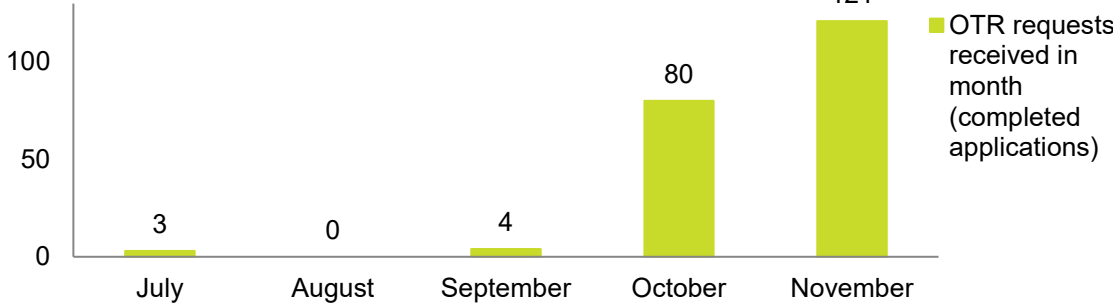
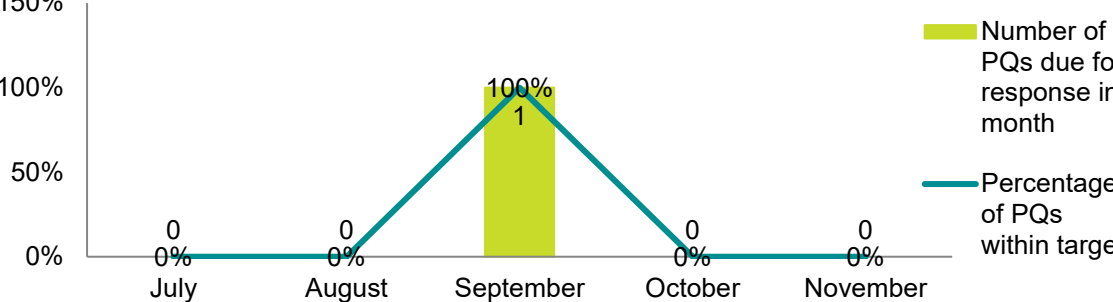
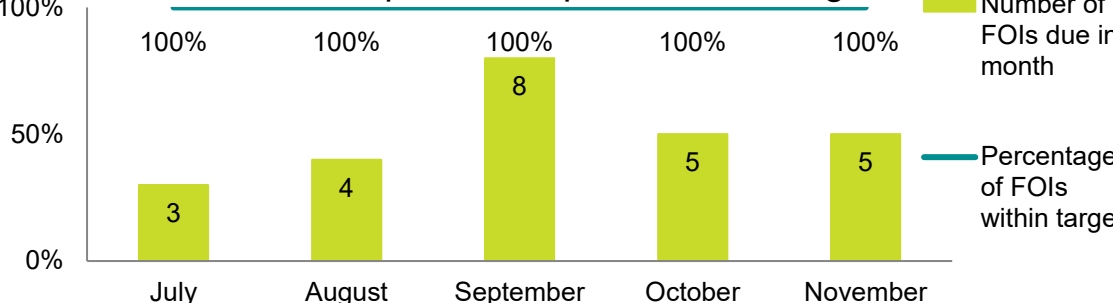
Forecast.

We are currently forecasting an underspend in expenditure against budget of £141k, this is largely due to underspends within our non-cash costs of £289k which we cannot benefit from.

A further review of plans and forecast will be undertaken in January 2021 at which point we should have a clearer idea of what the new accommodation costs will be. At present, we have replicated the charges from NICE for quarter four.

Annex 3 – Key performance indicators – Authority summary

Key performance indicator name and description	Graph showing performance trend for last 5 months	Commentary (if any)	RAG rating																		
<p>HR1 – Sickness</p> <p>Target: less than or equal to 2.5%. Target is based upon ONS 2018 data (2.7% for the public sector)</p>	<p>Sickness absence vs 2.5% target</p> <table border="1"> <caption>Sickness absence vs 2.5% target</caption> <thead> <tr> <th>Month</th> <th>Staff sickness absence rate</th> <th>2.5% target rate</th> </tr> </thead> <tbody> <tr> <td>July</td> <td>0.1%</td> <td>2.5%</td> </tr> <tr> <td>August</td> <td>2.0%</td> <td>2.5%</td> </tr> <tr> <td>September</td> <td>0.1%</td> <td>2.5%</td> </tr> <tr> <td>October</td> <td>1.5%</td> <td>2.5%</td> </tr> <tr> <td>November</td> <td>0.6%</td> <td>2.5%</td> </tr> </tbody> </table>	Month	Staff sickness absence rate	2.5% target rate	July	0.1%	2.5%	August	2.0%	2.5%	September	0.1%	2.5%	October	1.5%	2.5%	November	0.6%	2.5%	<p>Sickness absence is low this month.</p>	<p>Green</p>
Month	Staff sickness absence rate	2.5% target rate																			
July	0.1%	2.5%																			
August	2.0%	2.5%																			
September	0.1%	2.5%																			
October	1.5%	2.5%																			
November	0.6%	2.5%																			
<p>HR2 - Turnover</p> <p>Target: between 5 and 15% turnover for the rolling year.</p>	<p>Rolling annual turnover vs target range (5-15%)</p> <table border="1"> <caption>Rolling annual turnover vs target range (5-15%)</caption> <thead> <tr> <th>Month</th> <th>Turnover rate</th> <th>Target turnover range</th> </tr> </thead> <tbody> <tr> <td>July</td> <td>9.1%</td> <td>5-15%</td> </tr> <tr> <td>August</td> <td>10.1%</td> <td>5-15%</td> </tr> <tr> <td>September</td> <td>12.0%</td> <td>5-15%</td> </tr> <tr> <td>October</td> <td>12.0%</td> <td>5-15%</td> </tr> <tr> <td>November</td> <td>13.5%</td> <td>5-15%</td> </tr> </tbody> </table>	Month	Turnover rate	Target turnover range	July	9.1%	5-15%	August	10.1%	5-15%	September	12.0%	5-15%	October	12.0%	5-15%	November	13.5%	5-15%	<p>67- Headcount 68 - Establishment (posts)</p> <p>Turnover is steady - with 1 leaver in November.</p>	<p>Green</p>
Month	Turnover rate	Target turnover range																			
July	9.1%	5-15%																			
August	10.1%	5-15%																			
September	12.0%	5-15%																			
October	12.0%	5-15%																			
November	13.5%	5-15%																			
<p>Supplementary data - Public enquiries</p> <p>No target.</p>	<p>Emailed public enquiries vs last year</p> <table border="1"> <caption>Emailed public enquiries vs last year</caption> <thead> <tr> <th>Month</th> <th>Number of emailed public enquiries</th> <th>Emailed public enquiries in same month last year</th> </tr> </thead> <tbody> <tr> <td>July</td> <td>108</td> <td>131</td> </tr> <tr> <td>August</td> <td>84</td> <td>99</td> </tr> <tr> <td>September</td> <td>75</td> <td>96</td> </tr> <tr> <td>October</td> <td>86</td> <td>145</td> </tr> <tr> <td>November</td> <td>96</td> <td>116</td> </tr> </tbody> </table>	Month	Number of emailed public enquiries	Emailed public enquiries in same month last year	July	108	131	August	84	99	September	75	96	October	86	145	November	96	116	<p>Issues were identified with some earlier data and these have been updated. See note in management commentary above.</p>	<p>No target</p>
Month	Number of emailed public enquiries	Emailed public enquiries in same month last year																			
July	108	131																			
August	84	99																			
September	75	96																			
October	86	145																			
November	96	116																			

Key performance indicator name and description	Graph showing performance trend for last 5 months	Commentary (if any)	RAG rating	
<p>R1 – Percentage of Opening the Register requests completed within 30 working day target.</p> <p>(excludes counselling time)</p> <p>Target: changed from 100% in 20wd to 95% in 30wd from April 2020.</p> <p>Note KPI not used from November 2020 data, TBD when to reinstate this.</p>	<p>OTR requests received (tracker in lieu of KPI)</p>  <p>Note: the OTR team will be reviewing some of the earlier data since the applications listed here as received over the summer were partial applications, recorded to allow for counselling, not received fully during the period OTR was closed for submissions.</p>	<p>New tracker graph included.</p> <p>No new applications received until 20 October so partial month listed. We're not currently reporting against a target this is now a tracker – as agreed at Authority October 2020.</p>	Neutral	
<p>RI1 – PQs responded to within deadline set</p> <p>(Based on deadlines agreed with DHSC)</p> <p>Target: 100% within deadlines set.</p>	<p>Parliamentary questions completed within target</p> 	None due		Neutral
<p>RI2 - FOIs responded to within deadline</p> <p>Target: 100% within statutory deadlines.</p>	<p>FOI requests completed within target</p> 	3 subject access requests were also received in November		Green

Key performance indicator name and description

Graph showing performance trend for last 5 months

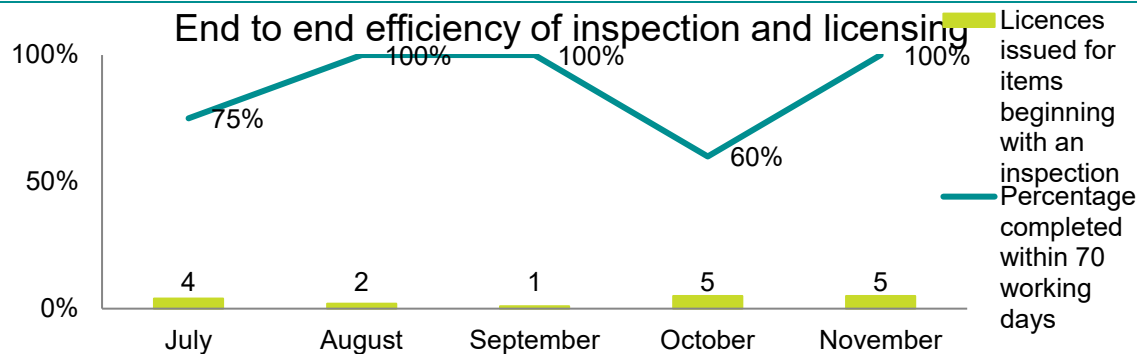
Commentary (if any)

RAG rating

C1 - Efficiency of end to end inspection and licensing process.

Target: 100% within 70 working days (wds).

% processed in 70 working days, for items where minutes were sent in month. Measured from inspection date to date minutes sent.



■ Licences issued for items beginning with an inspection
 — Percentage completed within 70 working days

Average working days taken: 38
 Most days taken: 67 working days
 Least days taken: 11 working days

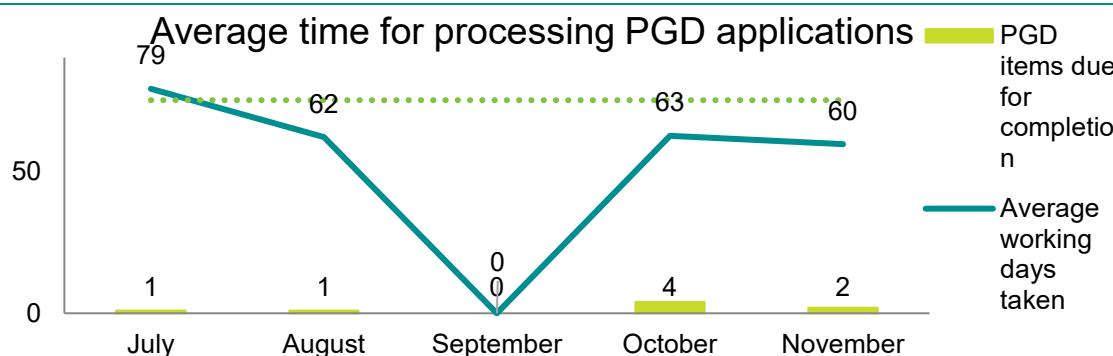
Green

C4 – Average PGD processing

Target: average processing time of 75 working days.

Average number of working days taken for those due in month.

Note: Target changed from 66 to 75 in April 2020.



■ PGD items due for completion
 — Average working days taken

Most days taken: 66 working days
 Least days taken: 53 working days

Green

Register Research Panel Annual Report

Details about this paper

Area(s) of strategy this paper relates to:	The right information
Meeting:	Authority
Agenda item:	8
Meeting date:	27 January 2021
Author:	Nora Cooke O'Dowd, Head of Research and Intelligence
Annexes	Annex A: Publication list - Approved Register Research Panel projects Annex B: Publication list - Anonymised Register data and FOI requests

Output from this paper

For information or decision?	For information
Recommendation:	
Resource implications:	
Implementation date:	
Communication(s):	
Organisational risk:	Low

1. Introduction

- 1.1. The HFEA holds the largest register of data on assisted reproduction treatments in the world.
- 1.2. The Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 state that the Authority may grant authorisation to a research establishment for the processing of disclosable protected information from the Register.
- 1.3. As a result, the HFEA is uniquely positioned to enable high quality research on patient care and outcomes via authorised access to Register data – full publication list included in appendices.
- 1.4. Under our strategic ambition to provide the best care, we want to continue to engage with researchers and work to enable access to relevant and valuable data on our Register, to inform high quality research.
- 1.5. The Authority delegates to the Register Research Panel, the power to authorise access to Register data for the purposes of medical or non-medical research. The panel meets every two months and is required to report annually to the Authority.

2. Research Register Panel activity in 2020

- 2.1. Since the last annual report, the panel met six times, reviewed four applications and approved two projects (Section 3 below).
- 2.2. The panel has also reviewed three project extension or amendment requests, all of which were approved (Section 4 below).
- 2.3. In addition, the panel approved an update to the application and annual report forms, and a new project change form. This is part of ongoing work to continually review and improve the running of the panel.
- 2.4. Additionally, the Research and Intelligence team has been in contact with 11 new researchers to discuss research projects in 2020.
- 2.5. In the last annual report, we noted a large increase in interest in the Register in 2019, which has not yet translated into large numbers of applications. We encourage researchers to speak to us as early as possible, and there is a long tail to much of this research as researchers work to gain funding, resource and REC approval.

3. Projects approved in 2020

- 3.1. **Associations between Assisted Reproductive Technologies and Women's Mental Health: an investigation using clinical data linkage, King's College London:** In the UK, approximately 20,000 children are born through ART each year. Despite isolated reports, remarkably little is known about the influence of ART on the mental health of the mother. This study will be the first to evaluate the burden of mental health problems associated with ART pregnancies in the UK. This project is waiting contract prior to data linkage.
- 3.2. **Effects of Assisted Reproductive Technology on long-term Birth Weight trends: A National Cohort Study, University of Manchester:** This study explores whether increased birth weight ART outcomes observed in a single-centre study are also observed in the national IVF cohort and naturally conceived cohort. The impact of IVF procedural factors on the time trends will also be explored. This project also seeks to further explore the extent of bias that

may arise due to methodological issues associated with the public HFEA dataset such as data banding and incompleteness. This project is currently awaiting REC approval.

4. Project amendments and extensions

- 4.1. **Prolonged Effects of Assisted reproductive technologies on the health of women and their children: a Record Linkage study for England (PEARL), University of Oxford:** The project requires a new bespoke dataset, linking information on fertility treatment held in the Register to health data held in the Clinical Practice Research Datalink (comprising primary care data, and linked to Hospital Episode Statistics and Index of Multiple Deprivation). Data has been shared with NHS Digital for the linkage work to begin and funding for this project is granted until May 2022. This project was initiated in 2016 but has experienced lengthy delays due to the complexity of agreeing a data flow and securing agreements across four organisations. We are working to standardise these processes and agreements where possible, so that these can be made more straightforward in future.
- 4.2. **Development and validation of prognostic models to predict pregnancy outcomes following in-vitro fertilization (IVF) treatment, University of Aberdeen:** Research on this project has been ongoing since December 2015. In May 2020, an amendment was approved to use the data in a COVID-19 project on prioritising IVF in the post COVID-19 era. The resulting paper, published in November 2020, highlighted that while delays in starting treatment was predicted to result in fewer babies in older women and those with a known cause of infertility, it has a less detrimental effect on couples with unexplained infertility, some of whom conceive naturally whilst waiting for treatment (Bhattacharya et al. 2020 below).
- 4.3. **Educational outcomes in children born after assisted reproductive technology; a population-based linkage study, University College London:** The study aims to address the question of whether children born after assisted reproduction are at a higher risk of developing learning or behavioural problems. The study will make use of a previously established database of linked records from the HFEA and ONS data, relating to now completed research addressing the question of whether children born after assisted reproduction have poorer health outcomes, approved in August 2012. Data access applications have been submitted to NHS digital and the Department of Education in order to carry out database linkage.

5. The year ahead

- 5.1. A researcher engagement day was planned to take place on 18 May 2020, but was cancelled due to the COVID-19 pandemic. The project has been put on hold and is due to be rescoped to consider whether the aims of the project can be met via alternative means.
- 5.2. We continue to work hard behind the scenes to improve processes to enable research while safeguarding our Register data. We recently recruited a new research officer to support this work, including the development of a section on our website dedicated to researchers interested in Register data.

Annex A: Publication list - Approved Register Research Panel projects

2020

- [Prioritising IVF treatment in the post COVID 19 era: a predictive modelling study based on UK national data](#), Siladitya Bhattacharya, Abha Maheshwari, Mariam Begum Ratna, Rik van Eekelen, Ben Willem Mol, David J McLernon, *Human Reproduction*, doi: 10.1093/humrep/deaa339 (23/11/2020)
- [Cumulative live birth rates following blastocyst- versus cleavage-stage embryo transfer in the first complete cycle of IVF: a population-based retrospective cohort study \(2020\)](#). Cameron Natalie, et al. *Human Reproduction* doi.org/10.1093/humrep/deaa186.

2019

- [IVF for unexplained subfertility; whom should we treat?](#), R van Eekelen, N van Geloven, M van Wely, S Bhattacharya, F van der Veen, MJ Eijkemans, DJ McLernon, *Human Reproduction*, doi:10.1093/humrep/dez072 (13/6/2019)

2018

- [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](#), CL Williams, ME Jones, AJ Swerdlow, BJ Botting, MC Davies, I Jacobs, KS Bunch, MF Murphy and AG Sutcliffe, *British Medical Journal*, doi:10.1136/bmj.k2644 (1/7/2018)
- [The growth of assisted reproductive treatment-conceived children from birth to 5 years: a national cohort study](#), M Hann, S Roberts SW D'Souza, P Clayton, N Macklon and D Brison, *BMC medicine*, doi:10.1186/s12916-018-1203-7 (28/11/2018)

2017

- [Cumulative live birth rates following miscarriage in an initial complete cycle of IVF: a retrospective cohort study of 112 549 women](#), NJ Cameron, S Bhattacharya and DJ McLernon, *Human Reproduction*, doi:10.1093/humrep/dex293 (20/9/2017)
- [Cancer risk in children born after donor ART](#), CL Williams, KJ Bunch, MF Murphy, CA Stiller, BJ Botting, WH Wallace, MC Davies and AG Sutcliffe, *Human Reproduction*, doi:10.1093/humrep/dex333 (2/11/2017)

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](#), DJ McLernon, A Maheshwari, AJ Lee and S Bhattacharya, *Human Reproduction*, doi:10.1093/humrep/dev336 (18/1/2016)
- [Predicting the chances of a live birth after one or more complete cycles of in vitro fertilisation: population based study of linked cycle data from 113 873 women](#), DJ McLernon, A Maheshwari, AJ Lee and S Bhattacharya, *British Medical Journal*, doi:10.1136/bmj.i5735 (16/11/2016)
- [Effect of ethnicity on live birth rates after in vitro fertilisation/intracytoplasmic sperm injection treatment: analysis of UK national database](#), W Maalouf, B Campbell, K Jayaprakasan, *BJOG*, doi:10.1111/1471-0528.14241 (19/8/2016)

2015

- [Live-birth rate associated with repeat in vitro fertilization treatment cycles](#), AD Smith, K Tilling, SM Nelson and DA Lawlor, *Jama*, doi:10.1001/jama.2015.17296 (22/12/2015)

2013

- [Effect of ethnicity on live birth rates after in vitro fertilisation or intracytoplasmic sperm injection treatment](#), K Jayaprakasan, D Pandian, J Hopkisson, BK Campbell and WE Maalouf, *BJOG*, doi:10.1111/1471-0528.12504 (6/11/2013)
- [Effect of age on decisions about the numbers of embryos to transfer in assisted conception: a prospective study](#), DA Lawlor and SM Nelson, *The Lancet*, doi:10.1016/S0140-6736(11)61267-1 (2/4/2013)

2011

- [Predicting live birth, preterm delivery, and low birth weight in infants born from in vitro fertilisation: a prospective study of 144,018 treatment cycles](#), SM Nelson and DA Lawlor, *PLoS Medicine*, doi:10.1371/journal.pmed.1000386 (4/1/2011)

Annex B: Publication list - Anonymised Register data and FOI requests

Publications from projects that used data from the HFEA through FOI requests or from the publicly available anonymised register.

2020

- [Machine learning predicts live-birth occurrence before in-vitro fertilization treatment](#), Goyal, A., Kuchana, M. & Ayyagari, K.P.R. *Sci Rep*, doi:10.1038/s41598-020-76928-z (01/05/2020)

2019

- [Secondary sex ratio in assisted reproduction: an analysis of 1 376 454 treatment cycles performed in the UK](#), PR Supramaniam, M Mittal, EO Ohuma, *Human Reproduction Open*, doi:10.1093/hropen/hoz020 (5/10/2019)
- [Zygotic splitting following embryo biopsy: a cohort study of 207 697 single-embryo transfers following IVF treatment](#), MS Kamath, B Antonisamy and SK Sunkara, *BJOG: An International Journal of Obstetrics & Gynaecology*, doi:10.1111/1471-0528.16045 (12/12/2019)
- [Perinatal outcomes in singleton live births after fresh blastocyst-stage embryo transfer: a retrospective analysis of 67 147 IVF/ICSI cycles](#), N Marconi, EA Raja, S Bhattacharya, A Maheshwari, *Human Reproduction*, doi:10.1093/humrep/dez133 (16/8/2019)
- [Hydatidiform molar pregnancy following assisted reproduction](#), M Nickkho-Amiry, G Horne, M Akhtar, R Mathur and DR Brison, *Journal of assisted reproduction and genetics*, doi:10.1007/s10815-018-1389-9 (5/1/2019)

2018

- [Reconceiving egg freezing: insights from an analysis of 5 years of data from a UK clinic](#), Z.B Gürtin, T Shah, T, J Wang and K Ahuja, *Reproductive Biomedicine Online*, doi:10.1016/j.rbmo.2018.11.003 (11/12/2018)

2017

- [Perinatal outcomes after gestational surrogacy versus autologous IVF: analysis of national data](#), SK Sunkara, B Antonisamy, HY Selliah and MS Kamath, *Reproductive Biomedicine Online*, doi:10.1016/j.rbmo.2017.08.024 (1/12/2017)
- [Pre-term birth and low birth weight following preimplantation genetic diagnosis: analysis of 88 010 singleton live births following PGD and IVF cycles](#), SK Sunkara, B Antonisamy, HY Selliah and MS Kamath, *Human Reproduction*, doi:10.1093/humrep/dew317 (23/1/2017)
- [Reproductive outcome following pre-implantation genetic diagnosis \(PGD\) in the UK](#), A Sharpe, P Avery and M Choudhary, *Human Fertility*, doi:10.1080/14647273.2017.1336259 (12/6/2017)
- [High-risk of preterm birth and low birth weight after oocyte donation IVF: analysis of 133,785 live births](#), MS Kamath, B Antonisamy, M Mascarenhas and SK Sunkara, *Reproductive Biomedicine Online*, doi:10.1016/j.rbmo.2017.06.013 (1/9/2017)

2016

- [Does age of the sperm donor influence live birth outcome in assisted reproduction?](#), NK Ghuman, E Mair, K Pearce and M Choudhary, *Human Reproduction*, doi:10.1093/humrep/dev331 (12/1/2016)

- [Live birth and perinatal outcomes following stimulated and unstimulated IVF: analysis of over two decades of a nationwide data](#), SK Sunkara, A LaMarca, NP Polyzos, PT Seed and Y Khalaf, *Human Reproduction*, doi:10.1093/humrep/dew184 (17/9/2016)
- [Obstetric and perinatal outcomes after either fresh or thawed frozen embryo transfer: an analysis of 112,432 singleton pregnancies recorded in the Human Fertilisation and Embryology Authority anonymized dataset](#), A Maheshwari, EA Raja and S Bhattacharya, *Fertility and Sterility*, doi:10.1016/j.fertnstert.2016.08.047 (24/9/2016)

2014

- [Association between response to ovarian stimulation and miscarriage following IVF: an analysis of 124 351 IVF pregnancies](#), SK Sunkara, Y Khalaf, A Maheshwari, P Seed and A Coomarasamy, *Human Reproduction*, doi:10.1093/humrep/deu053 (20/3/2014)

2011

- [Association between the number of eggs and live birth in IVF treatment: an analysis of 400 135 treatment cycles](#), SK Sunkara, V Rittenberg, N Raine-Fenning, S Bhattacharya, J Zamora and A Coomarasamy, *Human Reproduction*, doi:10.1093/humrep/der106 (10/5/2011)

2010

- [Towards single embryo transfer? Modelling clinical outcomes of potential treatment choices using multiple data sources: predictive models and patient perspectives](#), SA Roberts, L McGowan, WM Hirst, DR Brison, A Vail and BA Lieberman, *Health Technology Assess*, doi:10.3310/hta14380 (1/8/2010)