Human Fertilisation & Embryology Authority

Authority meeting

Date and time: 09 February 2022- 12.45pm to 4.30pm

Venue: via zoom

Agenda items	Time
1. Welcome, apologies and declarations of interest	12.45pm
2. Minutes of the meeting held 24 November 2021 and matters arising **For decision**	12.50pm
3. Chair and Chief Executive's report **For information**	12.55pm
4. Committee Chairs' reports **For information**	1.15pm
5. Performance report **For information**	1.30pm
6. Covid-19 update **For information**	2.00pm
7. Gamete and embryo storage **For information**	2.15pm
Break	2.45pm
8. Business plan 2022/23 **For approval**	3.00pm
9. Modernising fertility regulation: a plan for legislative change **For decision**	3.30pm
10. Annual Report on the Register Research Panel (RRP) **For information**	3.55pm
11. Any other business	4.20pm
12. Close	4.25pm

Minutes of Authority meeting 24 November 2021

Details:			
Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society		
Agenda item	2		
Meeting date	9 February 2022		
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 24 November 2021 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 24 November 2021 held at ETC.venues, Chancery Lane, WC2A 1HL and via teleconference

	In person	Via teleconference
Members present	Julia Chain, Chair Margaret Gilmore Gudrun Moore Alison Marsden Tim Child Catharine Seddon Ermal Kirby Yacoub Khalaf	Anita Bharucha Jonathan Herring Ruth Wilde Jason Kasraie Anne Lampe
Apologies	None	
Observers	Steve Pugh, DHSC	Csenge Gal, DHSC
Staff in attendance	Peter Thompson Clare Ettinghausen Richard Sydee Rachel Cutting Catherine Drennan Joanne Triggs Joanne Anton Paula Robinson Debbie Okutubo Georgina Allen Sonia Macleod	Neil McComb Danya Harris

Members

There were 13 members at the meeting – nine lay members and four professional members.

1. Welcome

1.1. The Chair opened the meeting by welcoming Authority members, observers and staff present both in person and online.

1.2. The Chair stated that the meeting was being 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.

1.3. Declarations of interest were made by:

- Yacoub Khalaf (clinician at a licensed clinic)
- Tim Child (PR at a licensed clinic)
- Ruth Wilde (counsellor at licensed clinics)
- Jason Kasraie (PR at a licensed clinic).

2. Minutes of the last meeting and matters arising

2.1. Members agreed that the minutes of the meeting held on 23 September 2021 were an accurate record and could be signed by the Chair.

2.2. Members noted the status of all matters arising.

3. Chair and Chief Executive's report

3.1. The Chair continued to engage with the decision-making functions of the Authority and with key external stakeholders. Members were advised that on 1 December 2021 she would be speaking at the Progress Educational Trust (PET) annual conference and in January 2022 she would be speaking at the Fertility 2022 conference.

3.2. The Chief Executive provided an update on the key activities he had been involved in since the last Authority meeting.

3.3. The Chief Executive gave a status update on PRISM. It was noted that PRISM launch was going well. The new system had been deployed to all stand alone clinics and we were receiving high-quality data. It was noted that IT staff had completed the work to re-establish HFEA billing processes through PRISM.

3.4. There was also evidence that clinics with data submission backlogs were making good progress to reduce their backlog. Before launch, the PRISM deployment deadline was 10 December 2021. This deadline had since been reviewed and new deadlines for completion of deployment would be communicated to clinics. The revised deployment times are:

- 10th December: All API solutions to be complete and accredited.
- End January 2022: All API solutions to be deployed to clinics.
- End March 2022: All clinics to be 'caught up' on submitting data.

3.5. Members were advised that the extension was caused by third party suppliers taking longer than originally estimated to deploy their API solutions.

3.6. Members commented that the extension would be welcomed because the original deployment date of 10 December was causing concern in some clinics. Members asked if the delay would have resource or financial implications.

3.7. The Chief Executive responded that the extension was cost neutral as relevant staff contracts had been extended to ensure support to clinics during the embedding period.

Decision

3.8. Members noted the Chair and Chief Executive's report.

4. Committee Chairs' report

4.1. The Chair introduced this item. She commented that some of the Members' terms of office were coming to an end which meant that there would be a change of committee chairs.

- It was noted that Margaret Gilmore will be stepping down as Chair of SAC and Jonathan Herring will be taking over.

- Jonathan Herring will be stepping down as Chair of the Licence Committee and Alison Marsden will be taking over.
- Anita Bharucha's term of office as a member and as the Chair of the Audit and Governance Committee (AGC) would end on 31 December and Catharine Seddon will take over as the AGC Chair from 1 January 2022.
- Yacoub Khalaf had already stepped down as Chair of the Scientific and Clinical Advances Advisory Committee and Tim Child had taken over.

4.2. The current Chairs were invited to give an update on their committees.

Audit and Governance Committee (AGC)

4.3. The AGC Chair (Anita Bharucha) thanked Margaret Gilmore who chaired the meeting held on 5 October due to illness. It was noted that the standard items were presented which included presentations from the internal and external auditors.

4.4. A lessons learned meeting on the digital programme was scheduled for December 2021. Once PRISM was complete, the AGC would refocus its agenda on other matters.

4.5. Anita concluded by thanking the team who made the running of the committee very smooth and wished Catharine Seddon all the best in her tenure as the next AGC Chair.

Statutory Approvals Committee (SAC)

4.6. The SAC Chair (Margaret Gilmore) presented this item. It was noted that mitochondrial donation applications and special direction applications where among the decisions made. They also had the annual review of committee effectiveness.

4.7. Margaret concluded by thanking the Licensing staff for their support and wished Jonathan Herring well in his new role as the SAC Chair.

Scientific and Clinical Advances Advisory Committee (SCAAC)

4.8. The SCAAC meeting held on 11 October was chaired by Tim Child who presented to the Authority. He thanked Yacoub Khalaf, the outgoing Chair.

4.9. The committee continued to monitor the effects of Covid on fertility assisted conception and early pregnancy.

4.10. It was noted that the annual review of the traffic light ratings for treatment add-ons had taken place. It was also noted that immunology tests and treatments had been separated on the HFEA web pages.

4.11. Yacoub Khalaf commented as he stepped down as an Authority member and the Chair of SCAAC that he had greatly enjoyed SCAAC and that at every meeting discussion was channelled towards patients' interests and on the efficacy of present and future treatments. He thanked everyone for their support during his tenure.

Licence Committee

4.12. The Licence Committee Chair (Jonathan Herring) commented on the meeting held on 11 November. It was noted that a number of complex issues were addressed at the meeting.

4.13. The annual review was also held to reflect on the effectiveness of the committee.

Decision

4.14. The Chair thanked all outgoing and new committee chairs for their time and commitment.

4.15. Members noted the Committee Chairs' reports.

5. Performance report

5.1. The Chief Executive commented that there were three red indicators on the performance scorecard:

- HR1 Sickness
- C1 Efficiency of end-to-end inspection and licensing process
- II1 Time taken to close internal incidents.

5.2. It was noted that sickness absence rates had worsened in September and that Covid had been a contributory factor. It was not felt that this performance figure would become a trend.

5.3. Turnover – indicator HR2 was amber at 17.6%. Looking ahead, turnover was likely to remain a concern as recruitment was getting more difficult for some roles, especially when other sectors including the NHS and the private sector were offering higher salaries.

5.4. Following on from the Authority discussion on performance at the last meeting, members were updated on the current status of items raised.

5.5. On the staff survey, members were advised that the headline results had been shared with staff and more details would be discussed at the AGC meeting in December. It was noted that the headline engagement response to the survey was at c.80%, which was above average in the civil service. There were however a number of issues that required action, including most notably the need for improved internal communication. All heads of service were discussing the results of the survey with their teams and the outcome would be taken back to the next Corporate Management Group (CMG) meeting.

5.6. Members asked about staff turnover and if it was similar in other similar-sized organisations and whether the public sector pay freeze was affecting staff morale. The Chief Executive responded that we were not seeing major changes in staff morale, but if recruitment continued to be difficult it would start to have an adverse effect and put additional strain on existing staff. Also, judging from the responses in the staff survey the civil service wide pay freeze was an issue.

5.7. The Chief Executive stated that we would continue to look at the business plan to ensure that our core statutory duties were being met should staff turnover become a major issue, but that we were not in that position yet.

5.8. The Chair asked how recruitment would be addressed. The Chief Executive responded that we planned to better articulate the benefits of what we can offer, for example that the pension is good, we have flexible working and good annual leave. We would also advertise in targeted markets and encourage moves between other smaller organisations.

5.9. Members were reminded that there was news from the Chancellor about public sector pay rises for 2022, but it was not clear whether it would be fully funded. We are awaiting guidance on this.

5.10. Members asked how we would get people back into the office. The Chief Executive responded that compared to other organisations we were sharing a floor with, we were doing very well. The

corporate policy which had been communicated to all staff with an office-based contract was that they needed to attend the office at least once a week. CMG meetings were now largely in person and there were some staff in the office more often than a day a week.

Strategy and Corporate Affairs

5.11. The Director of Strategy and Corporate Affairs gave an update on her area of work.

- On actions following publication of the ethnic diversity report in March 2021: there was follow up work to understand more about patient experience through our current patient survey. This would give us feedback on access to treatment via GPs, and other information on success rates; with clinics, we set up a small working group of Licence Centre's Panel members to look at some specific topics in workshops next year – success rates and access to treatment, multiple births and donor availability; following the patient survey we would do some further focused work looking at whether we should provide additional information on our website for specific groups of patients; we also had further discussions with the British Fertility Society (BFS) and representatives of the Royal College of Obstetricians and Gynaecologists (RCOG) Race Equality Taskforce about what more could be done and the impact our data could make on the NICE review of fertility guidelines.

5.12. An update was given on the patient engagement forum and how to make best use of it, and which projects would be making use of it early next year.

5.13. On the patient survey, members were informed that we got useful information on how we can get more engagement. We had previously received over 1,000 responses so would like similar or more this time around.

5.14. The State of the Sector report was published on 24 November 2021.

5.15. The multiple births report would be published in early 2022.

5.16. The Code of Practice was published at the end of October after sign-off by the Secretary of State for Health and Social Care and the sponsor team at DHSC were thanked for their help in ensuring it was laid in Parliament on the day it was published.

5.17. Stakeholder meetings were held with the Licensed Centre's Panel (LCP) on treatment add-ons and we had a scheduled meeting with the new Patient Organisation Stakeholder Group (POSG) and in early December with the Professional Stakeholder Group (PSG). The Treatment add-ons group meeting has been scheduled for 29 November 2021.

5.18. We are in the process of issuing responses to consultations including the Medicines and Healthcare products Regulatory Agency (MHRA) medical devices consultation.

5.19. On the licensing and governance front, by the end of 2021 we would have held three SCAAC, one horizon scanning and two treatment add-on group meetings; six Authority and ten AGC and PRISM oversight AGC meetings; 44 Executive Licensing Panel (ELP), Licence Committee and SAC meetings; and three Register Research Panel (RRP) meetings - all of which involve papers, minutes and background work in order to service meetings. The staff were thanked for their work in supporting these committees over the last year.

5.20. In response to a question regarding donor availability, the Director of Strategy and Corporate Affairs said that we were looking out for the results from the recent campaign on donor recruitment in Scotland to see if there were any findings we could use to support consideration of further work in future.

Compliance and Information

5.21. The Director of Compliance and Information commented on the red indicator on efficiency of the end-to-end inspection and licensing process – currently achieving 67%. She commented that the efficiency of the licensing process had been affected by a number of complex inspections, introduction of the new Compliance and Enforcement policy, increased workload due to the hybrid inspection process and the rescheduling of inspections which were cancelled between March and November 2020. These were necessary regulatory actions, and so the lengthening of the process did not reflect a performance issue.

5.22. Due to the change of inspection methodology and increased number of inspections the KPI is being reviewed.

Finance and Resources

5.23. The Director of Finance and Resources commented that there was significant underspend across a number of areas which meant that the long-term contingency has not been touched.

5.24. Members were informed that September was the first month that clinics were issued with invoices whose value is based on 2019/20 activity volumes whilst PRISM is embedded. Once PRISM data comes in, we would do a reconciliation and send out adjustments as required. The earliest we would be able to do this reconciliation will be the end of quarter three.

5.25. Members were also advised that the PRISM IT team would be kept on for a few more months to ensure handover and additional staff have also been recruited. All these will have an effect on the bottom line by year end.

5.26. In response to a question, the Director of Finance and Resources clarified that the effect of PRISM will only be known by the end of the financial year. At present there was no extra costs (as referred to earlier on in the meeting).

Decision

5.27. Members noted the performance report.

6. Covid update

6.1. The Director of Compliance and Information gave an update and commented that activity levels in clinics remained high.

6.2. There had been no further feedback from clinics regarding the shortage of blood tubes or consumables.

6.3. Concerns had been raised by support groups on partner accessibility when patients are attending clinic appointments, but it would appear that this was localised. This would continue to be monitored.

Decision

6.4. Members noted the Covid update.

7. State of the sector

7.1. The Director of Compliance and Information presented this item. Members were reminded that the State of the Sector report was our annual compliance report, summarising what had been seen through our regulatory work during the year.

7.2. The report was compiled from information gathered from HFEA regulatory activity, including inspections and other sources of information like our Register of fertility treatments, incident reports and patient feedback mechanisms.

7.3. The COVID-19 pandemic had a significant impact on the availability of fertility treatment in 2020/21 and this, combined with the changes we made to our approach to inspection during the year, means that data provided in this report is not directly comparable with previous years and should be interpreted with caution

7.4. It was noted that 103 clinics were licensed to provide treatment and of those 31 were based in the London area.

7.5. Due to the pandemic, 67 inspections were deferred by 12 months, which meant that the number of inspections decreased compared to previous years.

7.6. In total in 2020/21, 77 inspections were carried out, of which:

- 17 were completely desk-based
- 32 were a combination of desk-based assessment and onsite visit
- 23 were onsite visits with informal desk-based assessment
- 5 were risk-assessed with no onsite visit.

7.7. Members were advised that the number of severe OHSS incidents reported decreased in 2020/21 compared to previous years. It was noted that whilst we always encourage OHSS prevention, during the pandemic clinics were asked to adopt a more cautious approach to reduce any additional burden on the NHS. A professional member commented that in 2018/19 the way OHSS reported changed, which probably accounted for the rise to 103 incidents compared to 57 incidents the previous year.

7.8. It was noted that the number of complaints received in 2020/21 was similar to previous years and a number of them were themed around not being able to attend appointments with partners. In response to a question, it was noted that the number of Covid related incidents could be further broken down.

7.9. The Director of Compliance and Information thanked the Intelligence, Communications and Inspections teams who had worked collaboratively in producing this report.

7.10. The Chair commented that the clinics she had visited liked the new hybrid inspections as they felt that the desk-based analysis enabled them to provide more detail.

7.11. The Director of Compliance and Information responded that desk-based analysis allowed for a better line of questioning and drove compliance and improvement.

7.12. Members commented that we needed to look out for endemic cultures in clinics as a number tend to wait until inspection time before they do anything about their compliance. Members also commented that there should be collective responsibility amongst professionals in clinics.

7.13. The Director of Compliance and Information responded that eradicating such behaviour was one of the reasons why we issue the Quarterly Clinical Governance report via Clinic Focus.

7.14. In response to a question, it was noted that we have a statutory duty to inspect clinics every two years, therefore the timing of unannounced inspections could be predicted by clinics/Persons Responsible.

7.15. Members commented that the Authority should be proud of what it was achieving as there were a lot of positives, including reduction in multiple births, fewer incidents and no grade A incidents. These were all excellent achievements and generally the sector was in a safe place.

7.16. The Chair paid tribute to all the teams involved in developing and publishing the State of the Sector report.

Decision

7.17. Members noted the State of the Sector report.

8. 2022-23 Financial update

8.1. The Director of Finance and Resources presented this item. He commented that further scrutiny could take place at the AGC meetings, should the Authority agree.

8.2. Members were advised that since the September Authority meeting, initial conversations have taken place with the Department of Health and Social Care (DHSC) and have agreed a way to take any recommendation for a fee review through formal approval channels in HM Treasury (HMT).

8.3. However, our desire to have more flexibility in terms of managing our budget over more than one financial year, or accessing reserves, has been agreed as incompatible with HMT financial rules.

8.4. Members were advised that additional work had been undertaken to finalise a detailed draft budget for the 2022/23 financial year and we would also propose a more fundamental review of our fees model during 2022/23 to better reflect the drivers of regulatory costs.

8.5. The 2022/23 budget is balanced and based on a £5 increase in the IVF licence fee and an assumed 2% growth in activity. It was noted that the planned budget for 2021/22 was £7,048,000.

8.6. It was noted that without any increase in income, the Authority would struggle to deliver its business as usual activities. In recent years the HFEA had made significant efficiencies, reducing both its headcount and Grant in Aid (GiA) from Government.

8.7. Measured from the start of public sector austerity in 2010, headcount is approximately 25% lower and GiA is approximately 50% lower. These savings were achieved by prioritising the ‘front line’ and bearing down on corporate services.

8.8. It was now clear that the HFEA’s statutory responsibilities cannot be delivered within the current resource profile; an example is the increase in requests for Open the Register (OTR) and we are not yet in 2023 when the register will be opened up to more people.

8.9. Members commented that they were pleased with the report as it was reflective of their conversation at the September Authority meeting. Members wanted to know what would happen if it was not approved by our sponsor, DHSC and or HMT.

8.10. The Director of Finance and Resources responded that the biggest impact would be on some of our business as usual activities as they would be slowed down without the necessary resources.

8.11. Members commented that with the background of not having an increase for six years, a £5 increase was less than inflation and should be acceptable. Members also wanted to know if there was government pressure for us to seek full cost recovery. The Director of Finance and Resources responded that there was no such pressure.

8.12. The Chair commented that we would continue to pursue all options.

8.13. In response to a question, the Chief Executive reminded members of the current fee regime, what cycles incurred a charge and commented that the storage fee income was low because fewer patients used storage facilities.

8.14. Members commented that in addition to what had been presented, to make it a more persuasive paper to the DHSC and HMT we could include the increases in breadth and scope of the HFEA's work over the last 10 years which all require additional resources. Also, part of our plan was to review the current legislation which would be resource intensive.

8.15. Some members commented that some clinics would pass this added cost on to patients, and that there was therefore a need to have a communication strategy aimed at patients about this increase.

8.16. The Chair commented that a lot of work had gone into the report and thanked the Director of Finance and Resources and his team for their effort in putting it together.

Decision

8.17. Members agreed proposals to increase the HFEA's expenditure budget for 2022/23 and to approach DHSC and HMT to request an increase in the HFEA licence fee of £5 to £85 per treatment cycle from 1 April 2022.

9. Annual report and future proposal for OTR service

9.1. The Chair introduced this item and commented that regular updates on this issue would be coming to the Authority. She invited the Donor Information Manager and the Head of Information to present to the Authority.

9.2. The Donor Information Manager reminded members that applications by donor-conceived people, donors and parents for Register information are known as Opening the Register (or OTR). The HFEA has had a process in place for dealing with OTR applications by parents and donors since 2005, and donor-conceived people since 2007 (when the first cohort of donor-conceived people on our Register turned 16). The service was suspended in March 2020 until October 2020 owing to Covid and since then, there has been a large increase in applications which has led to a significant number of applications waiting to be processed.

9.3. Two new staff members have been temporarily recruited to address the backlog. Training is progressing well, and they are now able to work on the register, which will lead to a gradual decrease in the backlog. There is currently a backlog of 664 OTRs, of which:

- 360 OTRs have been responded to since re-opening the Register
- 52 OTRs have been responded to so far in November

- 201 OTRs are being worked on (28% of the waiting list)
- 98 OTRs are ready for second checking.

9.4. Members were advised that the HFEA had a 3-year contract with the Hewitt Centre for them to provide support and intermediary services (the contract expires March 2022). The Donor Information Manager shared some positive feedback from a patient who had contacted us and found the service beneficial.

9.5. The Head of Information spoke about the future of the OTR service from 2023, when anonymity is lifted. The changes included:

- Online application form that integrates with a new case management system
- A new case management system to keep all work done on OTRs in one place and find efficiencies
- New reporting through RITA.

9.6. Members were advised that the current staff resource was four in total and this was the minimum size required for the increase in workload. This figure would be kept under regular review to make sure the service does not become overwhelmed as the number of requests continues to rise.

9.7. At members' request, the full process of checking and releasing the donor identifying information was explained.

9.8. Members commended the team especially for the progress made in working through the backlog of cases. Members suggested that there was the need to raise further awareness of this service.

9.9. Members asked what percentage of people sought counselling. The Chief Executive responded that arrangements were in place to offer counselling support through the Hewitt contract, but it was not part of our statutory duty.

9.10. The Director of Compliance and Information commented that this project was to ensure that we meet the demand 2023 may bring and to ensure that the backlog was resolved. The system had improved but there was still more work to be done.

9.11. In response to a question, it was noted that all efficiencies had been explored and resilience would be built in and across the team.

9.12. Members commented on the low uptake of the intermediary service. There was also a suggestion that the uptake on the register of donors to remove anonymity was low, and therefore awareness could perhaps be improved.

9.13. Members noted that it would be helpful to have clarity on when the backlog could be expected to be cleared. On security, members would like assurance that we were up to date with cyber security and firewalls. It was also thought important that the Hewitt Centre's service provision was evaluated.

9.14. The Chair reiterated that we do not have a statutory duty to provide a counselling support service and we would need to keep the current position under review.

9.15. The Chair thanked the Head of Information and the Donor Information Manager and the rest of the Register Team.

Decision

9.16. Members noted the update on OTR activity and performance.

10. Update on treatment add-ons consultation plan

10.1. The Policy Manager and Scientific Policy Manager presented this item. Members were reminded that treatment add-ons are optional additional fertility treatments.

10.2. Members were reminded that at the last Authority meeting it was agreed that scoping work on how the presentation of the treatment add-ons rating system could be evolved should begin.

10.3. The Policy Manager and Scientific Policy Manager had since met with researchers with expertise in data presentation and risk communication, to gain their views for how the rating system could be evolved.

10.4. It was noted that based on the suggestions made by researchers 10 initial options were developed for how the current rating system could potentially be progressed.

10.5. After checking the feasibility of the options, there was a presentation at the Licensed Centres Panel (LCP) to gain the views of clinics and also at the Patient Organisation Stakeholder Group (POSG) to gain the views of patient organisations.

10.6. The various key suggestions from the groups were explained to members and proposed future activities were listed, as follows:

- Present the 10 options and the suggestions from researchers, LCP and POSG to the November TAG meeting
- Conduct patient interviews
- Develop three options based on the scoping work
- Conduct a targeted patient survey and a clinic survey on the developed three options
- Conduct patient focus groups based on the results of the survey.

10.7. Members commented that the work in the annex was thorough and clearly laid out. Members requested that before options are presented to focus groups staff should ensure they were feasible and that there are resources to implement them.

10.8. Some members suggested that user acceptance could usefully come earlier in the process.

10.9. Members suggested that clearly laid out information on what particular treatments involved could be published on our website for the benefit of patients and potential patients.

10.10. Members requested that staff should explore patients' understanding of terms such as 'no RCT (randomised controlled trials)' and 'no evidence' since there might be value in explaining this. It would also be important to check usability and accessibility in colours used, especially for patients and potential patients who have visual impairments.

10.11. The Director of Strategy and Corporate Affairs commented that there were two strands of work, one on the visual presentation, and secondly whether the evidence base for SCAAC's review of the traffic lights assigned to add-ons should change. The second part of this work would start in early 2022 and that had potential resource implications, depending on SCAAC's recommendations.

10.12. Members commented that it was important that the information on the website was simple and that if there was a way of making it even simpler then staff should pursue this. The use of infographics was also an option that could be explored further.

10.13. The Chair commented that SCAAC would be involved in some more detailed discussions and thanked everyone involved in the work to date.

Decision

10.14. Members noted the progress made and the direction of travel.

10.15. Members agreed the proposal for further engagement for evolving the rating scheme for treatment add-ons.

11. Next steps in transparency and regulation

11.1. The Director of Strategy and Corporate Affairs presented this item. It was noted that the term transparency was being used to mean the clarity of our regulatory information and the ease with which patients and others were able to access it on our website.

11.2. Members were reminded that we had a duty in the Act to ensure that we published information and as a regulator we had to ensure we were transparent. When this was last brought to the Authority in May 2021, members asked for more detailed options to be brought back, and this paper explored how our compliance decisions could be better published and publicised.

11.3. Members commented that they agreed that clinics should add more information on their websites. We could however go a step further by publishing themes of complaints brought to us as a regulator as this would flag emerging areas of concern.

11.4. Some members commented that this was an important piece of work; however with the number of challenging pieces of work and limited resources, they asked how urgent this work was.

11.5. Members noted that as a regulatory tool, transparent publications would give patients more information which would enable them to make more informed decisions, and further suggested that the Choose a Fertility Clinic (CaFC) function could be made more useful to patients.

11.6. There was therefore the need to publish everything we could for transparency purposes and make it more accessible.

11.7. The Chief Executive commented that once regulatory action was complete, the outcome became a matter of fact and could be published without prejudicing any formal decisions. We would however be careful to ensure we remained within our legal parameters.

11.8. The Director of Strategy and Corporate Affairs commented that all inspection reports and committee papers were published on our website, but we would do more work to ensure this was more accessible and easy to find.

11.9. Some members commented that members of the public must be in a position where they can find trusted information published by the HFEA and expressed that this should be a priority as the HFEA were behind where other regulator are in publishing their regulatory decisions for the public.

Decision

11.10. To bring back to Authority during 2022 options for how compliance information such as inspection reports and licensing decisions can be more visible and easier to find on the website.

12. Any other business

12.1. The Chair commented that we are awaiting Ministerial decisions on the appointment of new Authority members. In the meantime, it was noted that Margaret Gilmore, Ruth Wilde and Anne Lampe have had their terms of appointment extended by three months, which was very welcome.

12.2. Yacoub Khalaf and Anita Bharucha were stepping down as Authority members at the end of December, and so this would be their last Authority meeting. The Chair thanked them for commitment and hard work and commented that Yacoub Khalaf would remain on the SCAAC committee as an external member for a further year.

12.3. The Chair thanked all staff involved in ensuring the meeting was successful and ran smoothly.

Chair's signature

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

Signature

Chair: Julia Chain

Date: 9 February 2022

Authority meeting

Matters Arising

Details about this paper

Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science, and society		
Meeting	Authority meeting		
Agenda item	3		
Meeting date	9 February 2022		
Author	Debbie Okutubo, Governance Manager		
Output:			
For information or decision?	For information		
Recommendation	To note and comment on the updates shown for each item.		
Resource implications	To be updated and reviewed at each Authority meeting		
Implementation date	2022/23 business year		
Communication(s)			
Organisational risk	☐ Low	**X** Medium	☐ High

ACTION	RESPONSIBILITY	DUE DATE	PROGRESS TO DATE
Matters Arising from the Authority – actions from 7 July 2021			
5.7 PGT-M being out of target of the 75 working days	Director of Compliance and Information	July 22	This will be kept under review and will be reported to a future Authority meeting.
8.14 Fertility trends - Multiple birth – A report publishing our data on multiple births.	Head of Research and Intelligence	July 22	A paper on multiple births to be published February 2022. On track – due to be published 8 February 2022.
Matters Arising from the Authority meeting – actions from 23 September 2021			
5.18 Backlog on OTR	Director of Compliance and Information	March 22	Staff are gaining competence and there is a significant increase in the amount of OTRs being processed. An improved way of reporting the performance indicator is being discussed and will be introduced as an increased amount of applications in the backlog are now being worked on.
8.17 Permission to gain access to our reserves	Director of Finance and Resources	July 22	Completed.
9.15 Discussion to be held with multiple birth outliers	Director of Compliance and Information	September 22	To be raised at inspection
Matters Arising from the Authority meeting – actions from 24 November 2021			
11.10 Options on how compliance information including inspection reports and licensing decisions could be made more visible and easier to find on the website.	Director of Strategy and Corporate Affairs	November 2022	No further progress. Legislative change has taken priority at this point.

Chair and Chief Executive's report

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	3
Meeting date:	9 February 2022
Author:	Julia Chain, Chair and Peter Thompson, Chief Executive
Annexes	N/a

Output from this paper

For information or decision?	For information
Recommendation:	The Authority is asked to note the activities undertaken since the last meeting.
Resource implications:	N/a
Implementation date:	N/a
Communication(s):	N/a
Organisational risk:	N/a

1. Introduction

1.1. The paper sets out the range of meetings and activities undertaken since the last Authority meeting in November 2021.

1.2. Although the paper is primarily intended to be a public record, members are of course welcome to ask questions.

2. Activities

2.1. The Chair has continued to engage with the decision-making functions of the Authority and with key external stakeholders, as covid restrictions allowed:

- 25 November – interview with the Sunday Times
- 29 November – attended the treatment add ons working group meeting
- 1 December – spoke at the PET conference
- 6 December – interview on Women's Hour BBC radio 4
- 15 December – attended the PROGAR meeting
- 8 January – spoke at the Fertility 2022 conference
- 12 January – meeting with Raj Mathur and introductory meeting with Adam Balen
- 13 January – introductory meeting with Eddie Morris, president of the RCOG
- 18 January – introductory meetings with Abha Meshwari, PR of Aberdeen Fertility Clinic, Carole Gilling-Smith, PR of the Agora Fertility Clinic and Natalie Sutherland, partner from Burgess.me.com
- 19 January – introductory meeting with Ippokratis Sarris, Kings Fertility
- 20 January – introductory meeting with Kate Brian, Infertility Network UK and former Authority Member
- 26 January – introductory-meetings with Alison Campbell, CARE Fertility and Nick Macklon, London Women's Clinic
- 31 January – attended the SCAAC meeting
- 3 February – introductory meeting with Emily Jackson, Professor of Law at the LSE and former Authority Member

2.2. The Chief Executive has continued to support the Chair and taken part in the following externally facing activities:

- 29 November – chaired treatment add ons working group meeting
- 30 November – introductory meeting with Colin Sullivan, CEO of the HTA
- 8 December – attended the DHSC/HFEA Quarterly accountability meeting with our sponsor team and other members of SMT
- 9 December – attended our Audit & Governance Committee (AGC) meeting
- 17 December – attended the AGC PRISM lessons learned meeting
- 12 January – participated in UK/China Bioethics Law project
-
- 26 January – spoke at the PET event "Adding up what we know about fertility treatment add-ons - a global perspective"
- 31 January – attended the SCAAC meeting

Committee Chairs' reports

Details about this paper

Area(s) of strategy this paper relates to:	The best care/The right information/Shaping the future
Meeting:	Authority
Item number:	4
Meeting date:	9 February 2022
Author:	Paula Robinson, Head of Planning and Governance
Annexes	-

Output from this paper

For information or decision?	For information
Recommendation:	The Authority is invited to note this report, and Chairs are invited to comment on their Committees.
Resource implications:	In budget
Implementation date:	Ongoing
Communication(s):	None
Organisational risk:	Low

1. Committee reports

1.1 The information presented below summarises Committees' work since the last report.

2. Recent committee items considered

2.1 The table below sets out the recent items to each committee:

Meetings held	Items considered	Outcomes
Licence Committee:		
11 November 2021	1 Renewal 1 Renewal 1 Executive Update	Adjourned Granted Noted
13 January 2022	1 Initial Research 2 Research Renewals	All granted.
Other comments:	None.	
Executive Licensing Panel:		
16 November 2021	3 Renewals 1 Interim 1 Extension of Licence 1 Change of Person Responsible	1 renewal adjourned remainder granted/approved
30 November 2021	1 Initial 3 Renewal 2 Change of Person Responsible 1 Change of Licence Holder	All granted/approved
2 December 2021 (extraordinary meeting)	1 Special Direction (change of premises)	Granted
14 December 2021	1 Renewal 2 Change of Premises 1 Change of Centre Name 3 Licence extensions 1 Special Direction (continuation of licence)	All granted/approved
11 January 2022	2 Renewals 1 Interim 2 Licence extensions 1 Change of Premises 1 Change of Person Responsible	All granted/approved
25 January 2022	2 Renewals 2 Change of Premises 2 Change of Person Responsible	All granted/approved
Other comments:	The volume of items continues to be high.	

Meetings held	Items considered	Outcomes
Licensing Officer decisions:		
N/A	ITE certificates – 16 Change of Licence Holder – 4 Change of Centre Name – 1	All granted
Other comments:	None.	
Statutory Approvals Committee:		
28 October 2021	4 PGT-M applications 2 Special Direction applications	1 Special Direction adjourned, remainder granted
25 November 2021	3 PGT-M applications 2 Special Direction applications	All granted
16 December 2021	6 PGT-M applications	1 refused, remainder granted
27 January 2022	6 PGT-M applications 1 Special Direction application	The minutes from this meeting have not yet been finalised.
Other comments:	None.	
Audit and Governance Committee:		
9 December 2021	Internal audit recommendations progress External Audit planning report 2022/23 HR bi-annual report and staff survey feedback Strategic risk register review Resilience and business continuity Regulatory and register management and team structure	Noted Noted Noted Noted Noted Noted
Other comments:	This was the last meeting for the outgoing Chair, Anita Bharucha. Several AGC meetings for PRISM oversight also took place, including a lessons learned meeting.	

Meetings held	Items considered	Outcomes
Scientific and Clinical Advances Advisory Committee:		
31 January 2022	• Monitoring the effects of COVID on fertility, assisted conception, and early pregnancy.	• No changes to the HFEA's guidance on COVID were recommended. BFS and ARCS to review professional guidance.
	• Horizon scanning literature review presented and discussed.	
	• Committee workplan for 2022/2023 presented.	• Feedback regarding possible changes to the order of the priority topics on the committee work plan was received.
	• Literature review on updates to alternative methods to derive embryonic and embryonic like stem cells presented and discussed.	• Committee agreed research using human embryos will continue to be necessary. • The HFEA will continue to monitor alternative methods to derive embryonic and embryonic like stem cells.
	• Guest speakers from Newcastle Fertility presented confidential updates on the clinical use of mitochondrial donation.	
	• Review of the traffic light system presented.	• Feedback from Committee to be considered in the ongoing evolving the traffic light system project

3. Recommendation

3.1 The Authority is invited to note this report. Comments are invited, particularly from the committee Chairs.

Performance report

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	5
Meeting date:	9 February 2022
Author:	Shabbir Qureshi, Risk and Business Planning Manager
Annexes	Annex 1: Performance scorecard Annex 2: Financial management information Annex 3: High level KPIs

Output from this paper

For information or decision?	For information
Recommendation:	The Authority is asked to note and comment on the latest performance report.
Resource implications:	In budget
Implementation date:	Ongoing
Communication(s):	The Senior Management Team (SMT) reviews performance in advance of each Authority meeting, and their comments are incorporated into this Authority paper. The Authority receives this summary paper at each meeting, enhanced by additional reporting from Directors. Authority's views are discussed in the subsequent SMT meeting. The Department of Health and Social Care reviews our performance at each DHSC quarterly accountability meeting (based on the SMT paper).
Organisational risk:	Medium

1. Latest review

1.1. The attached report is for performance up to December 2021.

1.2. Performance was reviewed by SMT in January 2022.

2. Key trends

2.1. Performance was generally good across October, November, and December.

Red indicators – October (4)

2.2. The indicators classed as red are as follows:

- HR1: Sickness
- HR2: Turnover
- C1: Efficiency of the end-to-end inspection and licensing process
- C4: Mitochondrial donation application processing

Red indicators – November (2)

2.3. The indicators classed as red are as follows:

- HR2: Turnover
- C1: Efficiency of the end-to-end inspection and licensing process

Red indicators – December (2)

2.4. The indicators classed as red are as follows:

- HR2: Turnover
- C1: Efficiency of the end-to-end inspection and licensing process

2.5. The annexes to this paper provide a scorecard giving a performance overview, high-level financial information and the monthly management accounts and more detailed information on KPIs.

3. Follow up from previous Authority performance discussion

3.1. In response to the recent staff survey, a working group has been set up to explore actions, and further information will be brought to the Corporate Management Group (CMG) shortly.

3.2. Recruitment continues to be a concern, but we have improved our articulation of the positive aspects of being employed by the HFEA, including pension benefits, flexible working and good annual leave allowances. We are beginning recruitment to replace our Head of IT (due to retirement) and Head of Intelligence (relocating).

3.3. Guidance on public sector pay rises for 2022 is still awaited.

3.4. Following the recent changes in government guidance, we have reverted to requiring all office-based staff to work a minimum of one day per week in the office. We are currently drafting a new ‘Working from Home’ policy and will be offering permanent work from home contracts to all staff.

4. IT and Register performance reporting

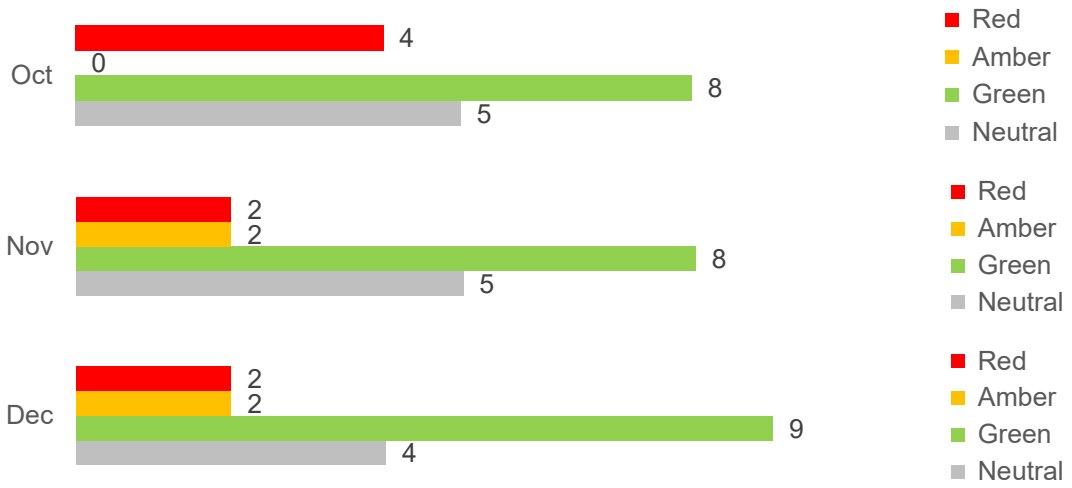
4.1. All clinics that used the old EDI system are now submitting data via PRISM. The first clinics using a third-party system are now also starting to come online; remaining clinics are due to be online by March.

4.2. Performance is good. Although it is not possible to directly compare current performance with old figures, we see an error rate of 1% currently for clinics using PRISM directly (37 clinics) with many clinics having zero errors. This compares with an average of 6 - 8% for clinics submitting through a third party system. The register team are working to get this level down to the level of those making direct entry to PRISM.

4.3. We are continuing to actively engage with clinics to support them in the transfer to PRISM.

Annex 1 HFEA Performance scorecard and management commentary – October to December data

Breakdown of total Red, Amber, Green and Neutral Indicators



RAG (October)	Area	Trend and key data
Red – not at target	**People -** Employee turnover Target: between 5%-15%	18.3% Turnover 2 leavers
Red – not at target	**Regulatory efficiency -** Time for end-to-end inspection and licensing process Target: 100% in 70 working days or less	40% within target. Average of 71 wds (items beginning with an inspection)
No target – more than double last month	**Engagement -** HFEA website sessions	71,447 sessions (71,112 in same month last year)
RAG (November)	**Area**	**Trend and key data**
Red – not at target	**People -** Employee turnover Target: between 5%-15%	18.9% Turnover 1 leaver
Red – not at target	**Regulatory efficiency -** Time for end-to-end inspection and licensing process Target: 100% in 70 working days or less	40% within target. Average of 83 wds (items beginning with an inspection)
No target	**Engagement -** HFEA website sessions	69,136 sessions (71,805 in same month last year)

RAG (December)	Area	Trend and key data
Red – not at target	**People -** Employee turnover Target: between 5%-15%	17.37% Turnover 0 leavers, 2 starters
Red – not at target	**Regulatory efficiency -** Time for end-to-end inspection and licensing process Target: 100% in 70 working days or less	58% within target. Average of 76 wds (items beginning with an inspection)
No target	**Engagement -** HFEA website sessions	58,755 sessions (67,251 in same month last year)

Summary financial position – December 2021 (Figures in thousands – £'000s)

Type	Actual in YTD £'000s	Budget YTD £'000s	Variance Actual vs Budget £'000s	Forecast for 2021/2022 £'000s	Budget for 2021/22 £'000s	Variance Budget vs Forecast £'000s
Income	**5,758**	**5,384**	**374**	**7,512**	**7,049**	**463**
Expenditure	**(4,795)**	**(5,305)**	**510**	**(7,048)**	**(7,044)**	**(4)**
Total Surplus/(Deficit)	**963**	**79**	**884**	**464**	**5**	**459**

Commentary on financial performance to 31 December 2021

Year to date we have a surplus against budget of £884k. This is largely due to licence fee income increase year to date (£374k) and underspends as detailed in the commentary.

Our forecast position as of 31 March 2022 is currently showing a surplus against budget of £459k which includes surpluses against our non-cash items.[1] We are forecasting a gross surplus overall of £464k, removing non-cash items reduces this to £183k. We will monitor this closely in the last few months, as it is possible that we may incur additional costs such as legal or contractor costs that may bring this figure down.

[1] Non-cash items are depreciation and amortisation of our fixed assets. We received cover from the DHSC of £515k for these costs which cannot be used to fund any other expenditure. Due to the delay in implementing PRISM, costs have not been incurred as budgeted for.

Management commentary

Across the last quarter, staff turnover has remained high. However, we had no leavers in December and two new starters. Comparatively high turnover will continue into the next quarter as we have two department heads due to leave, one through retirement and another relocating. Sickness, however, is now green after several months at higher levels, and Covid related absence was significantly lower in December.

The end-to-end inspection and licensing process has remained in red throughout the quarter with several inspections above the 70 working day target. We are doing work to better understand the impact of additional workload from inspections that were moved forward and to reduce the time taken for the DBA process as inspectors gain proficiency in using the system. A review of this KPI is in progress, and we are keen to ensure the KPI remains appropriately challenging but is also achievable.

We are also working with the OTR team to create better KPIs that reflect the true backlog in the OTR request system, and the team are gaining experience and working towards reducing the bottlenecks in closing each request. We expect to have better reporting and clarity in place in time for the next Authority meeting.

Our web manager has also started implementing new reports and heat maps using Google Analytics to better represent website activity and track social media impact. Again, we expect to have the new reports in place shortly. Following this we are also planning a review of the whole set of communications indicators over the next few months.

Red indicators in October:

HR:

- **HR1: Sickness.** In October, sickness continued to be significantly higher than normal, running at 4.42% compared to our KPI target of 2.5%. We had two employees on long term sick, one of whom returned before the end of October. We also had one employee absent after a minor operation who also returned in October.
- **HR2: Turnover.** Turnover was also still high (slightly higher than September, at 18.3%) with two leavers; however recruitment was running at a more steady, manageable pace compared to earlier months.

Compliance & licensing:

- **C1: Efficiency of the end-to-end inspection and licensing process.** As explained in the November Authority performance report, this indicator is under review and a proposal for changing the target will be considered by SMT shortly. In October, performance was at 40% of items being processed within 70 working days. There were three inspections over the KPI target. Reasons included outstanding payments and documents, constraints on inspectors' time, annual leave, and agenda pressures.
- **C4: Mitochondrial donation application processing.** It was necessary to schedule two items to a later SAC meeting because of the lack of availability of a mitochondrial donation expert adviser for the August SAC meeting. This meant that these two items were 12 days beyond the KPI target, by the time the minutes were issued.

Red indicators in November:

HR

- **HR2: Turnover.** Turnover remained high (18.9%) with one leaver.

Compliance & licensing:

- **C1: Efficiency of the end-to-end inspection and licensing process.** In November performance was still at 40% with six inspections over the KPI target (currently still 70 wd), for reasons including inspector workloads and annual leave, late payment of fees, and some IT issues at one centre which prevented us from obtaining timely data for register audits.

Red indicators in December:

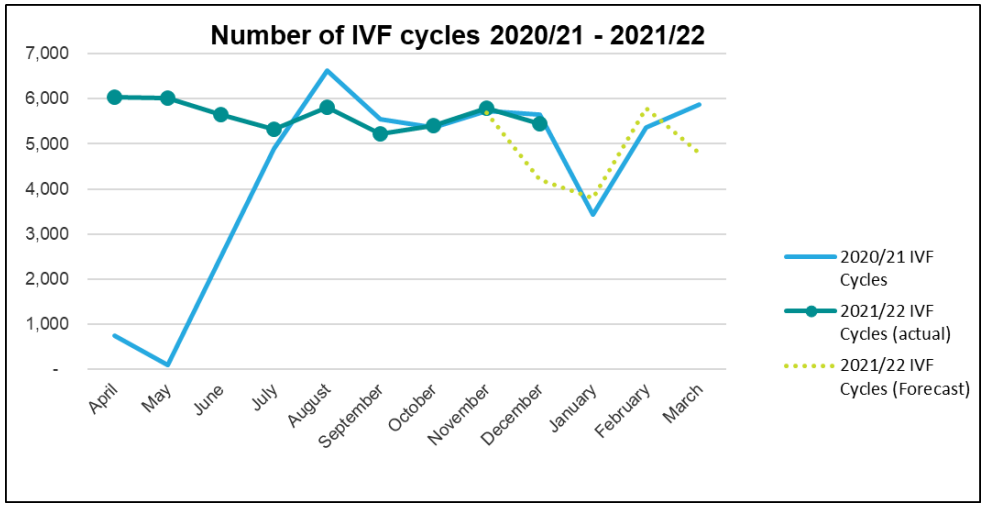
HR2: Turnover:

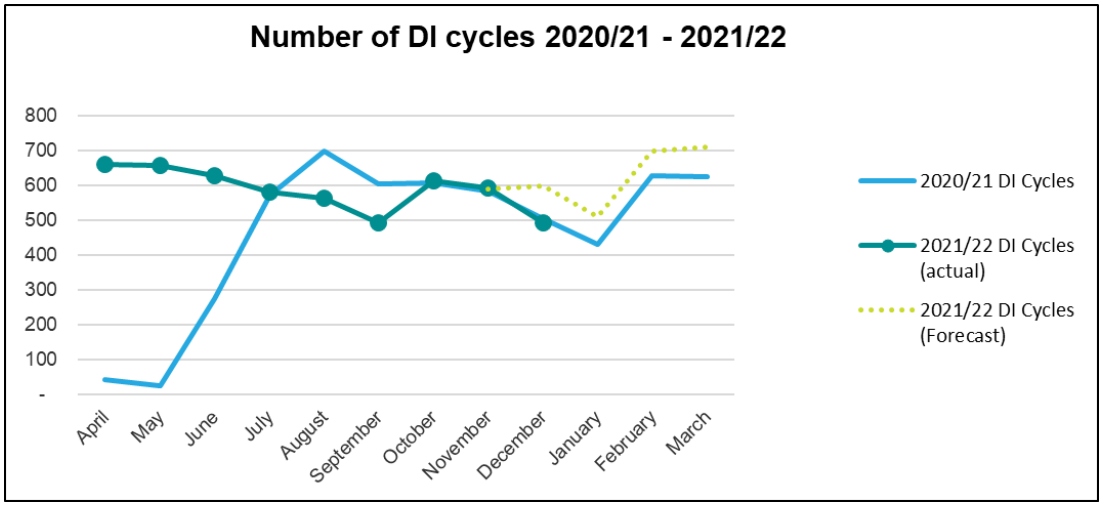
- **HR2: Turnover:** This improved slightly (to 17.4%) in December but remains a red indicator.

Compliance & licensing:

- **C1: Efficiency of the end-to-end inspection and licensing process.** In December performance improved slightly to 58%, with five inspections over the KPI target (currently still 70 wd), for reasons including the complexity of the report and a need for additional management review meetings, inspector workloads and annual leave.

Annex 2 Financial management information





IVF Cycles	YTD		YE Position	
	Volume	£	Volume	£
2020/21 IVF Cycles	37,127	2,970,160	51,795	4,143,600
2021/22 IVF Cycles (actual)	50,725	4,057,973	65,125	5,209,973
Variance	13,598	1,087,813	13,330	1,066,373

DI Cycles	YTD		YE / Forecast	
	Volume	£	Volume	£
2020/21 DI Cycles	3,912	146,700	5,598	209,925
2021/22 DI Cycles	5,281	198,038	7,201	270,038
Variance	1,369	51,338	1,603	60,113

YTD IVF volumes are up 37% on the same period in 2020/21 and 6% over budget. These increases are in spite of the estimated billing where we have taken a prudent view as to volumes.

Similarly, DI volumes are 12% higher than budget and 35% higher than the same period last year. This is a slight drop from November.

We continue to raise estimated invoices whilst clinics strive to submit a backlog of treatment forms. The deadline is March 2022 which will enable reconciliations to be conducted and any under recoveries to be collected via additional invoices.

HFEA Income & Expenditure Dec-21

	Year to Date				Full Year		
	Actual £'000	Budget £'000	Variance £'000	Variance YTD %	Forecast £'000	Budget £'000	Variance £'000
Income							
Grant-in-aid	923	825	(98)	(0)	1,256	1,098	158
Non-cash (Ring-fenced RDEL)	387	387	-	-	516	516	-
Grant-in-aid - PCSPS contribution	75	75	-	-	100	100	-
Licence Fees	4,299	3,987	(312)	-8%	5,529	5,188	340
Interest received	0	2	1	1	1	2	(1)
Seconded and other income	74	109	36	33	110	145	(35)
Total Income	5,758	5,384	(374)	**(7)**	**7,512**	**7,049**	**462**
Revenue Costs							
Salaries (excluding Authority)	3,423	3,376	(47)	(1)	4,720	4,447	(273)
Staff Travel & Subsistence	37	54	16	30	47	73	26
Other Staff Costs	51	84	33	40	114	111	(3)
Authority & Other Committees costs	167	179	10	6	269	234	(36)
Facilities Costs incl non-cash	385	675	289	43	656	954	298
IT Costs	357	481	125	26	569	642	73
Legal / Professional Fees	184	265	81	31	326	339	13
Other Costs	112	191	79	41	244	244	0
Other Project Costs	79	-	(79)	-	102	-	(102)
Total Revenue Costs	**4,795**	**5,305**	**510**	**10**	**7,048**	**7,044**	**(4)**
TOTAL Surplus / (Deficit)	**963**	**79**	**884**		**464**	**5**	**459**
Adjusted for non-cash income/costs	**742**	**38**	**703**		**174**	**4**	**170**

Management commentary

Income.
At the end of Q3 2021, our total income is 6.9% (£373k) above budget. Assisting this increase is our grant in aid which is above budget due to draw down of EU funding £158k. Our licence fee income is 7.8% (£312k) above budget. This includes the 4 months where we have issued estimated invoices to clinics. Offsetting these increases is an deficit against budget within our Secondee charges. The original budget assumes secondment costs monthly, however one staff member was on maternity leave and no pay therefore reducing the amount we would bill.

Expenditure by exception.
Year to date we are under budget by £357k.
Salary costs - excluding contract staff are under budget by £208k, an increase of £5k from November. This is offset by the overspend in contract staff of £255k and £1k underspend in Authority co costs. Contract staff costs are mainly related to PRISM.

Staff Travel & Subsistence - we are underspending here by £16k which relates to the reduced travel within the Inspections team.

Other Staff Costs - significant underspends are within Staff training, Recruitment, Pension processing (£32k. £1k and £10k respectively), offset by an overspend in staff welfare of £14k. Staff Welfare costs include unbudgeted costs for mediation, staff survey and job evaluations not budgeted for totalling £7.5k
Authority & Other Committee costs - £10k over budget which relates mainly to overspends within Advisors fees (£6.7k) and Travel and Subsistence (£3.9k).

Facilities costs - underspent by £289K, (an increase of £49k from November) of which £97k relates to our accommodation costs for 2 Redman Place which we are awaiting final figures from DHSC. In addition we have an underspend (£180k) within our non-cash costs, the majority of which relates an asset that has come to the end of its useful life. The balance is made up of small underspends within Office Administration costs.

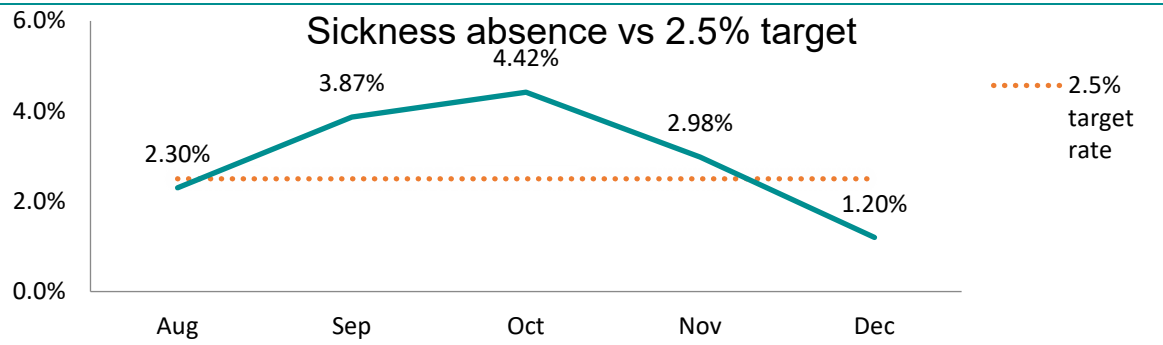
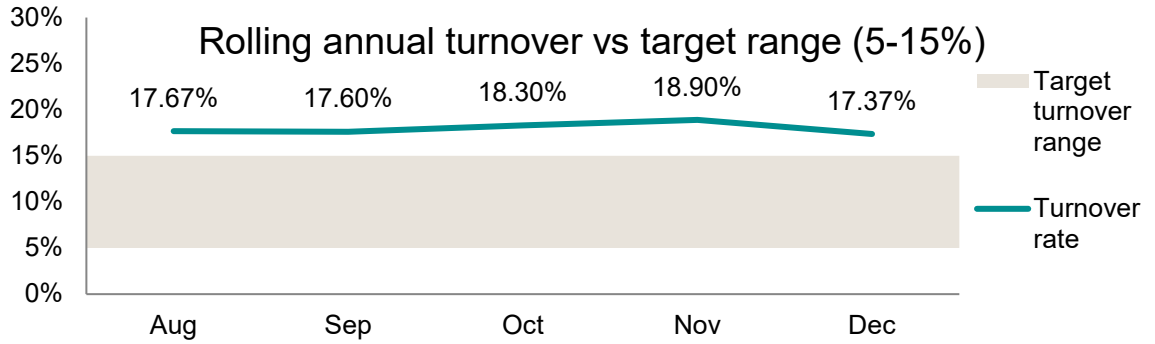
IT Costs - underspent by £125k. The main underspends are within our Support costs £54k and IT Subscriptions £67k. The reduction in both areas is due reduced usage of Alscient (Support contract) and within contract renegotiated for Microsoft Office subscriptions. The balance is made up of small under and overspends.

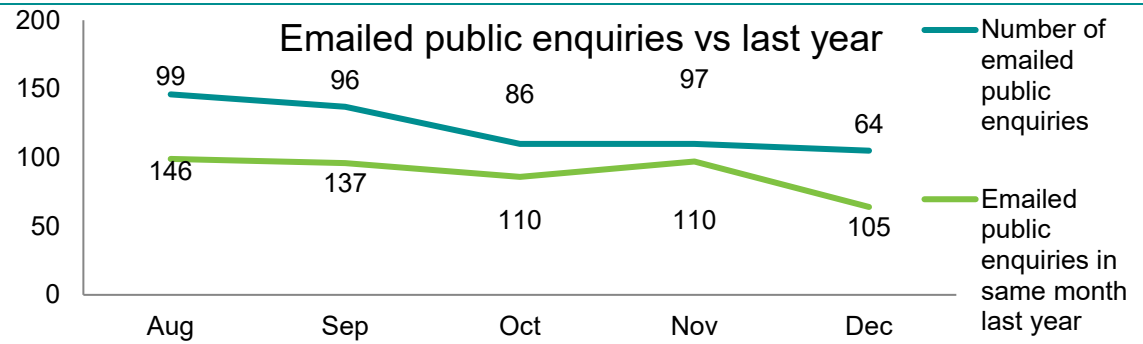
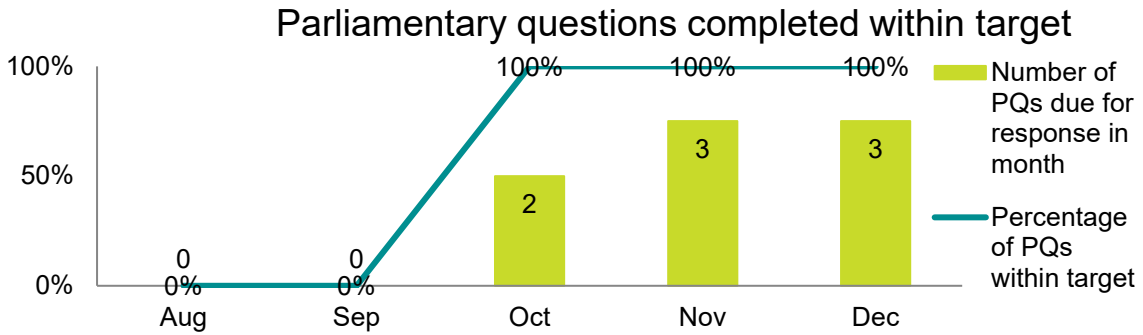
Legal/Professional fee - are under budget by £81k. This is represented by a contingency of £30k and the legal budget underspend by £51k. On discussions with the Head of Legal, we may see some increase in spend over the remaining quarter.

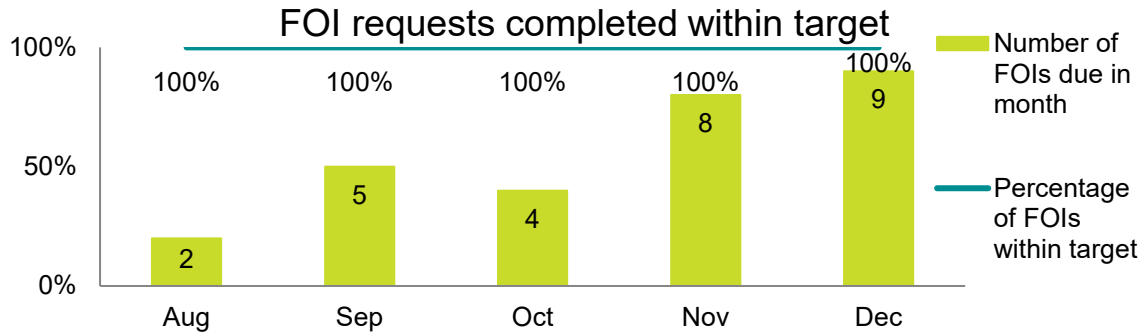
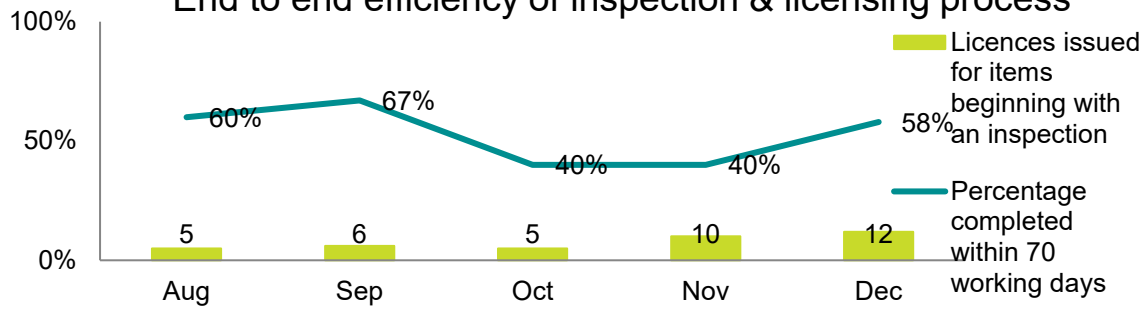
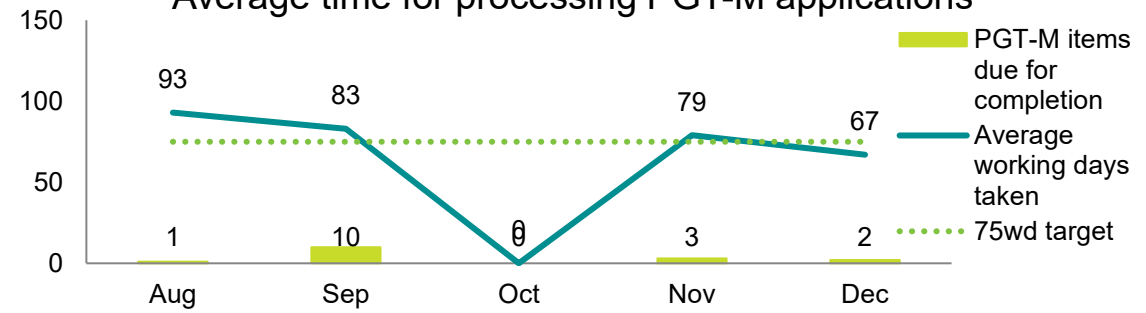
Other costs/Project Costs - are underspent by £79k. This is represented by underspends within Discretionary training (£6k),where staff have not utilised this funding. Stakeholder Engagements (£37k), this normally would be where the Annual Conference costs go, but as there has been no conference or workshops we continue to show an underspend. In addition to the above, we are underspending within Compliance Other (£24k), Communications costs £7k and Inspections Advisors costs (£5k). Project costs are for EU Transition for which funding has been drawn down.

Forecast.
A review of costs for the remaining quarter have been undertaken and has resulted in a forecast surplus against budget of £459k and includes the surplus (£283k) of non-cash income against non-cash costs which we cannot utilise. Net of this surplus our we are forecasting a surplus of £172k against budget.

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
HR1 – Sickness **Target**: less than or equal to 2.5%. Target is based upon ONS 2018 data (2.7% for the public sector)		Sickness is low for December, however, we had lots of employees on annual leave.	Green
HR2 – Turnover **Target**: between 5 and 15% turnover for the rolling year.		72 – Headcount 68 – Establishment (posts) There were no leavers in December (and two new starters).	Red

Key performance indicator name and description	Graph showing performance trend for last 5 months	Commentary (if any)	RAG rating
Supplementary data - Public enquiries No target.		Wide range of emailed enquiries, and 17 enquiries calls.	No target
R1 – Percentage of Opening the Register requests completed within 30 working day target. (excludes counselling time) **Target:** changed from 100% in 20wd to 95% in 30wd from April 2020. **Note: target not currently active.**	Partial data available over the last 3 months so graphs not available currently. This will be rectified after January data set. New OTRs received in month: 42 Number worked on in month: 223 Number closed in month: 68 Number ready for checking: 98 Total remaining on backlog at month end: 634	We are not currently reporting against our previous target – as agreed at Authority October 2020. A new target for tracking progress in eliminating the backlog will be developed in the first few months of 2022.	Neutral
RI1 – PQs responded to within deadline set (Based on deadlines agreed with DHSC) **Target:** 100% within deadlines set.		None.	Green

Key performance indicator name and description	Graph showing performance trend for last 5 months	Commentary (if any)	RAG rating
RI2 - FOIs responded to within deadline **Target:** 100% within statutory deadlines.		There were also 7 enquiries received in December.	Green
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.		Average working days taken – 76. Most days taken: 167 working days Least days taken: 24 working days.	Red
C3 – 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.		Average working days taken – 67 Most working days taken: 75 Least working days taken: 59	Green

Human Fertilisation & Embryology Authority

Gamete and embryo storage

Proposed changes to the law and HFEA implementation plan

Joanne Anton
Head of Policy (job-share), HFEA

Background

- HFE Act set out the storage limit at a maximum of 10 years.
- In 2009 the limit was extended to a maximum of 55 years – but only where a patient is or is likely to become prematurely infertile in the written opinion of a medical practitioner.
- Considerable stakeholder pressure for reform, arguing that the current rules are:
  - too restrictive and negatively impact on a persons' reproductive choice
  - administratively complex and can be difficult to implement.
- HFEA delighted that Government has now decided to change the consent regime via amendments to Health and Care Bill.
- Proposed changes are significant for the sector and if passed will come into effect 1 July 2022.

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Summary of proposed changes

Key points:

- Patients and donors will be able to store gametes and embryos up to a maximum of 55 years.
- Clinics will need to contact patients to renew their consent every 10 years – but not donors.
- It will no longer be necessary for patients to be 'prematurely infertile' to store for longer than 10 years however they will have to renew their consent in writing every 10 years.
- **Posthumous use:** where a patient consents to posthumous use, their gametes or embryos can remain in storage for 10 years from the date of their death.
- **Research and training:** gametes and embryos donated for research or training can be kept for up to 10 years from the date on which the patient consents to use for those purposes.

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Timeline

The proposed commencement date (provided the Parliamentary timetable goes to plan), i.e. when the amendments will come into effect is 1st July 2022.

- The new provisions introduce a **transitional period** and a number of transitional provisions which work to effectively enable gametes and embryos in storage under the old regime to transition over to being stored under the new framework.
- The transitional period will begin on the 1st July 2022 and end on the 30th June 2024**.**
- During this period it will be necessary for those categories of patients caught by the transitional provisions to have taken the necessary steps, with the help of their clinics, to have renewed their consent.

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Implementation

- 1 July 2022 commencement date means that between now and 1 July 2022 we will need to provide new guidance and consent forms to help clinics prepare for the new provisions.
- This is a priority for a number of teams, including policy, legal, and compliance.
- These changes will significantly impact clinics and will require significant change to clinic practices - it is vital that we support clinics to understand what they need to do to properly implement the changes.
- By early May 2022 we will need to:
  - Publish new and amended consent forms for patients
  - Introduce new guidance for clinics
  - Publish a draft guidance note on Storage (which will be incorporated into the Code the next time it is updated)
  - Delivered a communication plan for clinics and patients

Human Fertilisation & Embryology Authority

Authority decision

Authority are asked to agree:

- For the Executive to consult with a small number of Authority members (clinical) to seek advice, review documents and provide input where necessary, between February and May 2022.
- To delegate approval and sign off, where necessary, of any new or revised General Direction(s), guidance and other material necessary for the implementation of the proposed amendments to the Chair.

The Executive will provide regular updates to Authority on the progress of this work.

Human Fertilisation & Embryology Authority

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Human Fertilisation & Embryology Authority

Business plan 2022/23

Details about this paper

Area(s) of strategy this paper relates to:	The best care/The right information/Shaping the future
Meeting:	Authority
Agenda item:	8
Meeting date:	9 February 2022
Author:	Paula Robinson, Head of Planning and Governance
Annexes	Business plan 2022/23 – activities section

Output from this paper

For information or decision?	For comment and approval.
Recommendation:	The Authority is asked to approve the attached draft of next year's business plan. This will be subject to further development prior to publication.
Resource implications:	In budget for the financial year 2022/23
Implementation date:	1 April 2022 – 31 March 2023
Communication(s):	The business plan will be published on the website following formal approval by the Department.
Organisational risk:	Low

1. Introduction

1.1. The Corporate Management Group (CMG) met on 18 January 2022 to consider how best we could deliver key elements of our strategy in the coming year, bearing in mind current and new pressures on our capacity.

1.2. This was an important discussion to have, in a week where the tight timetable for the forthcoming work on storage limits was confirmed.

1.3. In all our CMG discussions we have had regard for the Authority's strategic vision: Regulating for excellence: Shaping the future of fertility care and treatment; and for the focus throughout the strategy on the best care, the right information, and shaping the future.

1.4. However, in the course of earlier discussions with the Authority we have also acknowledged that the business plan should identify our highest priorities, so that these can receive the most focus, particularly when additional essential work emerges and capacity is limited.

1.5. In light of this, we have identified the top priorities, and also some work that we should delay or scale down in order to ensure that the activities with the most practical and strategic benefit can be done successfully.

1.6. This paper sets out those priorities, and Annex 1 contains a draft of the full activities section of the business plan for the Authority's approval.

1.7. Other sections of the business plan, including a summary of this year's work, some year end performance data, and the financial information section will be produced over the next two to three months, in accordance with our usual cycle.

2. Prioritising our plans

2.1. It is important to acknowledge that the majority of our resource is expended on our core statutory work. Much of this core work also helps us in delivering our strategic vision of regulating for excellence and shaping the future of fertility care and treatment. These are the key activities that we must carry out, in order to perform our role, and the following are therefore automatically a top priority in the business plan:

Core statutory work

- Inspection and licensing regime
- Opening the Register requests
- Maintaining the Register
- Information for researchers
- Annual horizon scanning and maintenance of the Code of Practice
- Information provision (including CAFC update)
- Information requests
- Fulfilling wider DHSC or healthcare system requests.
- Meeting external legal requirements, for example responding to statutory information requests.

2.2. In addition to our core statutory work, we have identified the following activities as the highest strategic priorities for 2022/23:

Best care

- Completing the review of the treatment add-ons traffic lights and evidence base.
- Engagement with NICE on their fertility guidelines review.

Right information

- Work following the launch, in 2021, of PRISM and our new register of treatments. This work is necessary to ensure that PRISM is fully operational for clinics, and that various internal systems that were linked to the old register, are now linked to the new register to restore full functionality.
- Linked to this, working towards a fresh publication of our CaFC data in 2022.
- Clearing the backlog of OTR requests that built up as a result of clinic closures during the first Covid lockdown, combined with increased volumes of requests.
- Reviewing our communication activities to ensure we are getting the most impact with the tools and resources we have

Shaping the future

- Our Donor Information Service Development Project, which will help us to prepare for future, higher, levels of demand.
- Continued preparatory work to present our ideas for modernisation of the HFE Act.
- Other work relating to more imminent legislative developments, such as changes to gamete and embryo storage limits.
- A review of our fees regime (agreed previously with the Department of Health and Social Care and the Treasury).

2.3. This does not mean that no other work will be done. Our business plan continues to present a challenging and varied programme of work, which we aim to complete. However, given that the new work on storage limits will occupy a significant proportion of our resource for the first six months of the year, and the sizeable list of other essential work, we consider it wise to enter the business year with a clear sense of priorities.

2.4. While considering priorities, CMG also deprioritised several items of work. This was necessary given the additional pressures we are under. We will review in the future whether these intended activities will be achievable in the following business year.

2.5. Work that has been deprioritised or scaled down for the coming year includes:

- The project on reducing clinic variation (although we have retained some of the intended components of that project, such as work on transparency in regulation, and work on our intelligence dashboards).
- A review of guidance on the ten-family limit – we intend to resume scoping of this work in 2023.
- Active review of donor egg availability (beyond encouraging clinics to present up to date information on the Portal).
- Large-scale work with GPs on information provision to patients – however we will do targeted work, where we are able, to improve GPs' access to information.
- Further work on our guidance for clinics on conditional donation.

- Further work on encouraging responsible innovation and ensuring clinics assess innovative treatments (apart from some already planned work on authorising new processes, which has been scheduled for the second half of the coming business year).
- Guidance and information particularly focused on partners – this has been reduced in scope to a review of our website information and social media activity. Further work in this area may however arise from the Government's Women's Health Strategy, when it is published.

3. Next steps

3.1. There will be further editing after today's Authority discussion, and this will include refining the details and timing of pieces of work that are currently being planned, such as storage limits. In addition, other sections of the business plan (including end of year performance data and the financial section) will gradually be added as the relevant information becomes available, close to the end of the financial year.

3.2. Meanwhile our sponsors will consider a draft of the business plan and we will liaise with them over any comments provided.

3.3. Once the business plan (incorporating our budget) is approved by the Department, it is then published on our website.

4. Recommendation

4.1. Authority members are asked to:

- Note this paper and the recent discussions about prioritising our plans for the coming year so that we can focus our resources on the highest value strategic activities with the most benefit for our stakeholders.
- Approve the draft activities section for further development over the next two to three months, in liaison with the Department of Health and Social Care.

Annex A – Business Plan 2022/23 - Activities section

Our role and strategic aims

Who we are

The HFEA is the regulator of fertility treatment and human embryo research in the UK. Our role includes setting standards for clinics, licensing them, and providing a range of information for the public, particularly people seeking treatment, donor-conceived people and donors.

Our vision for 2020-2024 is:

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

We continue to put everyone who uses fertility services at the heart of everything we do - patients, partners, donors, donor-conceived people and surrogates. We want them all to receive excellent care, support and information.

Their experiences differ, based on their individual circumstances. Our strategic focus will be on providing the best, most effective care for everyone, recognising the diverse family structures in which treatment and donation take place. We want to ensure people can access the right information at the right time. As science and society change, we will shape and respond to future developments, helping ensure that the translation from innovative treatment to everyday care is ethical and responsible.

As the regulator of fertility services and research involving human embryos, we aim to be effective and efficient, providing consistent oversight and advice to clinic staff and researchers.

What can we do to achieve excellent care, support and information?

Our strategy for 2020-2024 focuses on three areas:

The best care

- Effective and ethical care that is scientifically robust, accompanied by excellent support, and provided by well-led clinics.
- A transparent evidence base so that patients can make informed choices, and more research and innovation to improve the evidence base.
- Improved recognition by clinics of partners' importance in the care process.

The right information

- Accurate and useful information that is provided at the right time.
- Improved information at the earliest (pre-treatment) stage, with new information flows to support primary care professionals and patients.
- Access to relevant and impartial information for all – particularly about the evidence base, add-ons and treatment options.

Shaping the future

- Proactively embracing new developments in the changing fields of modern family creation, genetics, and artificial intelligence.
- Engaging with and facilitating debates on changes in science, law and society, integrating new developments into our work.
- Preparing for future legislative and operational changes, to ensure we remain a modern, effective and responsive regulator.

The Department of Health and Social Care's planning priorities for 2022/23 are reflected where relevant in our plans, and our strategy is well aligned to the Department's vision, which is to enable everyone to live more independent, healthier lives for longer.

In the wider health system the aim is to fulfil this vision by supporting healthy behaviours, improving the UK's health and care system, and creating healthy environments. Our focus on the best care, the right information and shaping the future supports the Department's broad aims, within the specific context of fertility regulation and embryo research.

From 2020 and throughout 2021, we focused on responding to changes due to Covid-19, adapting our inspection regime and our other planned strategic work accordingly. In our work going forward we will continue to respond to Covid and any relevant Government guidance, ensure clinics are able to operate safely for patients, and provide up to date information.

Over the past two years we also implemented a raft of changes in our regulatory and licensing regime, and in our guidance and information, in response to EU Exit. We will continue to respond to any further changes relating to EU Exit that may impact on the fertility sector or our own work.

The Government's levelling up agenda also includes health inequality reduction as a key priority. We will continue to advocate for equitable access to high quality fertility services and to provide information to help patients and their partners in their decision-making.

The Government has also published, in December 2021, a vision for the Women's Health Strategy for England, and this includes a distinct focus on women's reproductive health needs, including fertility. The Government's ambition is to ensure women are empowered to make purposeful choices about their reproductive health and care, before, during and after pregnancy and pregnancy loss, with support from safe, high-quality health services. This aligns well with our own wish to see patients receive the best

possible care and better information, and to see more equitable access to fertility treatment across the UK. The Government's strategy on Women's Health will be published in spring 2022, and we look forward to working with Department colleagues on aspects related to fertility treatment.

Activities for 2022-2023

This business plan represents the second full year of delivery for our 2020-2024 strategy, outlined above, which launched in October 2020.

2022-2023 follows on from a year that continued to be somewhat affected by the coronavirus pandemic, for patients, the sector and our staff. 2021 was also our anniversary year, marking thirty years since the HFEA was established. As such, we began to look forward to the future of fertility treatment and regulation, and will be doing more work on this in the coming year, together with our stakeholders.

The pandemic has been challenging for the sector, and for the HFEA. The ways in which we deliver our core work have changed, and in the same time period, our workload has grown in a number of areas.

We have had to closely examine our priorities and resources to ensure we focus on the highest value areas. We have permission to increase our fees in 2022 for the first time since DATE which will provide much needed additional resource and go some way to alleviating staff pressures in key areas of our work. In the event of additional work arising during the year, we may need to alter the following plan to respond to that, and will consider this in light of our strategy.

Meanwhile, we consider our top priorities for 2022/23 to be:

- Continued delivery of our core statutory work – inspection, licensing and the provision of up to date guidance for clinics and information for patients and the wider public.
- Work following the launch, in 2021, of PRISM and the migration of data into our new register of treatments. This work is necessary to ensure that PRISM is fully operational for clinics, and that various internal systems that were linked to the old register, are now linked to the new register to restore full functionality.
- Linked to this, working towards a fresh publication of our CaFC data in 2022.
- Our Donor Information Service Development Project, which will help us to prepare for future, higher, levels of demand.
- Clearing the backlog of OTR requests that built up as a result of clinic closures during the first Covid lockdown, combined with increased volumes of requests.
- Continued preparatory work to present our ideas for modernisation of the HFE Act
- Other work relating to more imminent legislative developments, such as changes to gamete and embryo storage limits.
- Completing the review of the treatment add-ons traffic lights and evidence base.
- Reviewing our communication activities to ensure we are getting the most impact with the tools and resources we have
- Engagement with NICE on their fertility guidelines review.
- A review of our fees regime (agreed previously with the Department of Health and Social Care and the Treasury).
- Meeting external legal requirements, for example responding to statutory information requests.

The activities set out over the next few pages will help us to deliver our strategic objectives in 2022-2023.

The best care

Our first aim is for effective and ethical care for everyone. We have two strategic objectives relating to this aim and the activities planned to deliver these are set out in the tables below.

Table 1 - Strategic objective 1. Treatment that is effective, ethical and scientifically robust. Table outlining planned activities for April 2022 to March 2023

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	Benefits and outcomes	Timescale
Full programme of clinic regulation, encompassing all of our inspection, audit and licensing activities. This includes continuation of the revised approach developed in response to the Covid-19 pandemic.	All clinics and research establishments in the sector are: • appropriately inspected and monitored against the requirements of the act and published performance indicators, and • issued with licences for up to five years. Clinics that are well led and see compliance and the provision of high-quality care, including excellent support, as good business. Assurance of consistent standards and safety for the public and other stakeholders. Positive overall impact on quality of care, outcomes, safety, support, and information clinics publish (eg, on their websites) and provide to us. Patients know that all clinics are safe and appropriately licensed. Reduction in the number of critical, major and other non-compliances.	Throughout the year
Maintenance and adjustment as needed of our regulatory approach, and ongoing monitoring of Covid-19 risks and impacts on the fertility sector and the HFEA. Clear actions and communication.	Clear ongoing inspection plan and assistance for clinics in response to any new Covid-19 related situations and government guidance. Risk-based approach to inspection activity. Clinics continue to effectively respond to Covid-19 related risks. We effectively adapt and respond to any changes in Covid-19 circumstances, such as any local lockdowns and new government guidance, and also assist the sector to do so.	Throughout the year

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
Review of the Compliance and Enforcement Policy issued in 2021.	Ensuring the Compliance and Enforcement Policy remains fit for purpose and is being used in a correct and appropriate manner	December 2022
Responding as required to the public inquiry into the Covid-19 pandemic.	The HFEA meets its public duty to provide input as and when required.	Inquiry to commence in spring 2022
Collaborative and partnership working with other ALBs and health regulators UK wide as needed, to ensure streamlined regulation.	Joint working as and when required, including concluding work begun with the CQC in 2021/22 on streamlining regulation and clarifying responsiblities in relation licensed clinics, third party and satellite clinics. Implementation of any changes into the inspection regime. Continued savings and avoidance of unnecessary administrative or regulatory burden, by avoiding duplication of effort or uncoordinated approaches between regulators. Ability to capitalise on previously established relationships, eg, to address issues that require joint working in an efficient and coordinated way, or to establish the best approach if any new areas of regulatory overlap should arise. We maintain clear and appropriate memoranda of understanding (MOUs) to ensure that we have clearly defined responsibilities and ways of working collaboratively with key regulators.	Throughout the year
Continue our engagement work to address disparities in access, experience and outcomes, including those identified in our ‘Ethnic Diversity in Fertility Treatment 2018’ report (published March 2021) and patient survey. Use this information to identify where we, as a regulator, can take action to address these	Through our patient survey and discussions with patients, clinics, and other stakeholders (including through our Patient Engagement Group and stakeholder groups), we understand what disparities exist between ethnic groups in terms of patient experience, access to treatment and outcomes. HFEA website content is updated where needed to provide ethnicity minority patients with information about specific issues which may be relevant to them. We work with grassroots and other organisations to further understand cultural and religious beliefs that may impact on donor recruitment and help to overcome any barriers that may exist. We review whether changes to our Code of Practice are needed relating to information provision for ethnic minority patients.	Throughout the year

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	Benefits and outcomes	Timescale
inequalities and promote greater equity across the fertility sector.	We will explore the reasons why patients from some ethnic groups have higher multiple birth rates than White patients and consider this when reviewing our multiple births minimisation strategy. Continue to implement the actions identified as a result of the report on Ethnic Diversity in Fertility Treatment in 2018.	March 2023
Providing input into the review of NICE fertility guidelines.	Revised NICE guidelines are informed by HFEA input and data, such as on ethnic diversity and fertility treatment and family formations. NICE guidance updated to reflect current practice across the sector.	January 2022 to December 2023 approx.
Development of the HFEA's information on treatment add-ons looking at the presentation on the website and exploring any expansion of the evidence base beyond Randomised Controlled Trials (RCTs).	Ethically and medically responsible supply of add-ons, only where these are safe and appropriate, by clinicians/clinics based on good evidence. Where add-ons are offered, this is: • with full information so patients can make informed decisions • only to specific groups where there is evidence of effectiveness and safety. Patients and clinics understand the risks associated with add-ons. SCAAC annual review of add-on treatments so that patients and clinics have accessible information on sound scientific evidence. A refined presentation of the rating system and further consideration of the most appropriate forms of evidence to base it on.	March 2023
Better use of our register and information in data research using intelligence dashboards.	Development of internal resources and tools to enable our publications and responses to ad hoc enquires, FOIs and PQs. We'll also continue to work on our internal database to enhance the provision and usability of our data for researchers.	Throughout the year
Effective handling of and communication about: • clinical incidents and adverse events, including publication of 2020-2021 'State of the Sector'	Continued strong focus on learning in dialogue with the sector including engaging with clinic leaders. Sector provided with useful information about learning points from incidents and adverse events. Reduction in the number of clinic incidents, owing to a proactive approach being taken to learning from own and others' mistakes.	Throughout the year, with the state of the sector report

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
report and quarterly compliance reports • complaints about clinics	Learning gained, to inform future inspections. Patients' experiences used to make improvements and prevent recurrence. Better understanding of factors contributing to particular types of adverse events.	published in Autumn 2021
Ensuring governance tools underpinning licensing and other decisions are in place and effective.	Ensure that licensing decisions and other approvals are well governed. Efficient and effective decision-making is maintained. Decisions are evidenced, transparent and consistent. Committee governance arrangements and effectiveness reviewed annually.	Throughout the year
Processing applications for the licensing of preimplantation genetic testing for monogenic gene defects (PGT-M), human leukocyte antigen (HLA) and mitochondrial donation.	Applications handled effectively, efficiently and transparently and processed according to performance indicator timelines. Decisions on whether to authorise such treatments made, and communicated, in a proper and timely manner for the direct benefit of patients waiting for treatment. Mitochondrial donation and PGT-M approvals taken in an accountable and transparent way.	Throughout the year
Ongoing review of guidance for clinics to ensure this remains fit for purpose, including: • delivery of any necessary updates to the Code of Practice • issuing other clinic-facing communications, such as Clinic Focus, on issues that require further clarification to the sector. This will include a Code of Practice update project in 2023,	Guidance for clinics is up to date and reflects latest scientific developments, legal advice and policy decisions. A clear Code of Practice and other guidance for clinics. An update in 2023/24 incorporating updated guidance to clinics on the storage of gametes and embryos.	Throughout the year.

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
with the aim of publishing an updated Code in 2024.		
Servicing the legal information needs of the HFEA including: • provision of legal advice to inform other HFEA work • management of team of external legal advisers to support effective licensing processes. • supporting any changes to the law.	HFEA licensing decisions are sound and based on comprehensive legal advice. HFEA policy decisions and approaches are compatible with the regulatory framework.	Throughout the year
Maintain up to date information on the HFEA website about routine treatments, continuing our focus on clinics providing good support, and testing new information using the pilot patient engagement forum.	We use our communications channels to make sure patients receive the right information at the right time. Information is reviewed on a cyclical basis to ensure that it is fit for purpose and tested on members of the patient forum. New information added when needed. We use our social media channels to signpost people to the website information and if we include new information on the website, we promote this widely using our social media.	Throughout the year
Ongoing implementation and oversight of the changes that resulted from the end of the EU exit transition period, and responding to any new developments that may arise.	We continue to work with the DHSC and others on any issues arising from the Northern Ireland Protocol. We will engage with any changes to the EUTCD and work with others on the implications of these.	Throughout the year

Table 2 - Strategic objective 2. Improved recognition of partners' importance (of the same or opposite sex) in the care process. Table outlining planned activities for April 2022 to March 2023

Objective 2 Improved recognition of partners' importance (of the same or opposite sex) in the care process - methods and channels	**Benefits and outcomes**	**Timescale**
To review our website information and social media activity to ensure it is informative for partners and available for those who might use it.	Improved promotion of existing website content, so that the material reaches patients and their partners more effectively.	Throughout the year
To improve the reach and targeting of our signposting highlighting accurate sources of information about male fertility, making use of insights from the Patient Engagement Forum and the Patient Survey.	Patients and their partners are more easily able to find accurate information about male fertility, from the HFEA website. More dialogue encouraged about male (as well as female) fertility issues. Improved reach of this information, based on feedback from patients. We will use this feedback to adapt our communication channels and the information we provide to improve the reach of our information. We will adapt our information and how we communicate it based on insights. Feedback can be used to improve our information about the important of partners in fertility treatment.	Throughout the year

The right information

Our second aim is to ensure that people can access the right information at the right time. We have two strategic objectives relating to this aim and the activities planned to deliver these are set out in the tables below.

Table 3 - Strategic objective 3. Improved access to information at the earliest (pre-treatment) stage. Table outlining planned activities for April 2022 to March 2023

Objective 3 Improved access to information at the earliest (pre-treatment) stage - methods and channels	Benefits and outcomes	Timescale
Targeted activity where we are able to improve GPs' access to information provision so that it can be provided from the outset for patients, partners, donors and surrogates.	We will work with others to ensure information about fertility and treatment provided to patients at primary care level through targeted activities to ensure GPs have access to useful information. We will work with others when the Government's new Women's Health Strategy is published in Spring 2022, if this is a key priority.	Throughout the year
Utilising feedback from our 2021 Patient Survey, we will use our social media and other channels to communicate relevant information to the wider general public and those who are not having fertility treatment.	We will utilise feedback obtained from the Patient Survey to improve the information provided to the public and to position our information effectively. We will communicate via a range of channels and methods so people can access the right information at the right time for them. We will raise our profile and provide the general public, not just current fertility patients, with useful information. We will publish a report on the findings of the Patient Survey.	Throughout the year Spring 2022

Table 4 - Strategic objective 4. High quality information to support decision-making during and after treatment or donation. Table outlining planned activities for April 2022 to March 2023.

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
Maintaining communication with our stakeholder groups, the patient engagement forum and our followers on social media.	The information we publish is informed by stakeholder needs and insights. We meet with our patient and professional stakeholder groups twice a year and engage with them on a range of issues. We will start to involve members of the patient engagement forum to gain feedback on our work to inform what we do. We maintain our social media channels to reflect the work we are doing and try to make these as interactive as possible to encourage feedback and discussion.	Throughout the year
Utilising the feedback from our Patient survey in 2021, to ensure that patients, partners, professionals, surrogates, donors, donor-conceived people and their families all to have access to relevant and impartial information.	We will use any insights from the patient survey to inform any changes or new information for our website.	Throughout the year
Transparency in our regulatory activity.	To ensure that our information for patients and other clinics is transparent and easy to find. To review the inspection report front cover for any changes that would make it more patient-friendly. To redesign the inspection report to streamline the format for centres and to ensure it can provide useful and meaningful information to patients.	October 2022-March 2023
Evaluate the patient engagement forum after the pilot period.	We gain an insight into the patient experience in clinics and encourage good practice based on feedback. Patient feedback loop in place to ensure a regular flow of fresh feedback which can be incorporated into our stakeholder interactions and regulatory approach. We gain valuable insight into the experiences of those going through fertility and donor treatments, to inform our other work and the information that we publish.	Throughout the year

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
Maintain up to date and accurate information and advice on our public-facing website.	Patients see HFEA information as 'go to' impartial advice. People understand the possibilities and the difficulties of treatment and can weigh up the options open to them. People can easily find relevant information and signposting on our website to inform their next steps.	Throughout the year
Position and promote information via our various channels.	Access to relevant and impartial information for patients, partners, professionals, surrogates, donors, donor-conceived people, and their families. Maximising the positive impact of the information we provide. We ensure we make an impact with our information by using a range of metrics to evaluate the impact of our digital and social channels and media work. We use our social media channels to drive people to our information both online and in the media.	Throughout the year
Responding to media reports.	Balance and accuracy provided for issues the media is covering. Using the data and other information we hold to inform media coverage on a wide range of issues.	Throughout the year
Ongoing work to ensure that we maintain our compliance with accessibility requirements and make changes as necessary.	Stakeholders' accessibility needs are considered so that they are able to access our information. We ensure that our website meets the Government accessibility guidelines and that HFEA staff produce accessible documents, especially those for the website.	Throughout the year
Work following the completion of the new PRISM reporting system, to enable Choose a Fertility Clinic (CaFC) to be updated.	We ensure quality metrics and verification reports are in place. A verification exercise can take place to assure the data in the new register for the first time. We ensure that patients have access to regularly updated data on clinic performance to inform their treatment decisions. New CaFC data published for the first time from the new system. Increased ability to analyse data and report from the Register.	July 2022 June to October 2022 November 2022 Nov 2022

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
Continued support for the PRISM data submission system and ongoing engagement with clinics to ensure that their data can be submitted in a timely and accurate manner.	PRISM fully bedded in with clinics and data being submitted into the register. PRISM handover from contractors completed. Reduced transactional costs for clinics and increased user satisfaction. Minimal system downtime. 'Right first time' data quality and reduction in effort by clinics submitting the data.	May 2022 May to July 2022 Throughout the year
Further development work on the Register Information Team Application (RITA), to enable us to query the new register and run reports.	Targeted support to improve data quality across the sector. Reports being provided and the ability to query the new register to internal HFEA teams' requirements to enable Register team and OTR team to provide an acceptable level of service. Ability for OTR team to provide statutory service and search across the new register. Ability for register team to provide support to clinics and provide cross-sector reporting. Ability for register team to improve their data quality focus, addressing patterns or trends of data quality issues across sector or within specific areas.	By September 2022
Keep abreast of the impact of any Competition and Markets Authority (CMA) and Advertising Standards Authority (ASA) activities in our area.	Consider any changes to our guidance and other activities in response to any future changes by the CMA and ASA.	Throughout the year
To implement and embed the processes for a Data Review Board established in 2021/22	Data Review Board established. Clear methodology and process established for considering any future additions to the Register.	Throughout the year
Complete a review of our compliance against the NHS Digital Data Security and Protection Toolkit and submit a response to this.	We show significant progress on the quality of our submissions in the toolkit, in particular the areas of improvement highlighted by the auditors. Create a new oversight group that combines best practice from other organisations and collects toolkit documentation on an ongoing basis to allow for faster, more complete submissions going forward.	June 2022 (annual process) Throughout the year

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
	We assure ourselves that we are practising good data security and personal information is handled correctly.	
Maintaining effective Opening the Register (OTR) and counselling services.	OTR requests continue to be met in a sensitive manner. The backlog of requests stemming from the clinic closure period during the pandemic is dealt with, and normal response timescales restored. Counselling support is offered for all OTR applicants (those seeking non-identifying information) and for donor-conceived applicants receiving donor-identifying information. OTR applicants feel supported and prepared to deal with the information they receive from us.	Throughout the year
Performance management of Donor Conceived Register (DCR) services including counselling provision.	The provision of the DCR is properly performance managed against agreed KPIs, to ensure that it remains fit for purpose. Intermediary training and systems in place for dealing with identity release to donors and donor conceived people. Intermediary services are in place for when donors and donor-conceived people meet.	Throughout the year
We provide timely and appropriate responses to freedom of information (FOI), parliamentary question (PQ), and subject access requests.	We comply with FOI, PQ and DPA requirements. Requesters have access to accurate information in a timely fashion. We actively publish information on our business activities on our website, following best practice, to be transparent in our working whilst maintaining compliance with the FOI Act.	Throughout the year
To publish good quality statistical and other reports.	Preparing provisional reports on Covid treatment outcomes where fully validated Register data is not yet available from the new Register. We provide the public, patients, clinic staff and others with up-to-date, high quality information about treatments, trends and the performance of clinics. We provide important information to those affected by donor conception, including patients seeking treatment.	Throughout the year

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
	We make use of our data to help us to enhance the quality of care that patients and donors receive in clinics through our regulatory work.	
Effective handling of enquiries, complaints about the HFEA and whistleblowing.	These are handled efficiently and appropriately. Learning gained and actions identified where necessary to secure improvements.	Throughout the year
Maintaining the Register of Treatments and Outcomes and working with clinics to ensure they are accurately reporting their data.	Register data and forms continue to be processed and quality assured through liaison with clinics on errors and omissions and through validation and verification of Register entries. High quality data available to develop patient information and respond to information requests.	Throughout the year
Information provision for researchers requesting access to Register data, including ongoing review of the processes that support this.	Register Research Panel to oversee applications for data release and ensure approved data is released effectively and securely to researchers. Information for researchers is provided within specified timeframes. Register information is used to best effect, to increase understanding and facilitate good research and ultimately benefit patients. More researchers can access and use our Register data. Increased standardisation and clarity of processes and efficient use of time and resource. Anonymised Register dataset available for researchers.	Throughout the year
Ongoing compliance with government information requirements.	We respond to government requirements and new initiatives in a manner consistent with our legal status, and proportionately within our small resource envelope, carefully recognising our duties. Annual report published including required information.	Throughout the year
Effective records management and information governance.	Appropriate information governance policies and processes are in place, and regularly reviewed, ensuring roles and responsibilities and correct processes are clearly set out for staff. Good records management practice is embedded and maintained, including records retention and appropriate behaviours, to ensure access to information is maintained at all times.	Throughout the year

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
	Information governance arrangements comply with latest requirements. Records management and information governance risks are managed effectively.	
Responding to external consultations, calls for evidence and reviews including from the Department of Health and Social Care, other departments, regulators and wider public sector.	HFEA is part of discussions that may affect us, relevant legislation or the wider fertility sector.	Throughout the year
Induction of new Authority and other committee members.	HFEA governance and decision-making capabilities maintained. Effective induction to ensure new members are up to speed and able to carry out effective decision-making. Key knowledge is retained where possible, during a period of time when several Authority terms of office end and new members will join.	Throughout the year

Shaping the future

Our final aim is to embrace and engage with changes in the law, science and society. We have two strategic objectives relating to this aim and the activities planned to deliver these are set out in the tables below.

Table 5 - Strategic objective 5. Responding to scientific and social changes, particularly in modern family creation and the fields of genetics and artificial intelligence (AI). Table outlining planned activities for April 2022 to March 2023.

Objective 5 Responding to scientific and social changes, particularly in modern family creation and the fields of genetics and artificial intelligence (AI) - methods and channels	**Benefits and outcomes**	**Timescale**
Continued monitoring of patient-facing AI and data-driven new technologies that are in or potentially approaching clinical use, via the Scientific and Clinical Advances Advisory Committee (SCAAC) horizon scanning process and reviews. Ongoing horizon scanning on genetics policy issues.	We understand new developments and are responsive to these. We ensure that our regulatory regime and guidance is fit for purpose. Regular reports to SCAAC detailing issues raised used to inform our policy working and to be shared more widely as relevant. Our internal working group on AI meets regularly to monitor this. Regular horizon scanning information on genetics policy issues is considered by SCAAC and integrated into our other work as relevant (eg the work on the modernisation of the Act). Emerging new policy frameworks related to these areas are taken account of in our policy work. That responsible innovation is encouraged.	Throughout the year
To review the methodology for authorising new processes for use in clinics.	Robust and up to date methodology for authorising new processes. Processes on the authorised processes list are clear and reflect up to date practices. Awareness among clinics of the requirements for introducing new processes.	October 2022-March 2023

Table 6 - Strategic objective 6. Preparing for future legislative and operational changes. Table outlining planned activities for April 2022 to March 2023.

Objective 6 Preparing for future legislative and operational changes - methods and channels	**Benefits and outcomes**	**Timescale**
To produce proposals for modernisation of the Act.	Any future review is informed by well-informed proposals based on engagement with our stakeholders. The Government is provided with useful proposals setting out the ways in which the Act could be developed.	December 2022
Respond to any requests for consultation on legislation or emerging proposals and consider how these might impact the HFEA.	We inform any work by DHSC on legislation relating to our functions. Early consideration of possible impacts of any planned changes on the sector and the HFEA.	As these arise
Implementation of any legislative changes that occur, for example on storage limits.	Any legislative changes are successfully implemented as required. If the proposed amendment to the Health and Care Bill on gamete and embryos storage is successfully passed in Parliament, we meet the required commencement date. New guidance and consent forms in place to reflect the new legislation, including guidance documents for clinic staff and inspectors and patient information, amended and new consent forms, and updates to the Code of Practice and General Directions. Guidance and communication with the sector throughout the transitionary period.	January 2022 onwards (dependent upon external timeframes)
Conducting our annual horizon scanning exercise to ensure we identify relevant new scientific developments.	The Horizon Scanning Panel meets once per year. The Scientific and Clinical Advances Advisory Committee meets to discuss issues identified through horizon scanning three times per year. Policy developments and website material are informed by expert input and an understanding of scientific issues and future developments. Future work planning is facilitated by early identification of upcoming issues.	June 2021 Throughout year
Delivery of a project to prepare the ‘Opening the Register’ (OTR) service for future levels of demand.	The HFEA is operationally prepared for the existing and future growth in demand as more donor-conceived people become eligible to make OTR requests from 2023 onwards. Excellent OTR service maintained.	March 2023

Objective 6 Preparing for future legislative and operational changes - methods and channels	**Benefits and outcomes**	**Timescale**
Continuing to ensure that our working arrangements remain suitable following our office move in 2021, and continuing to put in place any required measures in relation to Covid safety.	We maintain appropriate ways of working, including relevant policies, taking full advantage of our modern, dynamic and collaborative facilities. Our People Strategy has highlighted key actions that will be put in place to help support staff welfare and wellbeing during and beyond Covid-19. We will put initiatives in place to support positive mental health such as awareness sessions carried out by our mental health first aiders and greater promotion of our employee assistance and counselling programs.	Throughout the year
Ensuring that we retain and recruit the staff we need in order to operate a good quality service and implement our People Strategy for 2020-2024.	We are able to maintain the staff capacity and capability to deliver our strategy and our core statutory duties. People strategy in place, setting out our vision for ensuring we strike the right balance of staff skills, capacity and capability to deliver our strategy and our core statutory duties. Continuing to develop our staff to ensure they have the skills they need through training and other means. We take into account equality and diversity in the design and implementation of our policies, to ensure that these are fair and appropriate for all staff. Skills mapping to enable better oversight of organisational skills mix and deployment of resource. Staff feel valued and motivated to deliver our strategic aims, by taking action on the results of our staff survey. We reflect our values and behaviours in all our work to ensure that quality and service improvement is part of our ongoing way or working.	Throughout the year
A structural review of the HFEA's fee regime, informed by our income forecasting model.	We ensure that we meet the financial needs for effective regulation through a fair and transparent fee structure.	April – December 2022

Modernising fertility regulation: a plan for legislative change

Details about this paper

Area(s) of strategy this paper relates to:	Shaping the future
Meeting:	Authority
Agenda item:	9
Meeting date:	9 February 2022
Author:	Clare Ettinghausen, Director of Strategy and Corporate Affairs
Annexes	Annex 1: 30th anniversary blogs Annex 2: Initial themes for changes to the Act

Output from this paper

For information or decision?	For decision
Recommendation:	To note the activities undertaken in 2021 and planned work on legislative modernisation in 2022
Resource implications:	Resources required from across the organisation to support internal drafting and external activities during 2022
Implementation date:	9 February 2022
Communication(s):	Communications to be ongoing and relevant to specific activities undertaken
Organisational risk:	Low

1. Introduction

1.1. The 30th anniversary of the HFEA in 2021 provided an opportunity to raise questions relating to the future of fertility treatment and research, and the laws surrounding this. We set out to do this in a number of ways as outlined at the Authority meeting in **September 2020**. The events and activities for the 30th anniversary would be used to:

- celebrate the UK's achievements in having an effective regulatory regime
- look to the future of regulation of fertility treatment and research, and
- (build a public conversation about future treatment and regulation.

1.2. This was planned during the Coronavirus pandemic and activities were amended during the year to account for the lack of in person events and the impact of the pandemic on organisational priorities and wider health sector.

1.3. This paper outlines what took place in 2021, key plans for 2022 and how we will engage with key professional (clinical, scientific and legal) and patient groups, licensed clinics and include patient input in our proposals for legislative reform.

2. 30th anniversary of the HFEA

2.1. In 2021, we marked the 30th anniversary of the HFEA by a series of activities outlined below. We also had 30th anniversary branding on social media and presentations. We had originally planned a wider high profile event with the then minister to mark the anniversary and look to the future, but this was curtailed by the pandemic and it was not felt that a virtual event would be a suitable alternative.

Blogs

2.2. A series of **blog** posts from experts were published to mark the 30th anniversary, raising issues of the future of regulation and scientific developments. A list of these is found in Annex 1. Although there have been some publicity and viewings, they have not had the impact we had hoped for, and we may want to re-publicise them in 2022.

Online event

2.3. An online event was held at the end of March 2021 to mark the 30th anniversary with a range of speakers connected with the HFEA reflecting on the last 30 years. This was then published on our **website.**

Modernising the Act

2.4. Throughout 2021, we developed an argument that elements of the HFE Act were now in need of modernisation to keep pace with changes in the fertility market, in science and medical technology, and in social and cultural mores. We focused on three themes: patient protection, scientific development and issues such as consent and data sharing. The then minister, Lord Bethell, agreed that modernisation was needed and the HFEA should work with DHSC towards an agreed way forward. To this end, we are aiming to present the DHSC with a set of proposals by the end of 2022.

2.5. Julia Chain, gave a **speech** at the Progress Educational Trust annual conference in December 2021 outlining key areas of change. There was some press and social media coverage of this and general support at the conference of the need for change. A further **speech** was given by Julia Chain at Fertility 2022 in January of this year.

3. Plans for 2022

3.1. It is important that during the first part of 2022 we develop our thinking on key areas for reform of the HFE Act. As noted above, we have already set out three broad themes where we think reform is most necessary - see Annex 2.

3.2. Looking ahead, we need to build on the initial engagement with professional and patient groups on these broad themes, draft key points in further detail and test ideas over the coming months. The aim of this will be to ensure the current challenges faced by clinics, patients and researchers are considered as part of the development of our proposals.

3.3. We are working on expanding the information found in Annex 2 during the first part of 2022 (subject to pressures from other immediate and time-dependent activities) to provide more detailed assessment of where reform is needed.

3.4. Once we have more details worked up, we will start engagement and consultative activities. As noted above, during 2021 we used opportunities such as stakeholder meetings to note that we were starting to think about law reform and would be developing this further during 2022.

3.5. Formal and informal engagement activities will take place to ensure we present, where possible, a consensus view of changes needed to the DHSC at the end of the year.

3.6. Engagement will be a mix of bespoke events and the use of standing committees such as the Scientific and Clinical Advances Advisory Committee and our stakeholder groups – the Professional Stakeholders Group, the Patient Organisation Stakeholders Group and the Licence Centres' Panel. We will also engage with the Patient Engagement Forum to test ideas directly with patients and via discussions with and surveys of HFEA licensed clinics staff and PRs.

3.7. In addition, we plan to set up a small expert advisory group to gather views and discuss ideas.

3.8. Authority members will be provided with updates on the thematic areas and for input on an ongoing basis. The final proposals will be subject to Authority approval before sending to DHSC.

4. Recommendations

4.1. The Authority is asked to

- note the outline of activities that took place during 2021
- approve plans for developing proposals for reform of the HFE Act during 2022.

Annex 1: 30th anniversary expert blogs published

09/02/21 - The HFEA at 30: where do we go from here?

2021 is the 30th anniversary of the HFEA. In this article Peter Thompson, our Chief Executive looks to the future of fertility treatment.

31/03/21 - The HFEA at 30: Is society ready for the law to change?

Outgoing HFEA Chair Sally Cheshire has her say on what our 30th anniversary means.

22/04/21 - Navigating your way through fertility information

Fertility Network's Kate Brian on the importance of access to good support and accurate information for fertility patients.

31/05/21 - Embryos, genes & regulation: the impact of scientific progress on future reproductive medicine and the HFEA

Andy Greenfield looks at the impact of scientific progress on future reproductive medicine and the HFEA.

08/09/21 - Anonymity for donors until children turn 18 – can this be maintained?

Debbie Kennett discusses whether anonymity for donors until children turn 18 can be maintained

30/09/21 - Future perfect: possible children, science and ethics

David Archard's thoughts on the Warnock Report's discussion about future possible developments in the gene editing of early-stage embryos.

12/11/21 - Harnessing the full power of CRISPR-mediated genome editing

Rebecca Lea and Kathy Niakan discuss the development of CRISPR-based techniques.

26/11/21 - The Sperm Donor's Dilemma

Professor Turi King looks at the sperm donor's dilemma

To be published - the HFEA 30 years on – what needs to change? – Julia Chain

Annex 2: Initial themes of changes to the HFE Act

Patient protection

- The Act is silent on patient centred care
- There is a limited range of enforcement mechanisms or sanctions to drive improvement and current sanctions are blunt or slow
- There are no economic sanctions which have been shown to be an effective driver of improvement in other competitive markets
- The Act assumes a clinician ownership model which largely no longer exists – where does that leave the 'person responsible'
- Work of the CMA welcome but raises questions of what should be within our remit and extent to which patients would be better protected if all aspects of the fertility sector were subject 'end to end' regulation by the HFEA
- The Act overly prescriptive - e.g. requires inspections every two years – which limits the scope to reward good compliance with more streamlined regulation

Scientific developments

- The Act is at risk of being overtaken by research advances
- 14-day rule has proved effective and any replacement would need to offer the same degree of certainty and regulatory clarity
- Process is overly prescriptive e.g. in relation to mitochondrial donation
- There are no means to encourage new technology or other innovation through trials or regulatory experimentation

Consent, data sharing, anonymity

- Consent is overly complicated which creates costs for clinics and increases risk of errors
- Patient and donor confidentiality and disclosure of register data maybe out of step with other areas of healthcare and with new challenges such as DNA testing websites. Is the idea of data confidentiality out of date? Where will this go in another 10 years or more?

Annual Report to Authority on Register Research Panel

Details about this paper

Area(s) of strategy this paper relates to:	The right information
Meeting:	Authority
Agenda item:	10
Meeting date:	9 February 2022
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:	As a result of data migration and PRISM launch: • The RRP was suspended. In March 2022, the decision to suspend the RRP will be reviewed and is likely to recommence • It will not be possible to publish Fertility Trends in 2022 • A COVID report will be published in 2022 looking at unvalidated treatment data from 2020 • The most recent data available throughout 2022 and into Q1 2023 in response to enquiries, FOIs and parliamentary questions will be unvalidated treatment cycles from 2020 and unvalidated outcome data from 2019.
Resource implications:	
Implementation date:	
Communication(s):	
Organisational risk:	Low/Medium/High

1. Introduction

1.1. The HFEA holds a Register of all patients, partners, donors, treatments and children born as a result of these treatments. It is believed to be the largest database of assisted reproduction treatment 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 – see Annexes A and B for further detail.

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. Under Standing Orders, 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 is required to report annually to the Authority (see section 2 below).

1.6. This paper also provides an update on related Register data activity undertaken in 2021. Section 3 summarises the release of anonymised Register data. Section 4 sets out the impact of our new data submission system (PRISM) and the new Register on the work of the Register Research Panel. Lastly, section 5 notes the impact on our annual Fertility Trends report for 2022 and our plans to publish instead a standalone report on the impact that the COVID pandemic has had on fertility treatment.

1.7. In summary, 2021 has been a year of change for data research using the Register, but the launch of PRISM and the new Register should mean that there will be greater opportunities to do more with the data we hold in the longer term, with potential benefits for the efficacy of treatment and patient outcomes.

2. Register Research Panel activity in 2021

2.1. The Register Research Panel is Chaired by a Director and has membership from staff with research, clinical and policy expertise.

2.2. The Register Research Panel met three times in 2021. It reviewed two applications and approved one project. The panel had no project extensions or amendment requests.

2.3. In addition, the panel approved updates to the data release form, data quality assurance form, and data destruction form as part of the wider work to improve the information provided to and received from researchers.

2.4. Additionally, the Research and Intelligence team has been in contact with 14 new researchers to discuss research projects in 2021. These are initial conversations at early stages where some projects will result in formal applications in due course.

2.5. The data released as part of the Register Research Panel is very sensitive and whilst the overall number of projects approved is low, we must uphold high standards of data protection. Work to improve the RRP processes continued and the research officer created a wide range of standard operating procedures and templates to make the processes more robust and to ensure we can support increased demand for our data in future. An external lawyer was also commissioned to create standard authorisation templates and a standard data processing agreement to be used where a third party is involved.

Projects approved

2.6. **Impact of aggregating IVF clinic success by maternal age, Washington University, USA**
The project uses HFEA data to examine whether age brackets used on the HFEA Choose a Fertility Clinic webpage and in clinic inspections influences when clinics transfer embryos in order to influence success rates.

3. Accessing anonymous Register data

3.1. The Register Research Panel is just one of many ways in which Register data is made available. The vast majority of people seeking to access Register data do not wish to access identifiable information. To enable researchers, clinicians and the public to undertake research using Register data, we proactively release as much data as possible through publications and the release of an anonymised Register. We also respond to freedom of information requests (FOIs), enquiries and parliamentary questions (PQs). See Annex B for details of anonymous Register data releases since 2010. Details on the work undertaken to release anonymous Register data can be found below.

3.2. Fertility trends is our annual statistical release and is the main point of reference for all data-related enquiries received throughout the year. It is published as a HTML report each year, with a large set of underlying data tables. **Fertility treatment 2019: trends and figures** was published in May 2021 and was viewed an average of two thousand times each month from May 2021 to December 2021.

3.3. On 23 March 2021 we launched a report and large underlying data set on **Ethnic diversity in fertility treatment**, highlighting how fertility treatment varies by ethnic group. The report covers the differences in access and use of fertility treatment by ethnicity, including IVF birth rates per embryo transferred, multiple birth rates, donation and NHS funding and led to a number of actions to understand this further that are ongoing and reported at each Authority meeting.

3.4. An updated version of the **Anonymised Register** is now available for download from the HFEA website. The Register contains data related to treatments carried out in 2017 and 2018. The data can be used for research without having to apply for approval or bespoke datasets; it also allows researchers to access a large and rich dataset that does not contain any identifiable information. There have been some additions to the dataset since the last publication: ethnicity data for both patient and partner is now available, partner type has been included and banded partner age has been added where available.

3.5. In the 2021 calendar year, the research and intelligence team dealt with 213 data related enquiries in the form of 55 FOIs, 146 enquiries and 12 PQs. These requests often result in the release of bespoke information.

4. Impact of PRISM and new Register on RRP

4.1. Owing to the work undertaken to deliver PRISM and the new Register, there was a backlog in making information available for approved research projects. This has now been cleared and no projects are awaiting data release.

4.2. As a result of data migration from the old to the new Register, the Register Research Panel was suspended in September 2021. We informed potential applicants via email and on our website that we would not be considering any new applications until further notice. In March 2022, the decision to suspend the RRP will be reviewed and is likely to recommence, pending completion of work set out below.

- The team is working with an external lawyer to prepare a decision tree for use in all Register Research Panel meetings, similar to those used by licensing committees. New training will also be delivered to all members of the Register Research Panel and a legal advisor will be available to advise on each meeting if needed.
- Data migration and the launch of PRISM completed in 2021. Work is now ongoing to rebuild the infrastructure to enable reporting (e.g. publications, FOI, PQs) from the new Register. The reporting database will also incorporate commonly requested research variables to enable more resilience in the team in future.
- A decision was taken some years ago to not collect 'reason for infertility' on the new Register. However, this is one of the most commonly requested variables and the RRP has agreed to include this for data up until 27 August 2021 when the old data submission system was closed. This will be linked into new Register from the old Register in the reporting database.

5. Fertility Trends in 2022

5.1. Register data underpins the work of the intelligence team. The launch of PRISM and the new Register requires all the tools that allow access to the Register to be rebuilt. In the short term, this poses challenges, though these are likely to create opportunities for longer term improvements.

5.2. As mentioned in 3.2, Fertility trends is our annual statistical release and is the main point of reference for all data-related enquiries received throughout the year, being viewed almost 3000 times in November 2021, six months after publication.

5.3. The HFEA is named in The Official Statistics Order 2018. It is recommended that data published by government bodies should be classified as official statistics unless there are very good reasons not to do so. It will not be possible to publish Fertility Trends as official statistics or otherwise in 2022 due to the challenges resulting from PRISM in terms of the cutover period from EDI to PRISM and the need to build back a full reporting infrastructure and validation processes.

5.4. However, a COVID report will be published in 2022 looking at unvalidated treatment data from 2020. This report will look at how access to treatment was affected by COVID and how clinics returned to treatment following the shutdown. It will also include qualitative information on patient experience collected in our patient survey.

5.5. Due to data quality issues, the COVID report will not be considered official statistics and will not include any information on outcomes.

5.6. As a result, the most recent data available throughout 2022 and into the first quarter of 2023 in response to enquiries, FOIs and parliamentary questions will be unvalidated treatment cycles for 2020 and unvalidated outcome data for 2019.

Annex A: Publication list - Approved Register Research Panel projects

2021

- Cohort profile: a national, population-based cohort of children born after assisted conception in the UK (1992-2009): methodology and birthweight analysis, Purkayastha M, Roberts SA, Gardiner J, Brison DR, Nelson SM, Lawlor D, Luke B, Sutcliffe A, *BMJ Open*, doi: 10.1136/bmjopen-2021-050931 (07/2021)
- Ethnic variation in the live birth rate and perinatal outcomes following frozen embryo transfer: an analysis of the HFEA database from 2000 to 2016, Sharpe A, Mascarenhas M, Balen A, *Human Fertility*, doi: 10.1080/14647273.2021.1913291 (04/2021)
- Live birth and perinatal outcomes using cryopreserved oocytes: an analysis of the Human Fertilisation and Embryology Authority database from 2000 to 2016 using three clinical models, Mascarenhas M, Mehlawat H, Kirubakaran R, Bhandari H, Choudhary M, *Human Reproduction*, doi: 10.1093/humrep/deaa343 (04/2021)

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, Cameron Natalie, et al. *Human Reproduction,* doi.org/10.1093/humrep/deaa186 (19/9/2020)

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 of which we are aware.

2021

- The predicted probability of live birth in In Vitro Fertilization varies during important stages throughout the treatment: analysis of 114,882 first cycles, La Marca A, Capuzzo M, Donno V, Mignini Renzini M, Giovane CD, D'Amico R, Sunkara SK, *Journal of Gynecology Obstetrics and Human Reproduction*, doi: 10.1016/j.jogoh.2020.101878 (03/2021)
- Analysis of IVF live birth outcomes with and without preimplantation genetic testing for aneuploidy (PGT-A): UK Human Fertilisation and Embryology Authority data collection 2016-2018, Sanders KD, Silvestri G, Gordon T, Griffin DK, *Journal of Assisted Reproduction and Genetics*, doi: 10.1007/s10815-021-02349-0 (12/2021)
- Female causes of infertility are associated with higher risk of preterm birth and low birth weight: analysis of 117 401 singleton live births following IVF, Sunkara SK, Antonisamy B, Redla AC, Kamath MS, *Human Reproduction*, doi: 10.1093/humrep/deaa283 (02/2021)

2020

- Machine learning predicts live-birth occurrence before in-vitro fertilization treatment, Goyal, A., Kuchana, M. & Ayyagari, K.P.R. *Scientific Reports*, doi:10.1038/s41598-020-76928-z (01/05/2020)
- The status of preimplantation genetic testing in the UK and USA. Theobald R, SenGupta S, Harper J, *Human Reproduction*, doi: 10.1093/humrep/deaa034 (04/2020)
- Population implications of cessation of IVF during the COVID-19 pandemic, Smith ADAC, Gromski PS, Rashid KA, Tilling K, Lawlor DA, Nelson SM, *Reproductive BioMedicine Online*, doi: 10.1016/j.rbmo.2020.07.002 (09/2020)
- ICSI does not improve reproductive outcomes in autologous ovarian response cycles with non-male factor subfertility, Supramaniam PR, Granne I, Ohuma EO, Lim LN, McVeigh E, Venkatakrishnan R, Becker CM, Mittal M, *Human Reproduction*, doi: 10.1093/humrep/dez301 (03/2020)
- Observational retrospective study of UK national success, risks and costs for 319,105 IVF/ICSI and 30,669 IUI treatment cycles, Bahadur G, Homburg R, Bosmans JE, Huirne JAF, Hinstridge P, Jayaprakasan K, Racich P, Alam R, Karapanos I, Illahibuccus A, Al-Habib A, Jauniaux E, *BMJ Open*, doi: 10.1136/bmjopen-2019-034566 (03/2020)
- The impact of selected embryo culture conditions on ART treatment cycle outcomes: a UK national study, Castillo CM, Harper J, Roberts SA, O'Neill HC, Johnstone ED, Brison DR, *Human Reproduction Open*, doi: 10.1093/hropen/hoz031 (02/2020)

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)