Human Fertilisation & Embryology Authority

Authority meeting

Date and time: 24 November 2021- 12.45pm to 4.30pm

Venue: ETC.venues 50-52 Chancery Lane, WC2A 1HL

Agenda items	Time
1. Welcome, apologies and declarations of interest	12.45pm
2. Minutes of the meeting held 23 September 2021 and matters arising **For decision**	12.50pm
3. Chair and Chief Executive's report **For information**	1.00pm
4. Committee Chairs' report **For information**	1.15pm
5. Performance report **For information**	1.30pm
6. Covid update **Verbal update - for information**	2.00pm
7. State of the sector **Verbal update - for information**	2.10pm
Break	2.30pm
8. 2022-23 financial update **For decision**	2.45pm
9. Opening The Register annual report and future proposal for the service **For decision**	3.05pm
10. Treatment add-ons rating system review – an update **For discussion**	3.35pm
11. Transparency and Publication – next steps **For discussion**	4.00pm
12. Any other business	4.25pm
13. Close	4.30pm

Minutes of Authority meeting 23 September 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	24 November 2021		
Author	Debbie Okutubo, Governance Manager		
Output:			
For information or decision?	For decision		
Recommendation	Members are asked to confirm the minutes of the Authority meeting held on 23 September 2021		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☒ Low	☐ Medium	☐ High
Annexes			

Minutes of the Authority meeting on 23 September 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 Emma Cave Ruth Wilde Jason Kasraie Anne Lampe
Apologies	None	
Observers	Csenge Gal (Department of Health and Social Care - DHSC)	Steve Pugh- DHSC Amy Parsons - DHSC
Staff in attendance	Peter Thompson Clare Ettinghausen Rachel Cutting Paula Robinson Debbie Okutubo	Richard Sydee Amanda Evans

Members

There were 14 members at the meeting – ten lay members and four professional members.

1. Welcome and declarations of interest

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

2.1. Members agreed that the minutes of the meeting held on 7 July 2021 were an accurate record and could be signed by the Chair.

3. Chair and Chief Executive's report

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

3.2. The Chair stated that she would be carrying out more informal visits to licensed centres across the UK.

3.3. The Chair noted that Lord Bethell had moved on as our minister and we were waiting to find out who would have the HFEA portfolio within the new ministerial team.

3.4. The Chair also commented on the government's plans to extend the time that frozen eggs, sperm and embryos could be stored to 55 years, which would bring the law in line with advances in science, changes to modern society and individual reproductive choices. The HFEA were supportive of these changes.

3.5. The Chief Executive commented that he continued to support the Chair and took part in a number of external facing activities.

3.6. The Chief Executive provided an update on our new data submission system PRISM. It was noted that as agreed with Audit and Governance Committee (AGC), the old data submission system EDI was switched off on Friday 27 August. A detailed cutover exercise was undertaken and was tested both internally and with selected clinics.

3.7. PRISM was launched on 14 September. As at 22 September, 29 clinics had logged into PRISM and conducted 2,184 units of activity, including adding new registrations, cycles, movements and amending legacy data.

3.8. Initial clinic feedback has been generally good and we were responding to clinic queries quickly.

3.9. Members were advised that PRISM was currently only available to those clinics that submitted data directly to the HFEA through EDI.

3.10. The next stage of the rollout was to ensure that the majority of licenced clinics that used a third party electronic patient record system (EPRS) could link automatically to PRISM. There are four current EPRS suppliers who needed to migrate to PRISM.

3.11. It was noted that Mellowood (IDEAS system) were the largest supplier with 40 clinics and that the expectation was for them to start deployment in October and complete by November.

3.12. Members were informed that the expectation was for all EPRS suppliers to have completed deployment by 10 December 2021 - 3 months after go-live.

3.13. The General Direction that sets out the rules governing data submission had been relaxed until that date.

3.14. The Chair thanked the AGC, the Chief Executive and the teams both past and present that had worked so hard to achieve the launch of PRISM.

3.15. Members commended the launch of PRISM and asked how long it would take before the system was working perfectly. The Chief Executive responded that a plan was being put in place but the expectation was that the links between the new Register and PRISM and most other HFEA systems should be in place by the end of this business year.

Decision

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

4. Committee reports

Statutory Approvals Committee (SAC)

4.1. The SAC Chair (Margaret Gilmore) presented this item to the Authority. It was noted that a number of PGT-M applications and Mitochondrial donation applications were granted in July and August when the Committee met.

4.2. An additional meeting was held in August to manage additional applications for Special Directions that would otherwise have been delayed. There was currently a higher number of Special Direction applications, possibly because of Covid-19 travel restrictions.

4.3. The SAC Chair noted that this was Emma Cave's last meeting and thanked her for her work and her inspiring contribution to the Committee to date.

Licence Committee (LC)

4.4. The LC Chair (Jonathan Herring) commented that two meetings had been held and both had to deal with complex issues.

Decision

4.5. 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 presented. Staff turnover was at 16% (just outside tolerance) but this was expected as Covid-19 restrictions were lifted and the public sector jobs market reopened.

5.2. It was also noted that we were getting fewer applicants to advertised positions compared to previous 12 months. It was not clear why this was the case but one likely factor was the civil service pay freeze. This would be kept on the agenda of the Senior Management Team (SMT).

5.3. The return to the new office meant that there have been discussions with staff about how we plan to use the office going forward.

5.4. Members asked if there was any scope to think creatively when it comes to salary increases, for instance flexibility around additional annual leave or training incentives. The Chief Executive responded that there was limited flexibility, but that we would continue to explore what was possible within the rules.

5.5. In response to a question about staff finding it worthwhile returning to the office, the Chief Executive commented that there was a discussion at the Corporate Management Group (CMG) about how often some meetings should be held in person, for instance team meetings. Guidance was being drawn up and we wanted to ensure that there was consistency across teams. This would remain an ongoing discussion in CMG.

Strategy and corporate affairs

5.6. The Director of Strategy and Corporate Affairs gave a summary of her area of work.

5.7. Members were advised that a new national patient survey would take place later this year. This would follow up on the first patient survey that the HFEA had undertaken in 2018. The follow up survey would enable some benchmarking against the earlier survey and importantly, help us to explore some of the issues that resulted from the Ethnic Diversity in Fertility treatment report from earlier in 2021.

5.8. The Patient Engagement Forum was launched with a soft target of 100 patients to enable greater patient involvement in our work. There had been over 160 applications, but we may need to do further work to ensure underrepresented groups were involved.

5.9. A formal in-person event for the 30th anniversary of the HFEA would not be held during 2021 because of the impact of Covid, but we would continue with our guest blogs on potential changes to legislation and the Chair would have two opportunities to set out the case for reform of the HFE Act later this year.

5.10. Members were advised that we would work with the DHSC as and when legislation to change the storage limits for eggs, sperm and embryos was introduced. This was likely to impact on other planned work as we will need to prioritise work of storage to ensure we give timely and effective guidance to clinics and patients.

5.11. In reporting back on the actions in the Ethnic Diversity in Fertility Treatment report, it was noted that progress was being made in a number of areas, for example, in understanding more about patient experience through the patient survey and follow up work with the new patient engagement forum; in working with some volunteers from clinics to look at the issues from the clinic perspective. We presented the findings of the report to the Royal College of Obstetrics and Gynaecology (RCOG) Race Equality Taskforce together with `Dr Raj Mathur, Chair of the British Fertility Society; the Chief Executive also spoke at the Primary Care Women's Health Forum annual conference to highlight our findings.

5.12. Following the launch of PRISM and some staff changes, a decision had been made to pause new applications to the Register Research Panel until we were able to access the data in the new Register. We would continue to support researchers interested in applying in future and would work to provide data to projects that had already been approved. The anonymised register had recently been updated on our website which would also be useful to researchers until we are able to provide data sets again next year.

5.13. In response to a question about the patient survey it was noted that we would not be using an external company and that the survey would be done in-house as we have the required tools. The survey would be publicised through social media and existing stakeholders.

5.14. The Chair commented that it was good to see patients wanting to engage with us through the patient engagement forum.

Compliance and information

5.15. The Director of Compliance and Information presented her area of work. She stated that one of the red indicators on the performance scorecard related to an increase in register errors. In the lead up to PRISM go live there was an increase in the submission of forms in preparation for EDI being switched off. In this period seven clinics had increased errors in the way they were registering patients. The Head of Information investigated this further and staffing issues seem to be a contributing factor to the increase in errors in the individual clinics. The Head of Information has worked with the individual clinics to correct the errors and ensure future errors are reduced. It was noted that PRISM flags errors up immediately on the users' home screen making it easier for centres to deal with errors immediately.

5.16. Regarding recruitments, the Chief Technical Officer position had not attracted suitable applicants. The interim plan therefore was for our Systems Manager to become the interim Head of IT. The vacant systems manager post is currently being advertised. This interim solution allows time to determine the IT needs of the organisation and put in place a workable structure in the future.

5.17. As previously reported, following suspension of the Opening the Register (OTR) service due to the Covid-19 pandemic there had been an increase in the number of applications, which led to substantial waiting times for applicants to receive information. To help reduce waiting times, two new staff members had been recruited on fixed term contracts until March 2022. Training is ongoing and from next month we should start seeing a decrease in the waiting list. Longer term, we intend to look at the service as a whole in preparation for 2023, which would include the application process and IT system.

5.18. The Chair remarked that the challenge in 2023 would be considerable and asked that the OTR service be a regular feature in reports to the Authority, especially in light of the backlog.

5.19. A Member commented that the OTR service was important and so was turnover of staff, but the end-to-end inspection and licensing process also had a red indicator and reasons for the delay needed to be explored.

5.20. The Chief Executive responded that we would be looking at the key performance indicators (KPIs) generally and we would bear this in mind.

Finance and Resources

5.21. The Director of Finance and Resources informed members that there was an underspend in some areas of the business. This was however still an interim position as we were yet to reach the full year forecast.

5.22. Members were advised that there was higher than planned activity and should the current trend in treatment activity continue, we could expect to exceed our income forecast by around 4%.

Decision

5.23. Members noted the performance reports.

6. Covid update

6.1. The Director of Compliance and Information presented this item to the Authority.

6.2. It was noted that there were no reported treatment delays relating to Covid-19 restrictions in licensed centres. However, in the referral pathways there were reported delays possibly due to delays in patients accessing surgery in secondary care prior to referral for fertility treatment.

6.3. Regarding the shortage of blood tubes, guidance has been issued by NHS England which states that diagnostic blood tests for fertility patients in primary care should be delayed in patients under the age of 35 where there is no known cause of infertility. There have been no issues reported from licenced centres.

6.4. To ease any potential blood tube shortages we have issued a communication to the sector that with regard to viral screening bloods, centres are allowed to risk assess individual patients if the initial treatment commenced after the 3 month window for screening. This would prevent repeat blood tests having to be taken.

6.5. Members asked about the shortage of carbon dioxide (CO2) and the possible impact on clinics and patient care. The Director of Compliance and Information responded that a major supplier had, in correspondence to the Chief Inspector, stated that CO2 was being prioritised for health care purposes. We presume that this is not an issue for the fertility sector as we have not received any communications from the sector on this; however, we would continue to keep this on our radar.

Decision

6.6. Members noted the Covid-19 update.

7. Developing the new approach to Inspection

7.1. The Director of Compliance and Information presented this item. Members were reminded that in response to the Covid-19 pandemic, inspections were suspended between March and November 2020. During that time the inspections methodology was updated and introduced post November 2020.

7.2. To assess the robustness of the process, the new inspection methodology was audited by our internal auditors, the Government Internal Audit Agency (GIAA). They gave our updated approach to inspections a 'substantial' rating (the highest available) and recommended that we should conduct a retrospective evaluation exercise with both internal and external users and conduct in time an assessment of cost savings.

7.3. Members congratulated the team on the 'substantial' rating and asked if the recommendations from the GIAA report could be adapted as a lessons learned tool across other business areas. The Chief Executive agreed to look into this.

7.4. Members also asked if Inspectors had shown any reluctance in attending onsite visits and whether all centres would now be visited within the 2 year legal requirement period.

7.5. The Director of Compliance and Information responded that we currently have the ability to extend licences by a year and have taken a risk-based approach. The majority of clinics would have an inspection within two years. In terms of workload, it was noted that it was being shared evenly and we had two new inspectors who were doing well with their training. We could also now use external inspectors should the need arise.

7.6. In response to a question, it was noted that unannounced inspections would be reintroduced when we were on the other side of the pandemic. At present, we are using the new methodology for the renewal inspections and would consider how this could be incorporated into interim inspections in time.

7.7. Members asked if persons responsible (PRs) were engaging in a timely manner. The Director of Compliance and Information responded that majority of PRs were, and that there was a system in place to chase twice and then a full inspection takes place if we still did not get a response.

7.8. Regarding patient feedback, Members asked how patient feedback could be gained by inspectors. The Director of Compliance and Information responded that we continue to encourage more feedback from patients and the compliance and communications team were working on this.

Decision

7.9. Members endorsed the recommendations and noted that there was continued use of the desk based analysis (DBA) and further refined inspection methodology. Also, that the GIAA actions had been completed.

8. Licence fee proposals 2022/23

8.1. The Director of Finance and Resources presented this item to the Authority. Members were advised that we had not increased our licence fees since 2016 and that we had been able to meet our statutory duties through internal savings and the growth in the number of IVF cycles undertaken each year. It was reiterated that the HFEA did not charge fees to patients.

8.2. Members were, however, advised that we were facing a number of additional demands this financial year which would require additional resources and that those demands were likely to continue.

8.3. The proposal was to increase the licence fee for an IVF cycle by £5. It was noted that the argument for any fee increase was complicated because presently there was higher treatment activity in clinics which should this become the trend, would generate additional funds similar to what could be realised through the proposed £5 fee increase.

8.4. Members were reminded that the HFEA continued to hold significant cash reserves and that government accounting rules prevented us from accessing these reserves without the approval of the DHSC.

8.5. Members asked how the current rate of £80 per IVF cycle treatment was arrived at.

8.6. The Director of Finance and Resources commented that like other regulators we were required by HM Treasury to recover the cost of regulation from the people we regulate. Under the current fee regime, the more treatments carried out by clinics the higher the fees income we receive. This reflected the increased cost of regulation.

8.7. Members commented that some clinics may choose to pass on any increase in fees to patients and asked what benefits could patients expect in return. Also, should it be the case that the increased revenue led to extra cash reserves which we would not be able to spend without permission, then it might not be worth raising fees.

8.8. The Director of Finance and Resources responded that the rules that govern public sector finance mean that we can only spend what is in our budget and that the licence fee meant that we were duty bound to spend it on patients.

8.9. The Chief Executive commented that in the longer term we would need to make a structural change to the fee regime.

8.10. Members commented that they agreed that we need more resources, however some thought that the rationale presented in the annex for the £5 increase needed more detailed work in light of the volatility of the operating income.

8.11. Members commented that the SMT should ask the DHSC for permission to gain access to our reserves and if the response remained no, we could then say to patients that we tried our best to avoid a fee increase but government rules did not allow for this.

8.12. Members suggested that there should be a breakdown on how the money was used.

8.13. Some members also commented that an increase of £5 seemed to be reasonable and appropriate and that we should therefore opt for a dual approach asking the DHSC and HM Treasury either to increase our revenue to cover our increasing costs, or to gain access to the reserves for the same purpose.

8.14. Members asked if we could spread the increase gradually over a three-year period rather than the increase of £5 all at once.

8.15. The Director of Finance and Resources commented that we would go back and ask to gain access to the reserves but in the past when we had asked, the answer had always been no.

8.16. The Chair commented that we needed more resources and that we were a good regulator and wanted the flexibility that the extra funds would give us. Therefore, if we did not get permission to use our reserves, a modest increase to our fees would be proportionate, so a dual approach was our best way forward.

Decision

8.17. Members agreed that a dual approach should be explored with the DHSC and HM Treasury.

8.18. The Director of Finance and Resource confirmed that the proposals would be worked up and brought back to the November Authority meeting.

9. Multiple births

9.1. The Director of Strategy and Corporate Affairs and the Research Manager presented this item.

9.2. Members were advised that the combined efforts of the HFEA and the sector had led to a significant reduction in the multiple birth rate in the UK. This had been achieved through the successful implementation of the multiple birth rate policy, beginning with the 'One at a Time' campaign to change the practice of multiple embryo transfer to a single embryo transfer where possible.

9.3. Most clinics had reached the 10% multiple birth rate target whilst maintaining or increasing their live birth rate.

9.4. Members were reminded that multiple births remained a health risk for patients and babies and the reduction in multiple births from IVF should be viewed a public policy success not only in limiting the risk to patients and babies, but also in potential savings to the NHS.

9.5. The current target of 10% had been in place since 2012 and was achieved for the first time in 2017. Since then, the national average had fallen further, to just 6% in 2019.

9.6. Members were informed that the continued decline in the multiple birth rate had not had a negative effect on the birth rate which continued to increase.

9.7. Looking below the national average, it was noted that in 2019 the 38-42 years age group had the highest proportion of multiple births. Between 2014-18, black patients experienced higher than average multiple births as they had the highest rate of multiple embryo transfer (46% of cycles) over that period.

9.8. One of the professional members commented that in the general population, naturally conceived multiple births (1%) had a higher chance of being non-identical, whereas IVF multiple births tended

to be identical. Only 0.3-0.4% of all naturally conceived births were identical, which is a larger differential.

9.9. A member suggested that younger private patients were unlikely to have had a number of previous NHS funded cycles and this might be why they would be more likely to have more than one embryo transferred. Though not presented, this data had also been considered and had a similar pattern.

9.10. Members were informed that HFEA inspectors actively engaged with clinics who had non-compliances with multiple births, but we were limited in our powers to force compliance. In 2011, the HFEA introduced a licence condition on multiple births, which was later withdrawn following legal challenge.

9.11. Nonetheless, it remained a requirement for clinics to have a multiple births minimisation strategy through General Direction 0003 and guidance in our Code of Practice (December 2019). We would therefore continue to target clinics that were not adhering to their own minimisation strategy.

9.12. It was suggested that as there was geographical diversity in funding for fertility treatment, we ought to look at areas where there is little to no NHS funding and whether higher rates of multiple embryo transfers were occurring in those areas.

9.13. Members commented that no one size fitted all, and that we needed to avoid being too prescriptive. Clinics that were outliers would need to be looked at.

9.14. Following further discussion on the reported four clinics that were outliers, members suggested that they be asked why this was the case.

9.15. In terms of international comparisons, it was noted that countries like Japan had a lower multiple birth rate. Some members commented that while we needed to be mindful of what was happening in the world, we also should remember that the culture in each country was different.

9.16. Some members felt that continuing with the 10% target was reasonable in order not to risk patients' success rates.

9.17. The Chair commented that the discussion should be opened with stakeholders and clinics regarding the 10% target and that this be kept under review. Also, to ensure that we do not become complacent, work should be done with looking at the outcomes of fresh and frozen embryo transfers as we still do not know the tipping point.

9.18. This also meant that the General Directions and Code of Practice guidance and consideration of other regulatory levels would continue to be looked at and kept under review.

9.19. Some members suggested that the discussion regarding the review of the 10% target with stakeholders and clinics should be time limited and further suggested that we should publish a version of the data we hold to focus that discussion.

9.20. The Chair stated that this item should be brought back to a future Authority meeting.

9.21. Members commented that the disparity especially in black patients could be because they tended to start fertility treatment later which might explain why they tend to have multiple embryo transfers. This therefore needed to be borne in mind during discussions.

9.22. It was noted that we it may not be appropriate to have different multiple birth strategies for different ethnic groups but clinics should be mindful of the data we have presented on a higher multiple birth rate in Black patients when reviewing their multiple birth strategies.

9.23. The Chair thanked everyone involved in the Intelligence team in analysing and presenting the data.

Decision

9.24. Members agreed

- to maintain the 10% multiple births target for now and continue to monitor on inspection;
- to encourage clinics to be mindful of their multiple birth minimisation strategy in relation to patients from ethnic groups;
- a report should be published outlining the data presented to the Authority to stimulate further discussion and following that;
- discussions should be opened over time with key stakeholders, patients and clinics, with the aim of considering a future review of the 10%.
- that the four clinics that were outliers, should be asked why this was the case.

10. Treatment add-ons next steps

10.1. The Director of Strategy and Corporate Affairs presented this item. It was explained that we currently employed a traffic light rating system consisting of red, amber and green that indicated whether the evidence showed that a treatment add-on was effective at improving the chances of having a baby for most fertility patients. Members were informed that patients had access to clear information on the HFEA website, enabling them to better understand the evidence and risks and potential benefits for each treatment add-on. Also, that information on each treatment add-on was framed with a reminder that for most patients, routine IVF remained an effective treatment.

10.2. The evidence that informs these traffic light ratings is reviewed on an annual basis by the Scientific and Clinical Advances Advisory Committee (SCAAC).

10.3. Members were informed that it was now proposed to carry out further policy work and consultation with experts, the sector and patients/public on how best to evolve the rating system for our treatment add-ons information. Members commented that the review of the rating system would be welcome if it makes information clearer for patients.

10.4. A member noted their view that we should not have any green treatment add-ons on our list as they should form part of routine treatment.

10.5. The Authority were also asked to agree to consider broadening the range of data that the HFEA consider when assigning ratings to treatment add-ons. There were a variety of views expressed. Some members raised concerns about broadening the range of data beyond randomised controlled trials (RCTs) as this was the ‘gold standard’ of evidence of effectiveness and it could discourage the sector from carrying out RCTs. Other members noted that patients were willing to take risks and wanted to be informed and make their own judgments and therefore a wider evidence base may help patients make informed choices.

10.6. Some members felt that the ratings for treatment add-ons needed to evolve and that there should be more differentiation than: red, amber, green. Members were asked if there could, for example, be degrees of amber rated add-ons.

10.7. In response to a comment, it was noted that although treatment add-ons with a red rating may not cause physical harm, they could still cause financial harm.

10.8. It was noted that the HFEA's website information on treatment add-ons may not be helpful when clinics offer patients a 'cocktail' of treatment add-ons as a package.

10.9. It was noted that in only using RCTs and the evidence of impact on live births, may not reflect the full range of decisions some patients face.

10.10. The Chair summarised the discussion: Members agreed that the rating system should be reviewed to see if it should be altered in any way, ensuring that patients remained the primary audience for any future system; Members also agreed that SCAAC should review the evidence base it considered as part of their add-ons review.

Decision

10.11. Members agreed the proposal to evolve the presentation of the rating system for treatment add-ons and to consider broadening the range of data that the HFEA consider when assigning ratings to treatment add-ons.

10.12. Members agreed for these issues to be brought back to a future Authority meeting.

11. Any other business

11.1. The Chief Executive advised members that the business plan was in draft and would go through various iterations before it was brought to an Authority's future meeting.

11.2. A member suggested that actions with dates should form an action tracker for the Authority meeting and should be reviewed at each meeting.

11.3. The Chair commented that this was Emma Cave's last meeting and thanked her for time, contribution and for being such a splendid Authority member. Other members and staff echoed this.

11.4. Professor Emma Cave thanked everyone for their kind words and the privilege of working as a member of the HFEA Authority.

Chair's signature

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

Signature

Chair: Julia Chain

Date: 24 November 2021

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	2		
Meeting date	24 November 2021		
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	2021/22 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 early 2022
Matters Arising from the Authority meeting – actions from 23 September 2021			
5.18 Backlog on OTR	Director of Compliance and Information	Nov 21	Staff are gaining competence and there is a significant increase in the amount of OTRs being processed. In November up to the 8th 20 requests have been signed off and 90 are now ready to be signed off.
8.17 Permission to gain access to our reserves	Director of Finance and Resources	July 22	
9.15 Discussion to be held with multiple birth outliers	Director of Compliance and Information	September 22	To be raised at inspection.
9.21 Multiple birth target	Director of Strategy and Corporate Affairs	September 24	More likely to be Sept 2024.

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:	24 November 2021
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 September 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:

- 27 September – introductory meeting with Geeta Nargund at CREATE Fertility
- 6 October – participated in DHSC led public appointments panel shortlisting potential applicants to the HFEA Board
- 11 October – observed the Scientific Clinical Advances and Advisory Committee
- 13 October – visited Wales Fertility Institute to meet Paul Knaggs and his team
- 21 October – visited Manchester Fertility Services to meet Debbie Falconer and her team
- 3 November – participated in Media Training
- 12 November – chaired HFEA Appointments Committee
- 15 – 18 November – participated in DHSC led public appointments panel interviews for potential applicants to the HFEA Board
- 23 November – introductory conversation (with Peter) with Simon Burrall at Sciencewise

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

- 5 October – attended the Audit & Governance Committee meeting
- 11 October – attended the Scientific Clinical Advances & Advisory Committee
- 12 October – spoke at staff induction day for new HFEA staff
- 13 October – participated in UKRI/Nuffield Council on Bioethics roundtable on Bioethics in the UK
- 3 November – participated in Media Training and later that day participated in Women's health roundtable event on assisted reproduction

- 23 November – introductory conversation (with Julia) with Simon Burrall at Sciencewise

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:	24 November 2021
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

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

2. Recent committee items considered

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

Meetings held	Items considered	Outcomes
Licence Committee:		
11 November 2021	2 Renewals 1 Executive Update	Minutes not yet finalised Minutes not yet finalised
Other comments:	Annual Review of Committee Effectiveness undertaken on 11 November 2021	
Executive Licensing Panel:		
21 September 2021	1 Extension of Licence 1 PTT (testing for tissue typing)	All granted
6 October 2021	2 Renewals 1 Interim 1 Extension of Licence 1 Change of Person Responsible	All granted
19 October 2021	1 Renewal 2 Special Directions	All granted
2 November 2021	4 Renewals 1 Extension of Licence	All
16 November 2021	3 Renewals 1 Interim 1 Extension of Licence 1 Change of Person Responsible	Minutes not yet finalised Minutes not yet finalised Minutes not yet finalised Minutes not yet finalised
Other comments:	None.	
Licensing Officer decisions:		
N/A	ITE certificates – 48 Change of Licence Holder – 1	All granted
Other comments:	The number of ITE certificates seems to be slowing down. We will continue to monitor this.	

Meetings held	Items considered	Outcomes
Statutory Approvals Committee:		
26 August 2021	6 PGT-M Applications 2 Special Direction Applications	1 adjourned and 5 granted 1 refused and 1 granted
4 October 2021	2 Mitochondrial Donations Applications 3 PGT-M Applications 2 Special Direction Applications	2 granted 3 granted 2 granted
28 October 2021	4 PGT-M Applications 2 Special Direction Applications	Minutes not yet finalised Minutes not yet finalised
Other comments:	Annual Review of Committee Effectiveness undertaken on the 28 October 2021	
Audit and Governance Committee:		
5 October 2021	Internal audit progress against recommendations Digital programme update (PRISM) Reserves policy Resilience and business continuity (interim structure of IT team) Counter Fraud Assessment feedback	N/A Agreed
Other comments:	Annual Review of Committee Effectiveness undertaken on the 5 October 2021	
Scientific and Clinical Advances Advisory Committee:		
11 October 2021	• Monitoring the effects of COVID on fertility, assisted conception and early pregnancy. • SCAAC Governance update. • Annual review of traffic light rating for treatment add-ons. New RCTs identified for six treatment add-ons, assessed by independent reviewer.	• No changes to the HFEA's guidance on COVID-19 were recommended. • Endometrial Receptivity Array (ERA) – red rating. • Immunological tests and treatments – split into separate red ratings. • No recommended changes for any other add-on traffic light ratings. • Executive to make updates to add-ons webpage.

Meetings held	Items considered	Outcomes
	• Evolving the treatment add-ons information update. • Expert speaker – new technologies in embryo testing including PGT-M and PGT-A.	• Comments from the Committee were noted.

Other comments: Previous Chair Yacoub Khalaf handed over to Tim Child as incoming Chair of the Committee.

3. Recommendation

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:	24/11/2021
Author:	Paula Robinson, Head of Planning and Governance
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 and upon the changes to the content of the 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 and including September 2021

1.2. Performance was reviewed by SMT on 1 November.

2. Key trends

2.1. In August and September performance was generally good. There were two red indicators in August and three in September.

Red indicators - September

2.2. The indicators classed as red were as follows:

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

Red indicators - August

2.3. The indicators classed as red were as follows:

- **C1 Efficiency of end to end inspection and licensing process**
- **C3 PGT-M average processing time**

2.4. 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. As reported to the last Authority meeting, discussions are ongoing to enable us to horizon-scan the future likely volumes and complexity of PGT-M items. This will enable us better to plan for the future and to ensure we continue to be able to manage the volume of items through the Statutory Approvals Committee.

3.2. Since the last meeting, we have set some new tracking indicators for Opening the Register requests, to enable us to monitor our progress in reducing the backlog of requests. We will report this data from October data onwards.

3.3. The Authority has previously asked us to review the end-to-end licensing process indicator (C1). It makes sense to do this now, since a number of things have changed since the last time we considered this indicator.

3.4. The current target is 70 working days. For the majority of centres in a standard inspection year this can be met. However, it is important to note that some inspections will inevitably be more complex and lead to management reviews or post inspection correspondence between the inspector and PR which may result in the report being delayed. This can be explained in the narrative as an acceptable reason for a breach.

3.5. A KPI should be achievable but should not necessarily be defined differently just to ensure it is green all the time. However, special consideration should be given in the current post pandemic situation and it may be appropriate to extend the number of working days. (This KPI is currently undergoing an in depth review).

3.6. Before March 2020 (2019-2020 financial year) 8.25 inspections were conducted on average per month. Inspections were then suspended between March 2020 and November 2020 and to ensure centres did not have a gap in their licence, some licences were extended to five years. One hundred inspections had originally been planned in 2020-2021, with 39 being conducted from November 2020 to March 2021. The centres not inspected at that time now need their inspections to be rescheduled within the current inspection schedule, leading to an increased number of inspections being conducted by inspectors - for 2021-2022, we currently have 122 inspections planned, equating to a monthly average of 10.16. This may increase with further additional inspections due to new centres applying for a licence or visits after an incident.

3.7. Further to this increase in workload, changes to the inspection process have been made in the last 12 months including the introduction of the DBA hybrid inspection model and a new compliance and enforcement policy.

3.8. These two large and fundamental changes have taken a while to embed into practice. The new compliance and enforcement policy drives consistency and robustness but does involve more post-inspection review meetings. During the pandemic the inspection team have not been able to use external inspectors which has also lead to an increase in workload for individual HFEA inspectors. We anticipate using external inspectors again from Spring next year.

3.9. Exacerbating the problem over the last 12 months is that training and sign-off of newly recruited inspectors to replace experienced inspectors who have left the organisation has taken longer due to the pandemic, since the ability to gain field experience was restricted due to the inability to perform on site visits. This was impacted further by a whole time equivalent inspector being on maternity leave.

3.10. In light of this, until inspection numbers return to pre pandemic levels it is proposed that either the KPI is extended or there is acceptance that breaches will be inevitable until pre-pandemic scheduling is resumed. Whilst the KPI is currently considered appropriate in terms of measuring the process in working days the KPI will be looked at in depth by the Chief Inspector to determine whether in the future this is the best way to indicate the efficiency of the overall licensing process.

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 on line.

4.2. Performance is good. Although it is not possible to directly compare current performance with old figures we see an error rate in PRISM of approx. 1.8% since launch. This compares with a very steady level of 5-6% in the old system. We think it likely that the error rate in PRISM should be higher now than its future baseline as staff become more familiar with it and bugs get fixed.

4.3. Conversations have started about new performance metrics in the new system and how to measure them.

Annex 1 HFEA Performance scorecard and management commentary – September data

Breakdown of total Red, Amber, Green and Neutral Indicators

Figure 1 – Three red indicators this month.

RAG	Area	Trend and key data
Amber – just above target	**People -** Employee turnover Target: between 5%-15%	17.6% 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	67% within target. Average of 59 wds (items beginning with an inspection)
No target – slightly higher than last month	**Engagement -** HFEA website sessions	65,651 sessions (61,766 in same month last year)

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

Type	Actual in YTD £'000s	Budget YTD £'000s	Variance Actual vs Budget £'000s	Forecast for 2021/2022 £'000s	Budget for 2021/2022 £'000s	Variance Budget vs Forecast £'000s
Income	**3,722**	**3,556**	**(166)**	**7,339**	**7,048**	**(291)**
Expenditure	**(3,162)**	**(3,519)**	**357**	**7,024**	**7,043**	**19**
Total Surplus/(Deficit)	**560**	**37**	**523**	**315**	**5**	**310**

Commentary on financial performance to end September

Year to date we have a surplus against budget of £523k. This is largely due to the increase in our income year to date (£166k) and underspends on our budgeted depreciation costs. Our expenditure is under budget (£357k) as explained in the detailed commentary.

The forecast position is currently a surplus against budget of £315k before taking account of non-cash costs. Excluding our depreciation (non-cash) expenditure, we are forecasting a small deficit against budget of £25k. A further review of both our income and costs will be conducted at the end of Q3 and when it is expected that PRISM will be embedded.

Management commentary

In September performance was generally good. There were 3 red indicators.

Our turnover was at 17.6% in August and September, rated amber. There were two leavers in each month (one of which had reached the end of a fixed term contract).

Sickness rates were also on amber in August, at 2.3%, and had worsened to 3.9% in September. Covid has been a contributory factor in our higher sickness rates.

In September, our PGT-M processing time was also rated amber, owing to some unavoidable processing delays (for example needing extra advice from a peer reviewer before the item could be prepared for the Statutory Approvals Committee). In August the same measure was rated red, but this related to a single complex item – explained in the commentary on red indicators below.

Our debt collection was affected by annual leave in the Finance team in September (achieving 80% within 40 days, compared to our target of 85%). We expect this to improve to normal levels in the October data.

Red indicators - September:

- **HR1 Sickness – 3.9%**

  Sickness levels were unusually high for the HFEA, due to a number of different factors affecting individuals' health. We do not think this is likely to become a trend. Two employees were on long term sick leave during September (and one has now returned).

- **C1 Efficiency of end to end inspection and licensing process – 67%**

  The efficiency of the end-to-end licensing process has been affected by a number of complex inspections, which have required additional interventions such as management meetings and requests for further information. These were necessary regulatory actions, and so the lengthening of the process does not reflect a performance issue. In addition, one licence renewal was delayed by eight days, awaiting the payment of the licence renewal fee by the clinic. One licence extension took 93 days to complete, due to the complexity of the report.

  The desk-based assessment process has taken some time to bed in, and is a more labour-intensive process. This has been a learning curve for staff, and we have had new inspectors joining the team, and one going on maternity leave.

  We are looking at this measure now, as outlined above, and plan to review it again in spring 2022, when the team will be at full strength.

- **II1 Time taken to close internal incidents – 83 average wd**

  The time taken to close internal incidents was high because there was only one incident, and we chose to keep this open for longer so that we could fully understand the issues involved. This required some time from a contractor who was also needed for PRISM delivery. All the actions needed to remedy the incident were undertaken quickly, but we refrained from closing the incident until we had a full understanding and could complete the final actions. In August, this measure was rated amber, for a similar reason – again there was one item, and it took 34 days to close.

Red indicators - August

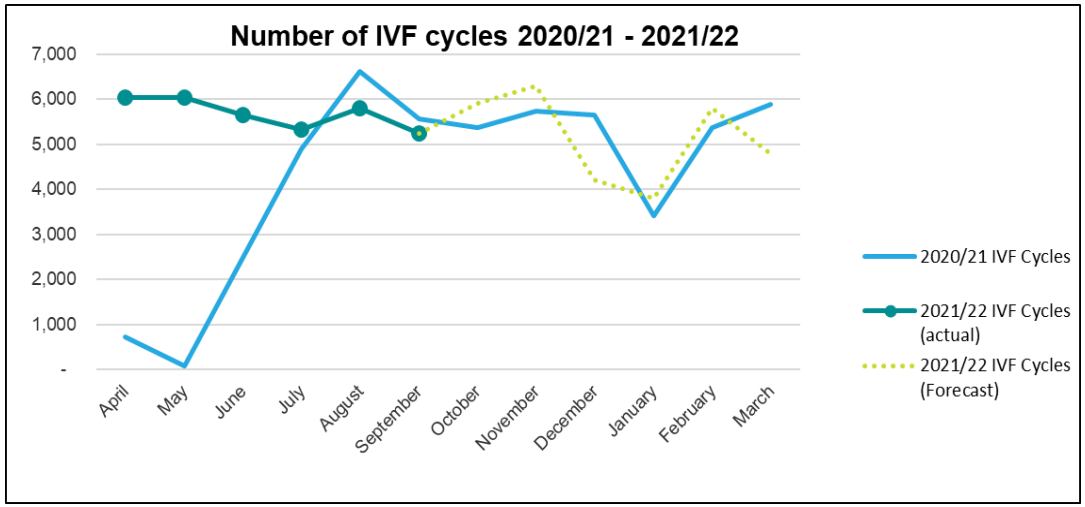
- **C1 Efficiency of end to end inspection and licensing process – 60%**

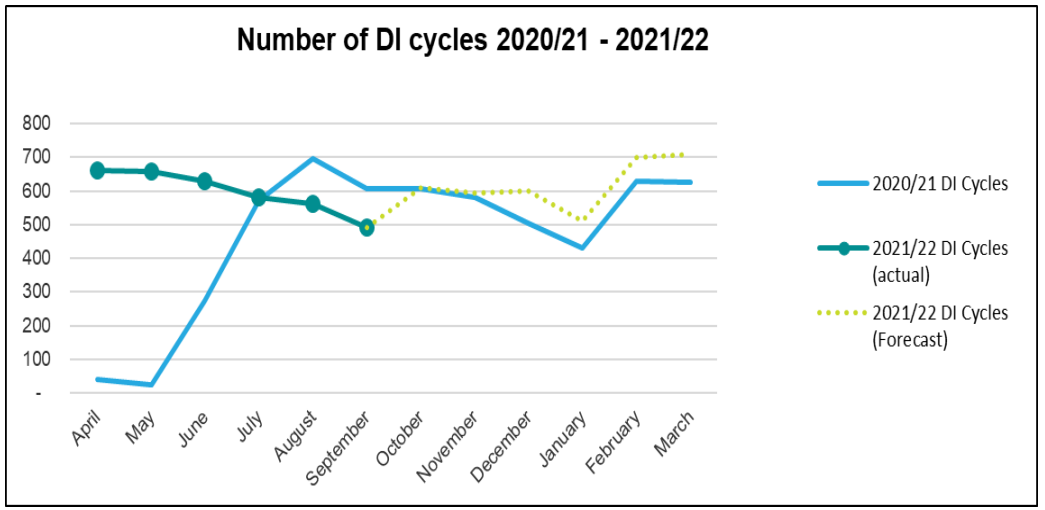
  Two items missed the KPI target in August. One of these missed the KPI narrowly, but the other item (a licence extension) took 142 days to complete, because necessary documents were not provided to the team in a timely manner.

- **C3 PGT-M average processing time – 0%**

  There was only one application in the system at that time, but it was complex to process and both the peer reviewer and the Genetics Alliance required additional time to produce their material. This also meant that the item needed to be re-scheduled to a later Statutory Approvals Committee meeting. The item took 93 working days to fully process, compared to our KPI target of 75 working days.

Annex 2 Financial management information





IVF Cycles	YTD		YE Position	
	Volume	£	Volume	£
2020/21 IVF Cycles	20,381	1,630,480	51,795	4,143,600
2021/22 IVF Cycles (actual)	34,073	2,725,813	64,465	5,157,173
Variance	13,692	1,095,333	12,670	1,013,573

DI Cycles	YTD		YE / Forecast	
	Volume	£	Volume	£
2020/21 DI Cycles	2,217	83,138	5,598	209,925
2021/22 DI Cycles	3,583	134,363	7,305	273,938
Variance	1,366	51,225	1,707	64,013

Although IVF volumes are lower when compared against September 2020/21 levels (by 5.8% or 323 cycles) the YTD position has exceeded the budget by 4.7%. If the activity levels remain constant we would expect to achieve a year end forecast position of c £5.2m.

With the switch over to PRISM not all clinics will be able to submit data on activity over the next quarter. Estimated bills, based on historic activity, will be provided in the interim and a reconciliation undertaken once submission resumes.

Similarly to the position reported for IVF activity, DI volumes are down against the same period last year (by 18.8% or 114 cycles) but are 22% above budget position for the cumulative year to date. This slight drop may also be a result of the cessation of data submission as we transitioned to PRISM, reducing reported activity.

HFEA Income & Expenditure Sep-21

	Year to Date				Full Year		
	Actual £'000	Budget £'000	Variance £'000	Variance YTD %	Forecast £'000	Budget £'000	Variance £'000
Income							
Grant-in-aid	490	550	60	0	1,098	1,098	-
Non-cash (Ring-fenced RDEL)	258	258	0	0	516	516	-
Grant-in-aid - PCSPS contribution	50	50	-	-	100	100	-
Licence Fees	2,873	2,622	(250)	-10%	5,479	5,188	292
Interest received	0	1	2	2	1	2	(1)
Seconded and other income	51	73	22	30	145	145	-
Total Income	3,722	3,556	(166)	**(5)**	**7,339**	**7,048**	**291**
Revenue Costs							
Salaries (excluding Authority)	2,360	2,305	(55)	(2)	4,749	4,447	(302)
Staff Travel & Subsistence	22	36	14	39	47	73	26
Other Staff Costs	42	56	14	25	129	111	(18)
Authority & Other Committees costs	110	121	10	8	269	234	(36)
Facilities Costs incl non-cash	245	396	152	38	657	954	298
IT Costs	207	321	114	35	606	642	35
Legal / Professional Fees	110	177	67	38	326	339	13
Other Costs	68	108	40	37	243	244	1
Other Project Costs	(1)	-	1	-	(1)	-	1
Total Revenue Costs	**3,162**	**3,519**	**357**	**10**	**7,024**	**7,043**	**18**
TOTAL Surplus / (Deficit)	**559**	**37**	**523**		**315**	**5**	**310**
Adjusted for non-cash income/costs	**402**	**(46)**	**449**		**25**	**5**	**20**

Management commentary

Income.
At the end of quarter two our income total income is 3% (£94k) higher than budget. Our licence fees are 10% higher than budget. September is the first month that clinics are being issued with invoices whose value is based on 2019/20 activity volumes whilst PRISM is embedded. The shortfall within seconded income is due one secondee who is maternity leave and therefore their costs have reduced.

Expenditure by exception.
Year to date we are under budget by £357k.

Salary costs - are over budget £55k which is due to additional costs of contract staff relating to completion of PRISM and post go-live.

Staff Travel & Subsistence and Other Staff costs - are under budget by £14k respectively. This relates to the change in our inspection regime where less site visits have been conducted.

Authority & Other Committee costs - the underspend here relates to the Members' travel and subsistence and Training (£29k) which are offset by overspends within Appeals Administration, Venue hire (£16k) and Non Authority Committee costs of £3k which are mainly advisor fees.

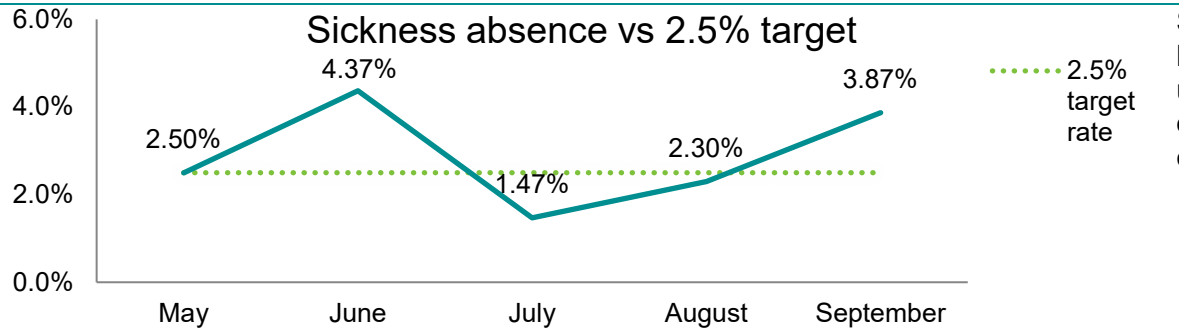
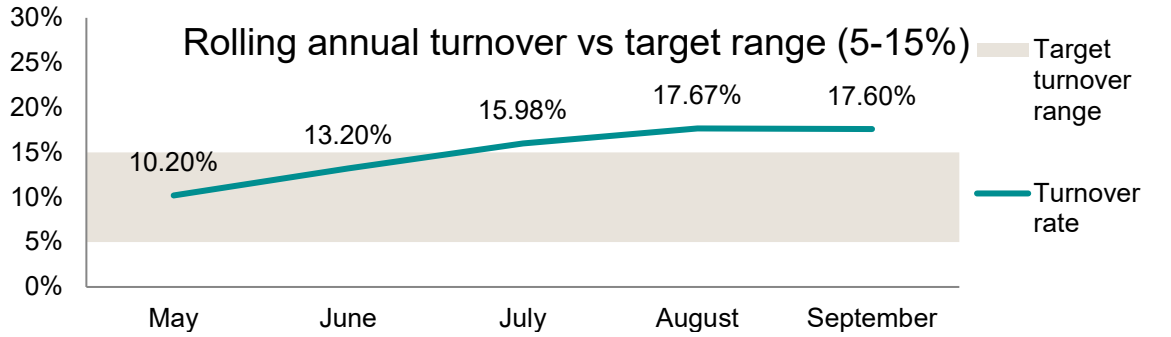
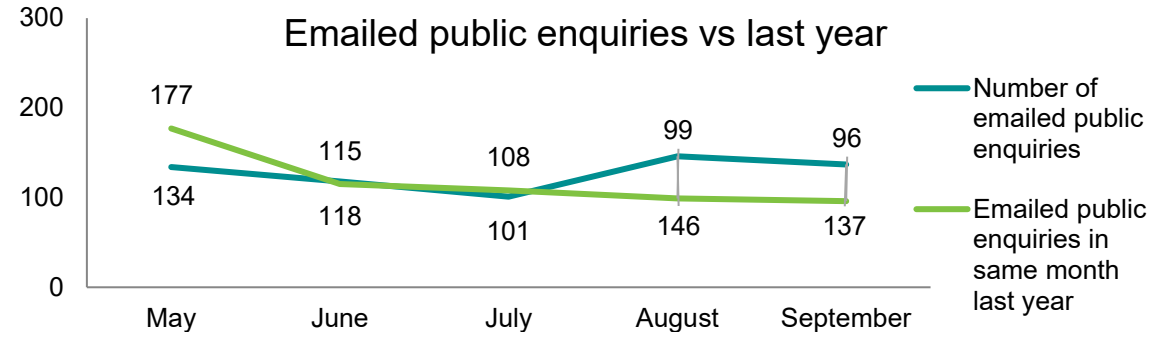
Facilities costs - underspent by £152k the majority (£58k) relates to our accommodation costs for 2 Redman Place. We have yet to be billed by DHSC for these costs. The budget was based on provisional costs provided by DHSC. In addition we have an underspend (£76k) within our non-cash costs. The majority of the underspend relates an asset that has come to the end of its useful life,.

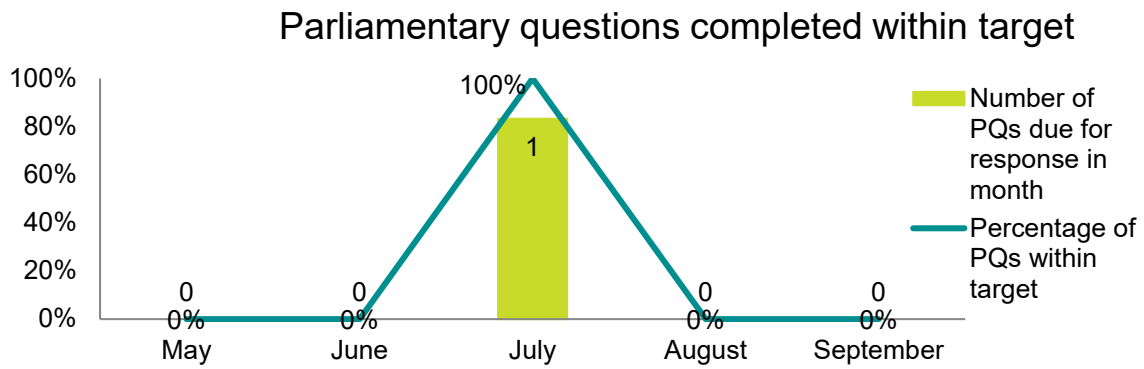
IT Costs - underspent by £114k**. T**he main underspends are within our Support costs £60k and IT Subscriptions £55k. The reduction in spend against IT Support costs is due to reduced usage of Alscient and within IT Subscriptions is due to the contract being renegotiated.

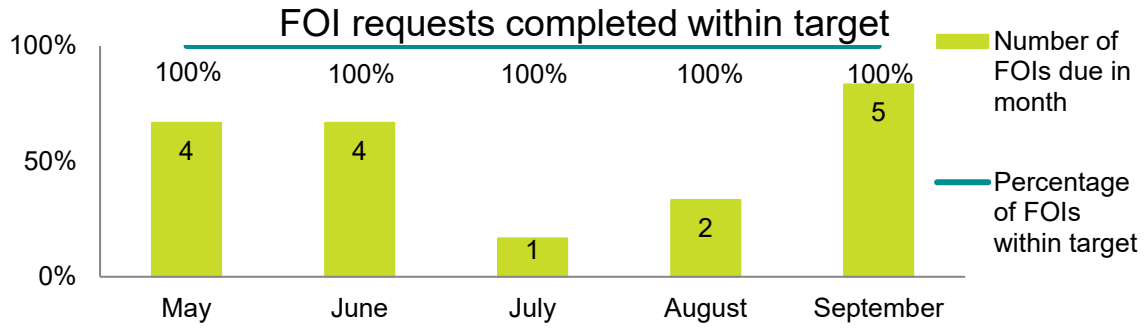
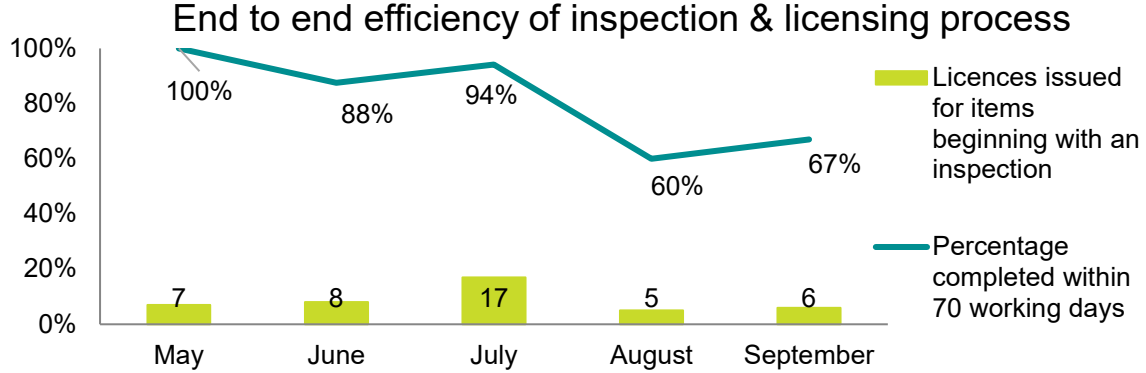
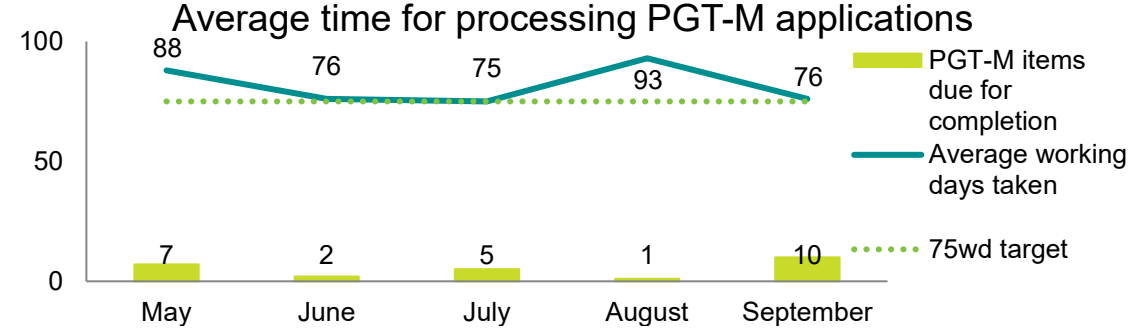
Legal/Professional fee - are under budget by £67k. This is represented by an underspend within Legal of £47k which includes a contingency of £20k.

Forecast.
Post our Q2 review with the directorates, we are forecasting a surplus against budget of £310k, this includes a surplus in our non-cash costs (income and costs relating to the depreciation of our fixed assets). Stripping these costs out, our forecast for the year is a small surplus against budget of £20k. A further review of costs and income will be conducted at the end of Q3.

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 rates have been higher than usual for a number of reasons – see earlier commentary.	Red
HR2 - Turnover **Target**: between 5 and 15% turnover for the rolling year.		67 - Headcount 68 - Establishment (posts) We had two leavers in September, although one was end of FTC.	Amber
Supplementary data - Public enquiries No target.		-	No target

Key performance indicator name and description	Graph showing performance trend for last 5 months	Commentary (if any)	RAG rating
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.**	Graph discontinued pending a new set of throughput monitoring indicators, to be reported from October onwards. We received 53 complete OTR requests in September. • 15 parent • 15 donor-conceived • 23 donor Additionally, we received 6 incomplete OTR requests where we had to contact the applicant to ask them to provide further ID or proof of address. These applications will not be counted as complete until the date all documents are received, but have had application forms saved and have been logged, which takes resource. The overall position is improving (85 are currently ready for final check, to be released). We received 5 Donor Sibling Link applications and processed 7. There were 3 sibling matches.	We're not currently reporting against a target. This measure will be replaced shortly. A detailed paper on the annual review of OTR appears elsewhere on the Authority's agenda.	Neutral
RI1 – PQs responded to within deadline set (Based on deadlines agreed with DHSC) **Target:** 100% within deadlines set.		-	Neutral

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 13 enquiries received in September.	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 – 59. Most days taken: 93 working days Least days taken: 27 working days	Red
C3 – Average PGT-M processing **Target:** average processing time of 75 working days. Average number of working days taken for those due in month.		Most days taken: 83 working days Least days taken: 66 working days	Amber

2022/23 Budget proposal

Details about this paper

Area(s) of strategy this paper relates to:	Whole Strategy
Meeting:	Authority
Agenda item:	8
Meeting date:	24 November 2021
Author:	Richard Sydee, Director of Resources
Annexes	N/a

Output from this paper

For information or decision?	For decision
Recommendation:	That members agree proposals to increase the HFEA's expenditure budget for 2022/23 and an increase in the HFEA licence fee of £5 to £85 per treatment cycle from 1 April 2022
Resource implications:	N/a
Implementation date:	N/a
Communication(s):	Subject to final HM Treasury sign off Licensed Centres will be advised of this in December 2021
Organisational risk:	High

1. Introduction

1.1. Following a paper on proposals for an increase in the HFEA's 2022/23 expenditure, and funding, at its September meeting the Executive were tasked with discussing options for additional funding for the 2022/23 financial year with DHSC and HMT, bringing a more detailed paper on budget plans to the November Authority meeting.

2. Background, resource pressures, budget, and income assumptions

2.1. The HFEA raises most of its operating income via license fees charged to licensed treatment and research establishments. Approximately 80% of the HFEA's income is raised this way, with the remainder provided through Grant in Aid (GIA) from the Department of Health and Social Care (DHSC) and other income such as from staff seconded to other organisations.

2.2. The HFEA has not increased its licence fee since April 2016 and has, until this point, been able to meet increases to its cost base through internal savings and the growth in number of IVF cycles undertaken each year.

2.3. As indicated in the September paper the HFEA faces a number of additional demands this year and these will continue to increase from the next (2022/23) financial year, these include:

- Opening the Register (OTR) – both increase in current demand and preparation for the change in the law in 2005 that removed donor anonymity which we anticipated will increase demand further from 2023
- Use of data – the requirement to "up our game" in relation to the data we provide to researchers, other regulatory stakeholders and share with the public as well as how we better use our data to inform and provide regulatory oversight and intervention
- Information technology – linked to the above but focussed on the need to increase IT support to existing and new systems
- In addition to BAU support additional funds are also required to enable much needed upgrades to, or migration from, legacy technology tools and systems.

2.4. We have taken an increase to both our IT staff and OTR staff at risk for the remainder of this financial year by prioritising recruitment as vacancies arise, and utilising a combination of savings released from our relocation out of Central London in November 2020 and temporary reductions in travel and accommodation costs related to Covid 19 restrictions to site visits and meetings.

2.5. To fully realise the Authority's ambitions for the next strategic period we will need to fully fund these additional in year posts and further increases to our headcount. As requested in the September meeting Annex A sets out the planned expenditure budget for 2022/23 and income forecast based on current licence fees and activity volumes and also the impact of revised activity assumptions and a fee increase.

2.6. Additional expenditure, primarily on staff costs but with some minor increases in IT service provision, is £518k higher than our 2021/22 budget. Without an increase in either licence fee volumes or the fee itself this would lead to shortfall of £432k.

2.7. Our income planning assumption assumes 2% growth in activity, which provides c £100k increase in income, although not guaranteed this is consistent with the activity increase in the first half of this financial year. An increase in the IVF licence fee of £5 (6.25%), to £85, would raise a further £320k in licence fee income and provide a balanced budget.

2.8. As ever our budget contains assumptions around staff turnover and other activity driven costs that may vary, these are the levers we use to managed slight fluctuations in our assumed licence fee volumes.

3. Consultation with DHSC and HMT

3.1. Section 35A of the HFE Act 1990 establishes that any increase in licence fee proposed by the Authority would need the agreement of DHSC and HM Treasury. As agreed with Authority we have held initial discussions with DHSC sponsor and finance teams regarding our 2022/23 pressures and the options to either access reserves or increase fees to fund the budget shortfall outlined in the September paper.

3.2. As previously advised Government finance rules preclude the HFEA planning for a deficit position in 2022/23, and both HFEA and DHSC finance teams have concluded that this would be an untenable position from which to proceed.

3.3. DHSC colleagues have discussed, in principle, proposals to increase HFEA licence fees with HMT. Although a formal submission is yet to be made (this would follow the Authority's approval of a fee increase) we understand that a fee increase of the kind proposed would be likely to be acceptable.

4. Future budgets and fees

4.1. This work has highlighted the shift in the drivers of our regulatory cost, although we do not anticipate continued year on year growth akin to this proposed budget increase, we recognise that some pressures relating to IT costs and OTR will likely continue to require additional investment in future years.

4.2. It is also clear that the focus of future regulatory change, and the likely increase in the HFEA's role as an information provider**,** requires us to consider whether the current IVF and DI licence fee model recovers the cost of regulation from the drivers of our cost base. It is important we review our fee model to ensure equitable full cost recovery of regulatory costs.

4.3. We propose to review our fee recovery model during 2022 and bring any identified proposals for change to the Authority for consideration.

5. For discussion

5.1. Members are asked to:

- Agree the proposed HFEA operating budget for 2022/23
- Agree the proposal for a £5 (6.25%) increase in the IVF licence fee from 1 April 2022
- Agree that, subject to final DHSC and HMT approval, this fee increase will be communicated to licenced centres as soon as is practicable, ideally during December 2021
- That the HFEA will proceed with work in 2022 to review the current model for fee recovery and consider whether changes are required

Draft 2022/23 Budget

	Current Fee and Activity		Increased fee and Actvity	
Budgeted Income	**£**		**£**	
Licence Fees - Activity	5,397,613		5,831,965	
Licence Fees - Renewal	16,125		16,125	
Licence Fees - Storage	900		900	
Licence Fees - Research	7,125		7,125	
EUTD Fees	11,500		11,500	
Interest Received	1,300		1,300	
Miscellaneouse Income	145,193		145,193	
DHSC Funding				
Grant in Aid	938,000		938,000	
Ring-fenced RDEL	515,777		515,777	
Pension funding	100,000		100,000	
		7,133,533		**7,567,885**
Budgeted expenditure				
Wages and salaries	4,635,264			
Other Staff costs	296,900			
Authority & Committee costs	240,866			
IT Costs & Development	894,354			
Legal Costs	215,000			
Other costs	349,760			
Accommodation	418,174			
Non-cash	515,777			
		7,566,096		**7,566,096**
Net Income		**- 432,563**		**1,790**
2021/22 Planned budget		**7,048,000**		

Opening The Register annual report and future proposal for the service

Strategic delivery:	☒ The best care	☒ The right information	☒ Shaping the future
Details:			
Meeting	Authority		
Agenda item	9		
Meeting date	24 November 2021		
Author	Danya Harris, Donor Information Manager Neil McComb, Head of Information		
Output:			
For information or decision?	For information		
Recommendation	The Authority is asked to note: • the update on OTR activity and performance; • the supportive way in which OTRs are handled by the team; • the level of applications in 2019, 2020 (before and after re-opening the service) and in 2021 • the planning underway to address the current increased demand and prepare for the potential further increase in applications expected in 2023 following donor anonymity changes in 2005		
Resource implications	Investment required for both IT systems and staffing resource.		
Implementation date	OTR service ongoing		
Communication(s)	OTR service on website		
Organisational risk	☐ Low	☐ Medium	☒ High

1. Introduction

1.1. For some years now, we have provided the Authority with an annual report on the number and type of donor information requests (known as Opening the Register (OTR)) and associated counselling support. This paper updates the position to cover activity in 2019, 2020 and 2021 to date.

1.2. OTR activity increased significantly after the service re-opened in October 2020. This paper includes an overview of the increase along with steps taken so far to manage the backlog created by the temporary closure during the COVID-19 pandemic.

1.3. Looking ahead, we can expect a further increase in OTR applications from late 2023 onwards when the impact of the change in the law in 2006 on donor anonymity takes effect. It is, however, extremely difficult to accurately predict the increase in OTR volume we can expect, but the total number of donor conceived people who are able to submit an OTR will increase by between 100-200 most months between 2024-2028. A project is underway which aims to implement an efficient operational service model which addresses both the current increased demand on the service since reopening in October 2020 and future demand in late 2023.

1.4. This project's goal is to streamline the service in preparation for the predicted increase in applications in late 2023 and to deal with the current backlog of applications. Areas of work we will be considering for the improved service include looking at internal staffing redesign and resourcing, policy development, a defined legal framework, and implementing a new, more efficient IT system. This project will not fundamentally alter how the service operates or the overarching principles of how the service is delivered.

2. Background

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

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

- 16-year-old donor-conceived people can find out:
  - if they are donor-conceived
  - non-identifying information about their donor
  - the number, sex and year of birth of any donor-conceived genetic siblings
  - if their donor has removed their anonymity (since 2005)
  - if they might be related to an intended spouse or partner
- 18-year-old donor-conceived people can find out:
  - identifying information about their donor (if the donor is identifiable)
  - identifying information about their donor-conceived genetic siblings, if both sides consent (via Donor Sibling Link (DSL))

- Donors can:
  - find out the number, sex and year of birth of any children conceived from their donation
  - remove their anonymity - which is relevant to those who donated before the law changed on 1 April 2005

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

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

2.4. As noted above, applications by donor-conceived people, donors and parents for Register information are known as Opening the Register (or OTR). The HFEA has had a process in place for dealing with OTR applications by parents and donors since 2005, and donor-conceived people since 2007 (when the first cohort of donor-conceived people on our Register turned 16).

3. Performance

3.1. The OTR service is provided by a small, dedicated in-house team of four staff. Since 2019 applicants apply online using a secure platform called DocuSign. In order to be sure of the applicants' identity we require proof of identity and address and we retain a copy of their documents for 5 years to enable applicants who wish to re-apply for updated information at a later date to do so with more ease.

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

3.3. The table below shows the trend in applications since 2012. The figures for 2019 show a 70% increase in the number handled compared to 2018 when the last update was given to Authority. Applications from all groups grew in 2019, due to the increased ease in applying for information online using DocuSign, with donor-conceived and donor applications rising the most. Anecdotal information also suggests that there has been an increase in applicants who have used direct-to-consumer DNA testing websites with the aim of understanding genetic backgrounds.

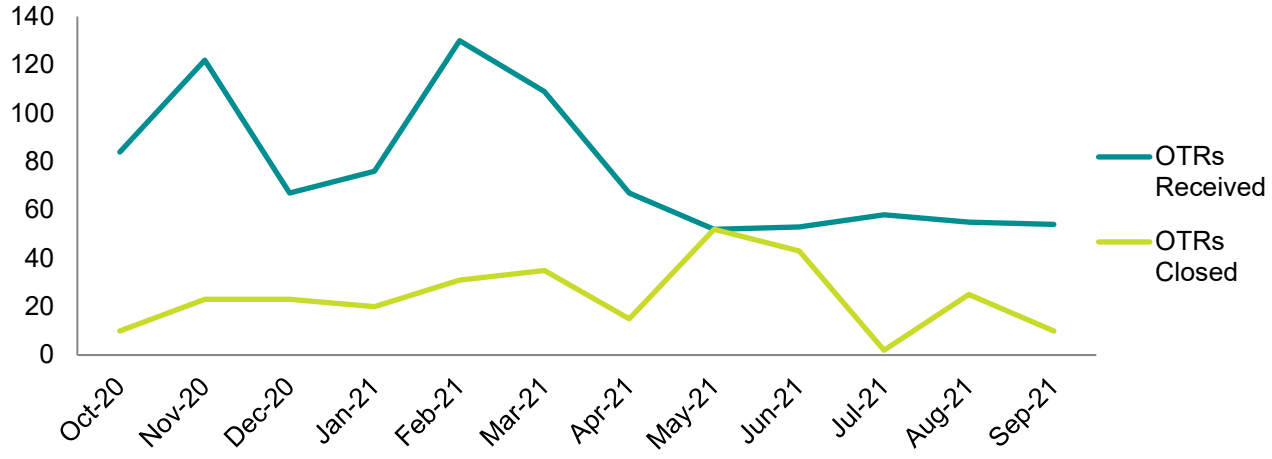
Number of applications responded to within 20 working days

	2012	2013	2014	2015	2016	2017	2018	2019	2020
Parents	103	111	119	159	112	94	106	128	61
Donors	66	76	101	82	100	62	127	158	65
Donor-conceived	14	28	36	36	45	78	75	152	65
Joint applications	0	1	0	0	0	1	1	0	0
Pre-1991	3	1	4	1	6	1	1	2	4
Total	186	217	260	278	263	236	310	438	191

3.4. The lower number of applications responded to in 2020 reflects the fact that the OTR service was paused in April that year (Authority decision of 21 April) because of the impact of Covid-19 on staff in both the HFEA and clinics (which made it impossible to check and verify data). At that point there were 38 open OTRs, all of which were dealt with over the summer. The figures above only run until April as was agreed with Authority that when the service reopened in October 2020 we would not report against a target while we dealt with pent-up demand.

3.5. When the OTR service reopened we received an unprecedentedly high number of applications, which was beyond the capacity of the small team to process to our usual timescales. From this point we recorded the number of applications received and closed each month, which are set out in below.

Applications received and closed: October 2020-September 2021



3.6. There are currently 648 applicants on the waiting list, and they have all been given an approximate waiting time and donor-conceived applicants have been made more aware of support available to them. The current waiting time for applications submitted is kept up to date on the website and we have received very few complaints. There is an approximate wait of 6-8 months for applications submitted now.

3.7. Although applicants are waiting longer than normal for their information, the service has not compromised on the accuracy of the information provided to applicants, and a high level of customer care has been maintained despite these pressures.

3.8. Steps have been taken to address the backlog, including recruiting two new members of staff to work to a four-person structure which doubles the number of applications the team can process. Because the complexity involved in processing OTR applications it takes some time to train new members of staff, nonetheless we expect to see significant impacts on the backlog by Qrt4 of 2021/22.

3.9. As of the end of September 2021**, 385** donor-conceived people had joined Donor Sibling Link, our voluntary contact register where people join to make contact with their donor-conceived genetic siblings. The evidence suggests that this service is becoming more popular: **74** registrants joined in **2019,** compared to the **29** who joined in **2018**. In **2020 59** registrants joined DSL in the six months the service was open, and **11** matches were made. In **2021** so far **64** registrants have joined DSL with **9** matches being made so far. In each case, support and intermediary assistance is offered. More details can be found in the Annex.

3.10. Those wishing to join DSL need to have donor-conceived half-siblings, and to have had their donor and sibling information verified (if possible) before they join DSL. Therefore, they or their parent need to have done an OTR first. More details can be found in the Annex.

3.11. In **2018** around **a quarter** of donor-conceived individuals who received donor and sibling information joined DSL, and in **2019** this went up to **almost half.** This may have been due to the ease of joining online through DocuSign rather than by post. In **2020 91%** of those who had done an OTR that year joined DSL during the 6 months of the year DSL was open. In **2021** so far **83%** of donor-conceived individuals who have received a response to their application have joined, However, most who have submitted an OTR in 2021 have not yet received the response to their application yet so are not yet eligible to join. More details can be found in the Annex.

3.12. As of the end of September **2021, 221** applications from donors wishing to remove their anonymity were received. These donors donated after the HFEA was set up and before the change in law in April 2005 whereby all donors would be identifiable to their donor-conceived offspring once they turned 18 years old.

3.13. When the children conceived after the change in law turn 18 in late 2023, the increased publicity created around donation may prompt interest from such anonymous donors to remove their anonymity. We will be taking this into account when planning for the future.

3.14. We have so far received **7** applications from donors to remove their anonymity in **2021**. Additionally, there are **2** donors who are waiting to receive information on the outcome of their donation before having removal of anonymity form processed, and **25** donors who are waiting for information who have expressed an interest in finding out more about removing their anonymity. Recent numbers of donors removing their anonymity and a breakdown of egg and sperm donor figures can be seen in the Annex.

3.15. The first application for identifying information to be released to an adult donor-conceived child was received in **2013**. In total, we have received **26** applications of this kind, with three in 2020, and four applications received in 2021**. 23** applicants have proceeded with receiving the identifying information, with the remainder deciding not to proceed with their application. Of these **2** applicants have not requested it, and another **1** requested it but then cancelled the request as she was already in contact with her donor via a direct-to-consumer DNA testing and matching website. In each case, support and intermediary assistance was offered where desired to the donor and donor-conceived person involved.

4. Recent updates to the OTR service

4.1. We have made a number of improvements to the OTR service over the last two years. As noted above, applicants now apply online as a default using DocuSign, a safe online electronic portal for applicants to complete the application and upload supporting identity information securely.

4.2. From October 2020, donors wishing to re-register as identifiable now use an electronic donor-registration process which enabled donors to remove their anonymity while remote working was in place. A full privacy impact assessment was conducted ahead of its implementation.

4.3. As also noted above, we have temporarily increased the number of staff from two to four to address the backlog. In time, this will double our capacity to process applications. The process of OTRs is detailed and time-consuming and involves checking that the information about all the instances in which the donor was used with the fertility clinic that registered the donor. As a consequence, all applications are processed by two members of staff to reduce the chance of error.

5. The future of the OTR service

5.1. As noted above, the first cohort of adult donor-conceived people whose donors donated after the change in law regarding donor anonymity turn 18 in 2023. A project is underway to update and refine our donor information service; ensuring we can provide the best possible service to donors, donor-conceived people, and their parents.

5.2. The project aims to implement an efficient operational service model which addresses both the current increased demand on the service since reopening in October 2020 and future demand in 2023. An improved, streamlined process will be put in place, ready to meet these service demands.

5.3. Areas of work we will be considering for the improved service include looking at internal staffing redesign and resourcing, policy development, a defined legal framework, and implementing a new, more efficient IT system. The early stages of scoping the current OTR process and identifying areas for improvement has already taken place and we have received legal advice on a number of issues.

5.4. In thinking about the demands on the service from late 2023 onwards, it is important to note that the task we have to carry out will not change (processing applications, checking the Register etc), rather the challenge is meeting the expected increase in applicants. We have already performed a demand and capacity review analysing the entire cohort of donor-conceived people becoming eligible to apply for identifying donor information in late 2023 and the impact on the service of different rates of application. This has shown the importance of retaining the current team of four at a minimum. Going forward, we will need to regularly review required staffing levels in the light of demand.

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

6. Support and intermediary service

6.1. In March 2014, as part of its commitment to providing improvements to the levels of support offered to people affected by donation, the Authority agreed a three-year 'pilot' service to provide enhanced support services at a national level. The contract to do so was awarded to PAC-UK in 2015, an adoption support agency with relevant expertise and suitably qualified staff.

6.2. The contract was retendered in April 2019 and was awarded to Hewitt Fertility Centre as part of the contract to run the Donor Conceived Register. The Hewitt Centre is a long established HFEA licensed centre providing services to NHS and private patients with relevant expertise and suitably qualified staff. The contract is for 3 years and runs until March 2022.

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

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

6.4. For the duration of the service provided by the Hewitt Centre, 67 referrals were made to the support service. A breakdown of the referrals can be found in the Annex.

6.5. An intermediary 'post box' service has been set up for the purposes of anonymous communication prior to exchanging identifying information. This enables donor-conceived individuals to send messages back and forth with their identifiable donor (once they have applied to the HFEA for their identifying information) or donor-conceived half-sibling in the case of DSL matches without disclosing their contact details or identifying information. They can then to go on to meet their donor or sibling remotely, as facilitated by the support service (with a presence from an intermediary optional) using the NHS "Attend Anywhere" service.

3 pairs of referrals to the intermediary service were made in 2021.

6.6. As noted above, the contract for this service is due to end in March 2022. If a decision is made to continue with the support and intermediary service then it is likely that extra funding will be required, on the assumption that an increase in OTR numbers will inevitably lead to an increase wishing to access support services.

6.7. Counselling provision is not in the current OTR project and will be reviewed when we review the above contract.

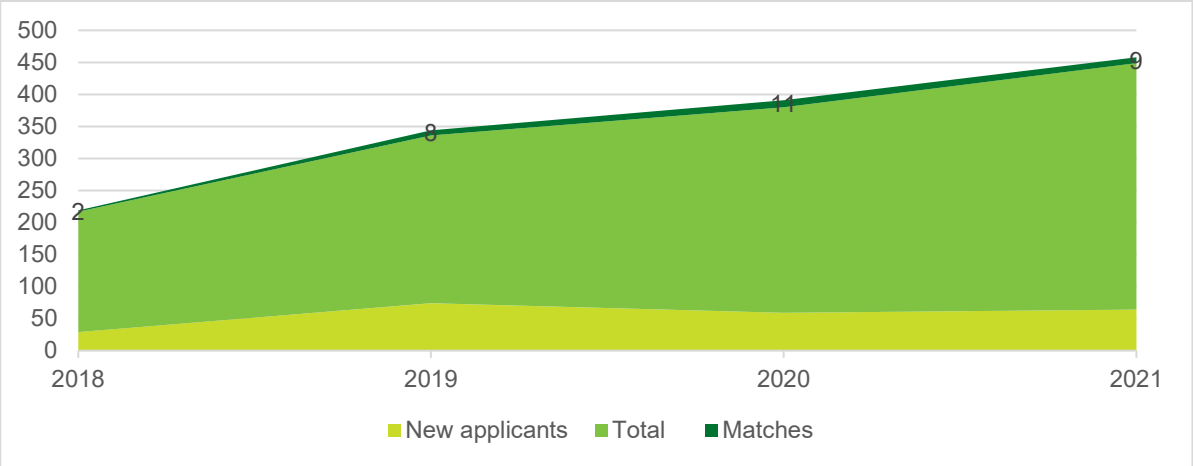
7. Recommendations

7.1. The Authority is asked to note:

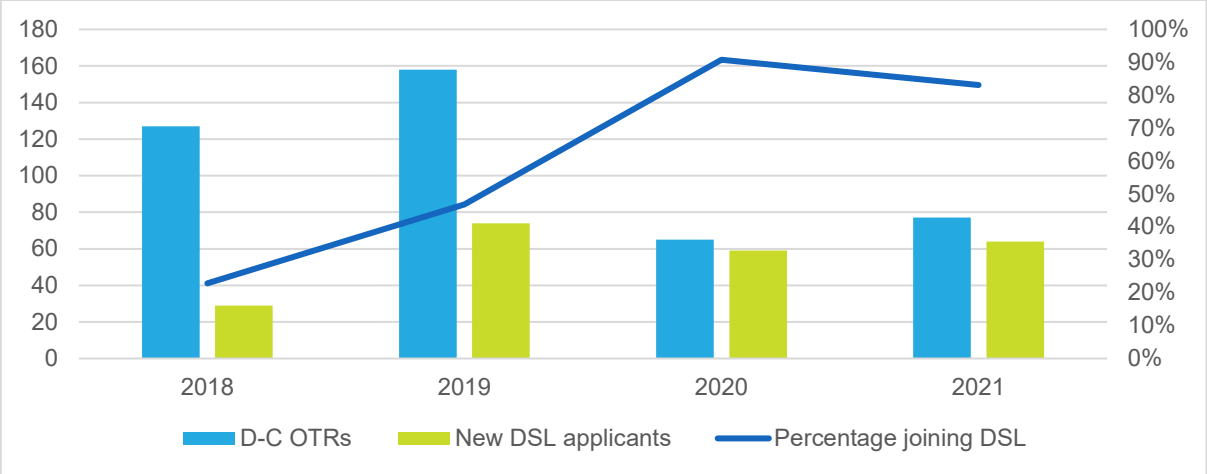
- the update on OTR activity and performance
- the supportive way in which OTRs are handled by the team
- the suspension of the service in 2020 and the effect on the service
- the increase in the number of applications received since re-opening in October 2020, resulting in a significant backlog of applications being received in the past year
- potential further increase in applications from late 2023 following donor anonymity changes in 2005
- the OTR redesign project currently underway

Annex

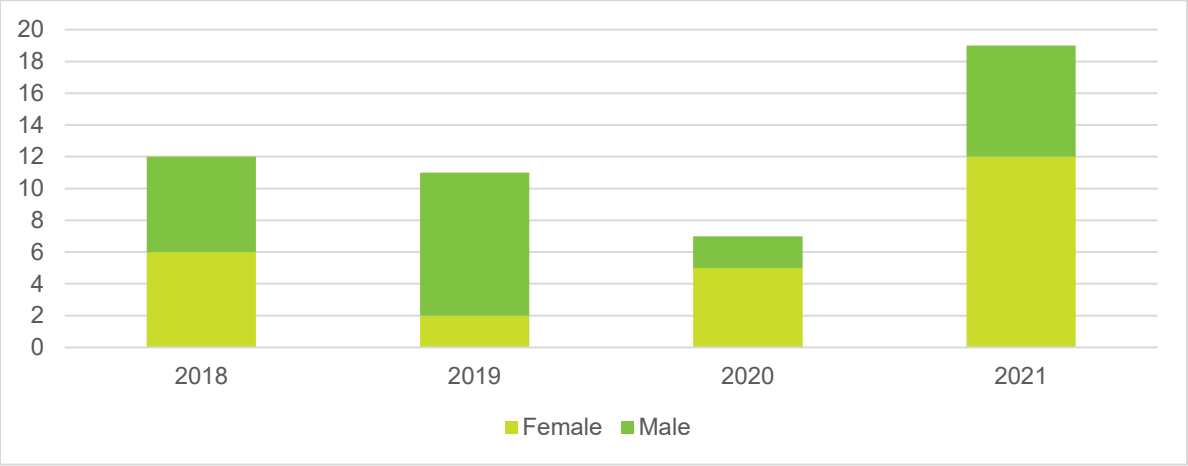
Donor Sibling Link matches and yearly new applicants



Donor-conceived OTR applicants who go on to join Donor Sibling Link



Donors removing anonymity



Referrals to the support Service

67 referrals have been made to the Hewitt Centre to date (4 in 2019, 24 in 2020 and 39 in 2021)

- 29 were for donor-conceived adults who have applied for information about their donor and any donor-conceived siblings
- 8 were for donors considering removing anonymity
- 3 were for donors where their identifying details have been requested by people born as a result of their donation
- 2 referrals were made for donor-conceived individuals who found out they were donor-conceived who did not yet wish to apply for information
- 1 referral was made for a parent here we felt support was needed
- 6 were made for donor-conceived people who had matches on Donor Sibling Link
- 7 were made for people considering joining Donor Sibling Link (this includes 3 who were also applying for information)
- 4 were made for donor-conceived individuals for other reasons where we felt support was needed
- 1 was made for a donor for other reasons where we felt support was needed
- 6 (3 pairs of individuals) were made for using the intermediary services for anonymous messaging

Treatment add-ons rating system review – an update

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.
Meeting:	Authority
Agenda item:	10
Meeting date:	24 November 2021
Author:	Georgina Allen, Policy Manager Sonia Macleod, Scientific Policy Manager
Annexes	Annex A: 10 Options presented to LCP and POSG Annex B: Key findings from scoping work. Annex C: LCP and POSG's preferred options

Output from this paper

For information or decision?	For decision
Recommendation:	The Authority are asked to consider and agree the proposed directions on: • The engagement strategy for potentially evolving the add-ons rating system.
Resource implications:	The patient and clinic engagement work can be carried out within existing resources. Any radical changes may require extra funds for either website development or external reviewer time.
Implementation date:	With immediate effect

Communication(s):	A full communications plan to engage patients and clinics in this work will be developed following the Authority meeting to be implemented in early 2022.
Organisational risk:	Medium

1. Introduction

1.1. Treatment add-ons are optional additional treatments, which are also referred to as 'supplementary', 'adjuvants' or 'embryology treatments'; they often claim to be effective at improving the chances of having a baby (live birth rate) but the evidence to support this for most fertility patients is usually missing or not very reliable; and are likely to involve an additional cost on top of the cost of a routine cycle of proven fertility treatment. Some treatment add-ons can cost hundreds or thousands of pounds each.

1.2. Addressing how treatment add-ons are offered by clinics and information given to patients is a key feature of our organisational strategy for 2020-24.

1.3. A key element of our work on add-ons is the use of a traffic light system for rating some treatment add-ons. The rating system first went onto the HFEA website in 2017 and has been subject to minor revisions since.

1.4. The current traffic-light rating system, consists of three colours (red, amber and green or RAG), that indicate whether the evidence, in the form of high-quality Randomised Control Trials (RCTs), shows that a treatment add-on is effective at improving the chances of having a baby for someone undergoing fertility treatment.

1.5. Our work on treatment add-ons so far means that patients can access clear information on our website which may enable them to better understand the evidence, risks and potential benefits for each add-on. Information on each add-on is framed within a reminder that for most patients, routine IVF is an effective treatment.

1.6. At the Authority meeting in September 2021it was agreed that we would undertake work to further **evolve the presentation of the rating system for treatment add-ons**, specifically that we would:-

- Carry out scoping work on the extent to which the current rating system could evolve and improve (e.g. do we stick with RAG or move to a different rating scale) and/or introduce multiple ratings per add-on (e.g. for various outcomes for each add-on).
- Come back to a future Authority meeting to report the outcome of that scoping work and set out a proposed engagement strategy.
- Come back to an Authority meeting in 2022 with a recommendation on how best to evolve/change the rating system based on engagement findings.
- Aim to agree any changes to the rating system by July 2022 so that the required work to inform the October 2022 SCAAC meeting (at which ratings will be allocated to our list of add-ons as part of their annual review) can be undertaken.

1.7. The Authority also agreed to consider broadening the range of data that the HFEA consider when assigning ratings to include other evidence types in addition to RCTs and to recommend whether any should be included in the HFEA's annual review (currently

using the GRADE methodology1) of evidence for treatments add-ons. This will be brought back to Authority in 2022 and is not the subject of the paper today.

1.8. This paper outlines the work we have carried out to date to review the presentation of the add-ons ratings. Section 2 looks at the scoping work we have done with researchers and feedback from stakeholders. Sections 3 and 4 outlines engagement work we plan to undertake; section 5 sets out the next steps in terms of our engagement with the Authority; and section 6 asks the Authority to discuss the progress made to date.

2. Scoping work

2.1. Since the September Authority meeting we have carried out scoping work on evolving the presentation of our add-ons rating system.

2.2. We have met with:

- Researchers:- Professor Brian Zikmund-Fisher[2], from the University of Michigan, and Dr. Claudia Schneider[3], Dr. Alexandra Freeman[4] and Dr Gabriel Recchia[5] from the Winton Centre for Risk and Evidence Communication, University of Cambridge, to gain their views and insights on the current RAG rating system and into how best to present health data to patients in a simple yet informative and clear way.
- The VALUE study lead (Dr Sarah Lensen)[6] to discuss their progress and insight into how we could evolve our traffic light rating system.
- Our Licensed Clinics' Panel (LCP)[7] to gain the views from licenced clinics.

[1]GRADE is an approach for grading the quality of evidence and the strength of recommendations. It was developed by the Grading of Recommendations, Assessment, Development and Evaluation Working Group.

[2] **Professor Brian Zikmund-Fisher** is a professor of Health Behaviour and Health Education at the University of Michigan. He uses his background in decision psychology and behavioural economics to design and evaluate methods of making health data more intuitively meaningful and clear.

[3] **Dr. Claudia R. Schneider** is a researcher at the Winton Centre for Risk and Evidence Communication at the University of Cambridge. Her focus is on how the quality of the evidence underlying scientific claims and numbers can be best communicated to support comprehension, transparent information sharing, and information decision making.

[4] **Dr. Alexandra Freeman** is the Executive Director of the Winton Centre. She has a particular interest in helping professionals communicate numbers and uncertainty in a clear way to inform but not persuade.

[5] **Dr. Gabe Recchia** is a researcher at the Winton Centre. His current research concerns the communication of information in ways that support comprehension and information decision-making taking into account the audience's needs and preferences.

[6] The **VALUE Study** is a research project between Melbourne University in Australia and Sheffield University in the UK interested in understanding the decisions making processes that occur when patients, doctors and embryologist think about, or opt to use add-ons in an IVF or ICSI cycle. The study aims to improve the care of future IVF patients, by better understanding how information and add-ons should be shared.

[7] LCP members are drawn from a number of clinics that the HFEA licence.

- Our new Patient Organisation Stakeholder Group (POSG)[8] to gain the views from patients and patient organisations.

Researchers' Opinions:

2.3. When we discussed evolving the treatment add-ons information with researchers, they suggested:

- **Rating the effectiveness of an add-on and the strength of the evidence for that add-on separately**.[9]
- Using **layered information** (information on another page when you click on a link) because it balances the need for simplicity and clarity with providing detail for those who want or need it.
- **Colour choice** is important because some colours, particularly red and green, intuitively convey certain messages, such as 'stop' and 'go'.
- RAG may not be the most effective way to communicate information[10], and that other evidence-based approaches (e.g. using + and – symbols) should be considered.

2.4. Other key findings from our engagement with researchers can be found in **Annex B**.

2.5. Based on input from researchers we developed 10 different presentation options, which we tested with LCP and PSOG (see below). These options are listed at **Annex A**. A feasibility check with the HFEA communications team indicated it would be possible to implement any of these options on the HFEA website.

LCP Opinions:

2.6. The discussion with the LCP gave rise to 3 preferred options:

- To **keep the current rating system** (i.e. option 1 in Annex A) because it worked well to communicate clear and easy to understand information and patients and clinics were used to using it.
- To **change the red rating to demonstrating 'evidence of potential negative effects' and adding another rating (e.g. grey) to demonstrate 'no evidence'** (i.e. option 2 in Annex A). LCP members suggested that we should consider **changing the grey to a yellow** and that we should also review the **ordering of the ratings** (i.e. moving the red to the bottom so that the ratings go in order from the best to the worst).

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[8] The membership of the POSG is made up of organisations which represent different patient groups to raise the views of patients and highlight how decisions may affect certain patients.

[9] Examples of the Education Endowment Foundation, and the College of Policing Quality scale and their Effect Scale were provided.

[10] 'Communicating evidence in icons and summary formats for policymakers: what works?'

- To include **additional outcomes** (i.e. option 9 in Annex A) because it would provide patients with more information about the add-ons. Members also suggested we should consider **changing from additional outcomes to additional patient groups** (e.g. those at risk of OHSS) rather than only looking at 'most fertility patients'. **We will need to look into the feasibility of rating add-ons for additional patient groups.**

2.7. More information on the views of LCP members can be found in **Annex B**.

POSG Opinions:

2.8. The discussion with the POSG gave rise to 3 preferred options:

- To **keep the current rating system** (i.e. option 1 in Annex A) because it works well for patients as it can be easily understood quickly. However, they were of the view that some patients want **more information and suggested adding this through drop downs or layered information.** They felt this would be useful for patients because it would allow access to more information when and if wanted/needed whilst also ensuring that the simple, clear and easy to understand ratings are not lost.
- To **change the red rating to demonstrating 'evidence of potential negative effects' and adding another rating (e.g. grey) to demonstrate 'no evidence'** (i.e. option 2 in Annex A). They suggested that this provides more information (particularly about when there is potential negative effects) and may be clearer for patients to understand, although some members thought it could potentially add more confusion.
- To **including additional outcomes** (i.e. option 9 in Annex A) because it would be useful to patients as it would provide more information, which is what patients have communicated to some POSG members they want. They suggested that using either Option 1 or Option 2 would provide a lot of clear information quickly. They suggested we could provide ratings for **additional patient groups** as well as providing ratings for additional outcomes and have these in two different tables. **We will need to look at the feasibility of rating add-ons for additional patient groups**

2.9. More information about views of POSG members can be found in **Annex B**.

3. Future scoping work planned (until February 2022)

3.1. The Treatment Add-ons Group (TAG) meeting on 29 November will consider the 10 different presentation options outlined in Annex A and the suggestions made by LCP and POSG (outlined in Annex B and C). Their preferred options will be used to inform which options should be presented in the public engagement.

3.2. TAG is made up of the treatment add-ons consensus statement signatories and it is therefore important that there is broad support among members for the direction of travel on any changes to the rating system.

3.3. In thinking about evolving the rating system we need to take account of the differing circumstances in which the information on our website is read. While some patients may do so in the presence of a clinician, others may not and so we need to ensure that the

rating system is capable of being understood without expert input. It is, therefore, essential that patients are involved in any evolution of the RAG rating.

3.4. We already have some information about patient views from the survey on add-ons carried out in 2020. In addition, we plan to carry out some in-depth one-to-one interviews with patients in early 2022. Findings from these interviews will be used to establish their: -

- Understanding of the current RAG rating system.
- Understanding of the alternative options.
- Top three preferences for evolving the current rating system.

3.5. Based on feedback and views from researchers, stakeholders, patients and TAG, we will develop options for evolving the current RAG rating system for treatment add-ons which will be presented in a public engagement. The current RAG system will be one of the options presented in the engagement. We intend to present a maximum of two other options, but this will be contingent on the results of the scoping work which is currently not completed.

3.6. It should be noted that some of the ten options we have used in the scoping phase will have cost implications. For example, if outcomes other than live births are included then the evidence base for these outcomes will need to be externally reviewed. This would involve a one-off retrospective review of eligible papers reporting the selected outcome(s) as well as an annual review of any new papers reporting that outcome. Until we have greater clarity on the outcomes of interest it is not possible to determine the scale of the cost implications. Once we have narrowed down to the three options in the engagement we will be able to clarify the costs implications of each of these options for Authority final decision.

4. Public and clinic engagement

4.1. The results of the scoping work will be analysed and we will create both patient and clinic surveys on evolving the RAG rating.

4.2. An online targeted patient survey, planned to start in Spring 2022, will present a maximum of three options for evolving the RAG rating system. We will use the findings from this targeted survey and the national patient survey to assess patient views on the three options. The targeted patient survey will be promoted as part of a wider communication plan to ensure we maximise our reach. We will monitor respondent demographics so we can check we have a broadly representative sample.

4.3. At the same time we will conduct an online clinic survey on the same three options. This will mean we have both the patient and clinic perspectives on the potential evolutions of the rating.

4.4. We also plan to conduct focus groups from members of the Patient Engagement Forum. These will take place after the targeted surveys so we can gain a deeper understanding of patient views.

4.5. The results from this engagement work and the information gained during the scoping phase will be used to develop a recommendation for the evolution of the RAG rating system.

5. Next Steps

5.1. We will come back to a future Authority meeting, tentatively the July 2022 meeting, with a recommendation on how best to evolve/change the rating system based on the work outlined above.

5.2. As noted above, alongside the work on the presentational aspects of the rating system is the work on expanding the evidence base. This will run in parallel, so that a recommendation on this will be sought at the same time as the recommendation on evolving the rating system. Recommendations made at the July Authority meeting should enable SCAAC to undertake their annual review at the October SCAAC meeting based on the modified rating system/evidence base. This is with the caveat that if either the rating system or the evidence base changes substantially then more time may be required for external reviewing before SCAAC can be asked to review each add-on.

5.3. Any changes to the RAG rating system will be subjected to extensive user-acceptance testing, and published as part of the wider communications plan, including infographics for use on social media, social media posts on all platforms and an article in Clinic Focus

6. Recommendations

6.1. The Authority is asked to note the progress made in relation to scoping the add-ons rating system and agree the proposals for engagement on evolving the rating scheme for add-ons.

Annex A – 10 options presented to LCP and POSG

- Below are the options presented to LCP and POSG.
- Please note that the options below cannot be taken as fact and do not reflect the true current situation on add-ons.

1. Option 1 - The current rating system

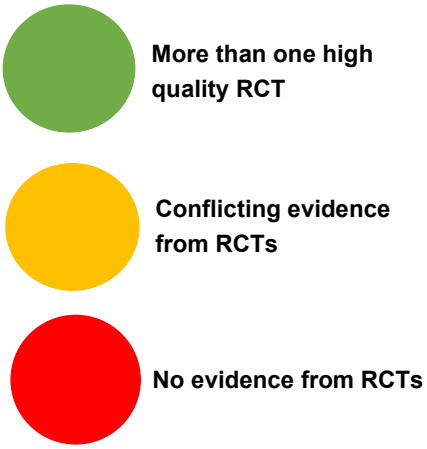
1.1. This would mean that there is no change to the current RAG (red, amber, green) rating system on our website.

1.2. Only looks at whether the add-on is effective at increasing the chances of successful birth in most fertility patients.

1.3. Uses RCTs.

1.4. Currently, no add-on is rated as green because any add-on which would have been rated as green becomes part of the standard fertility treatment.

1.5. Additional outcomes could be rated in this way as shown in Option 9.



2. Option 2 – An additional rating (grey)

2.1. This would mean that there are four colours (grey, red, amber, green) GRAG.

2.3. Red would change to mean that there is potential detriment (or negative effects).

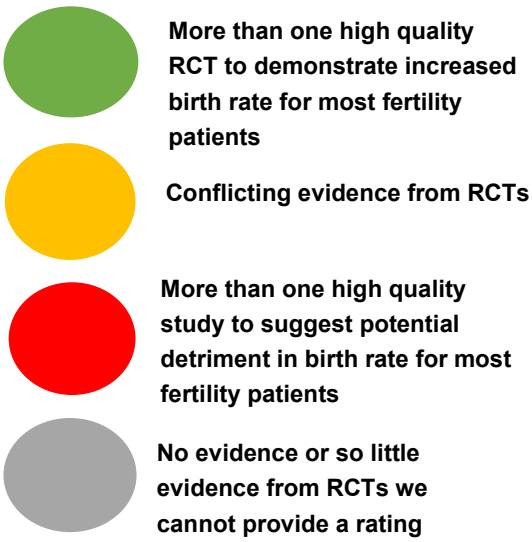
2.4. Grey would mean that there is no evidence (i.e. what red currently means).

2.5. Only looks at whether the add-on is effective at increasing the chances of successful birth in most fertility patients.

2.6. Uses RCTs.

2.7. There would be no green ratings as any add-ons which would be rated as green would be part of the standard fertility treatment.

2.8. Additional outcomes could be rated in this way as shown in Option 9.



3. Option 3 - Colour gradient

3.1. Does not use red, amber green.

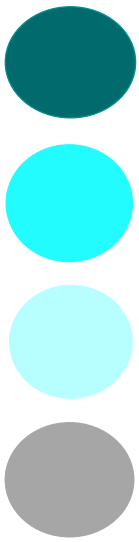
3.2. Uses a gradient of one colour where the darker the colour the more evidence there is that the add-on is effective at increasing birth rates for most fertility patients.

3.3. The grey would demonstrate that we have no evidence and so are unable to rate the add-on.

3.4. Only looks at whether the add-on is effective at increasing the chances of successful birth in most fertility patients.

3.5. Uses RCTs.

3.6. There would be no dark turquoise colour as any add-ons which would be rated as dark turquoise would be part c treatment.



More than one high quality RCT to demonstrate increased birth rate for most fertility patients

Conflicting evidence from RCTs

More than one high quality study to suggest potential detriment in birth rate for most fertility patients

No evidence or so little evidence from RCTs we cannot provide a rating

3.7. Additional outcomes could be rated in this way as shown in Option 9.

4. Option 4. - STAR ratings

4.1. The stars demonstrate how much evidence there is for each add-on.

4.2. There is no colour distinction to demonstrate how much evidence each add-on has.

4.3. It is not possible to demonstrate through a star rating system whether there is evidence of negative effects.

4.4. Only looks at whether the add-on is effective at increasing the chances of successful birth in most fertility patients.

4.5. Uses RCTs.

4.6. There is likely to be no 3 star rated add-on (similarly to how there is no green rated add-on) because any add-on which would be rated three stars would be part of the standard fertility treatment.

No evidence from RCTs

Conflicting evidence from RCTs

Some RCT of lower quality

More than one high quality RCT

5. Additional outcomes could be rated in this way as shown in Option 9.Option 5 – Symbols

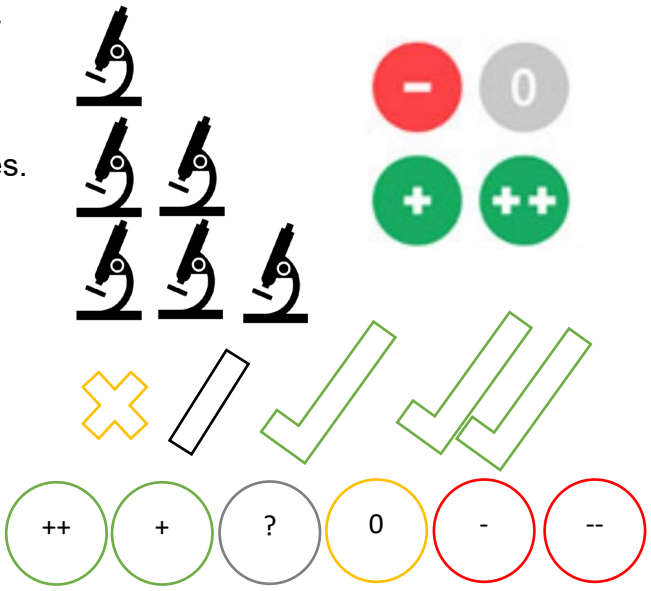
5.1. Any kind of symbols can be used. These are a few examples.

5.2. Different symbols could convey both positive and negative impacts, for example the ticks and crosses.

5.3. Symbols can provide nuance such as showing the difference between 'no evidence' and 'evidence of no impact'.

5.4. Symbols can also be used to distinguish between substantial positive impact and moderate positive impact and vice a versa for negative impacts.

5.5. Some symbols create a better intuitive understanding than others, so care is needed when matching the symbol to the outcome it represents.



5.6. Only looks at whether the add-on is effective at increasing the chances of successful birth in most fertility patients.

5.7. Uses RCTs.

5.8. Additional outcomes could be rated in this way as shown in Option 9.

6. Option 6 – Wording

6.1. This would be where there are only words to describe how much evidence there is and what the evidence shows for each add-on.

6.2. It could reduce the intuitive understanding/misunderstanding of symbols and colours.

6.3. However, the choice of words could influence a person's choice.

6.4. This option may have accessibility issues for people where English is their second language, for those with low literacy and those with disabilities (e.g. dyslexia).

More than one high quality RCT to demonstrate increased birth rates for most fertility patients.

Conflicting evidence from RCTs.

No evidence.

More than one high quality study to suggest potential detriment in birth rates for most fertility patients

6.5. Only looks at whether the add-on is effective at increasing the chances of successful birth in most fertility patients

6.6. Uses RCTs.

6.7. Other outcomes could be rated in this way as shown in Option 9.

7. Option 7 – Letter Grading

7.1. The letter/grade would be what rates the add-on.

7.2. A demonstrates good evidence and a positive effect and D is good evidence with a negative effect.

7.3. It could reduce the intuitive understanding/misunderstanding of symbols and colours.

7.4. This option may have accessibility issues for people where English is their second language, for those with low literacy and those with disabilities (e.g. dyslexia).

A.	**More than one high quality RCT to demonstrate increased birth rates for most fertility patients**
B.	**Conflicting evidence from RCTs**
C.	**No evidence**
D.	**More than one high quality study to suggest potential detriment in birth rates for most fertility patients**

7.5. Only looks at whether the add-on is effective at increasing the chances of successful birth in most fertility patients.

7.6. Uses RCTs.

7.7. Additional outcomes could be rated in this way as shown in Option 9

8. Option 8 – Number Rating

8.1. The numbers would be what rates the add-on.

8.2. The lower the number the more evidence there is.

8.3. It could reduce the intuitive understanding/misunderstanding of symbols and colours.

8.4. This option may have accessibility issues for people where English is their second language, for those with low literacy and those with disabilities (e.g. dyslexia).

1. **More than one high quality RCT to demonstrate increased birth rates for most fertility patients**
2. **Conflicting evidence from RCTs**
3. **No evidence**
4. **More than one high quality study to suggest potential detriment in birth rates for most fertility patients**

8.5. Some people may get confused with the rating as they may think that the higher number is better. Therefore, if this is preferred, we will need to assess what is best.

8.6. Only looks at whether the add-on is effective at increasing the chances of successful birth in most fertility patients.

8.7. Uses RCTs.

8.8. Additional outcomes could be rated in this way as shown in Option 9.

9. Option 9 – Additional Outcomes

9.1. We could use any of the rating systems suggested above (Options 1-7 in Annex A) or any other rating system if it is preferable. **This is only an example.**

9.2. Rates other outcomes outcomes rather than only rating whether the add-on is effective at increasing the chances of successful birth in most fertility patients.

9.3. We have included in our example reduction in miscarriage, time to conception and OHSS risk (already looked at by SCAAC), however, any outcome could be considered.

Treatment add-on	Outcome			
	Successful birth	Reduction in miscarriage	Reducing the time to a positive pregnancy test	Ovarian Hyperstimulation Syndrome
Artificial egg activation calcium ionophore	●	●	●	●
Assisted hatching	●	●	●	●
Elective freeze all cycles	●	●	●	●

9.4. The add-on itself would not have an overall rating for increasing birth rates, but each outcome would be individually rated for each individual add-on.

9.5. Each additional outcome could be rated green (or equivalent) but it is unlikely that there would be green ratings (or equivalent) for successful birth rates.

9.6. Uses RCTs.

10. Option 10 – Split evidence and effectiveness

10.1. Currently, the evidence and the effectiveness are merged together in one rating (e.g. green would currently demonstrate that there is more than one high quality RCT which demonstrates the add-on is effective at increasing birth rates for most fertility patients).

Treatment Add on (Please click on the add on for more information)	Impact	Evidence
Artificial egg activation calcium ionophore	-	🔬🔬🔬
Assisted hatching	0	🔬🔬🔬
Elective freeze all cycles	+	🔬🔬🔬

10.2. This option would split evidence and effectiveness so that they are rated distinct from each other to show how much evidence there is and what this evidence shows the effect is. This could potentially allow for nuances where there is a small amount of evidence all showing a positive effect or occasions where there is a lot of evidence showing no effect etc.

10.3. There are suggestions from researchers that doing this could reduce confusion about how much evidence there is and what this evidence indicates to help patients make a more informed choice as they know how much evidence there is and what this evidence suggests.

10.4. We have used symbols in this example, however, any of the rating systems suggested above (options 1-7 in Annex A) or any other rating system if it is preferable. This is only an example of what it could look like if we split the evidence and effect (impact).

10.5. Only looks at whether the add-on is effective at increasing the chances of successful birth in most fertility patients.

10.6. Uses RCTs.

10.7. Additional outcomes could be rated in this way as shown in Option 9.

Annex B – Key findings from scoping work

- Please see below further information from our conversations with researchers, LCP and POSG.

1. Further key findings from researchers:

1.1. Other key suggestions and information provided by our conversations with researchers include:

- **Symbols** can be more effective at communicating information to people than text alone.
- **Tables communicate information in a simple and comprehensive way**[11] even to those with lower literacy skills as they are a good way to recognise patterns and trends at a glance.
- **A scale of effect** (e.g. ++, +, 0, -, --, ?) should be considered. This will allow nuanced communication. For example, the difference between 'no evidence to show any impact' and 'evidence of no impact'.
- When patients are offered add-ons they are faced with a choice of taking the add-on (i.e. a positive action) or not taking it (i.e. no action). **Our add-ons webpage should include information on what standard IVF treatment entails as it indicates to patients that they are already acting positively.**
- As green rated add-ons are not possible in our current rating system, this can cause confusion and misunderstanding. Therefore, it was suggested that **each rating should be at least possible to achieve** otherwise we are setting unachievable standards.

2. Key information for LCP discussion:

2.1. When we met with LCP members we went through each of the 10 options which we had developed to gain their opinions on each option. LCP members thought:

- **Option 1 (i.e. the current rating system) is useful for patients** to see clear messages and is straightforward for clinics to explain to patients.
- **Option 2 (i.e. the addition of a grey rating) would be an improvement from the current rating system** because it would ensure that red means 'stop'. They

[11] 'Risk communication in tables versus text: a registered report randomized trial on 'fact boxes'

suggested that the **red rating should be at the bottom** rather than the grey so that the ratings flowed from the best to the worst and that we should **consider changing the grey to another colour such as yellow**.

- **Options 3 (i.e. colour gradient) would not be an improvement from the current rating system** as it would be difficult to know intuitively what each colour meant and so would be difficult for patients to understand and for clinics to describe the rating to patients.
- **Option 4 (i.e. stars), would not be an improvement from the current rating system** and was potentially confusing as stars are already used for rating clinics. Also, stars denote good practice and even one star would be a reward or praise when that would not necessarily be what the star is showing (e.g. conflicting evidence).
- **Option 5 (i.e. symbols) could potentially be confusing for patients** particularly those who are neurodiverse. LCP members agreed this option may provide nuance and provide patients with more information, but they argued this potential benefit of symbols was outweighed by the risk of misunderstanding and confusions as symbols would be more difficult for patients to quickly understand. They felt it would be **difficult for clinics to explain the symbols**.
- **Option 6 (i.e. wording), option 7 (i.e. letter grading) and option 8 (i.e. number rating) were not an improvement from the current rating system** as they are all too texted based and the lack of colour makes it difficult to see trends quickly potentially leading to accessibility issues.
- **Option 9 (i.e. additional outcomes) was seen as a useful improvement from the current rating system** as it would provide more information to patients. Members suggested that **instead of additional outcomes we should consider additional patient groups** such as those who are at risk of OHSS and those who have had multiple miscarriage and at risk of further miscarriages etc. This would ensure that patients receive more information and information about their specific group.
- **Option 10 (i.e. splitting the impact and evidence and rating them separately) was seen as too confusing for patients and so was not seen as a useful improvement from the current rating system**. Members explained that patients often want a 'yes' or 'no' answer and splitting impact and evidence would not provided them with this. It was suggested, however, that **this information could be useful to provide to clinics** to help them explain the ratings to patients.
- **Tables seemed to be useful** at communicating information.

3. Key information from POSG discussion:

3.1. When we met with POSG members we went through each of the 10 options which we had developed to gain their opinions on each option. POSG members thought:

- **Option 1 (i.e. the current rating system) is useful for patients** to see clear messages and is straightforward for clinics to explain to patients. Although the current rating system is useful to provide simple information they suggested that where patients want more information we should include more detailed information about

each add-on (e.g. a link to the RCTs themselves) on our website through drop downs or layered information. They felt it would be particularly helpful to include information about how many people have had a baby after using that add-on. It was noted that the current system may be difficult for patients with colour blindness and that adding 'red', 'amber' and 'green' inside the dots would resolve this.

- **Option 2 (i.e. the addition of a grey rating) is likely to be more useful to patients than the current rating system.** It was suggested that some patients may see the red rating and think it is dangerous meaning they may not want to use it and may cause them to worry about their clinic if their clinic is suggesting they use an add-on which is rated red. Therefore, changing the definition of the red rating to show potential harm or negative effects could be useful to patients. There was some debate about whether a grey rating would be useful, but in general members agreed that the grey rating would be useful to show where there is no evidence at all and for the red rating to demonstrate potential negative effects or harm as this is something patients often want to know. It was noted that the current system may be difficult for patients with colour blindness and that adding 'red', 'amber' and 'green' inside the dots would resolve this.
- **Options 3 (i.e. colour gradient) would not be an improvement from the current rating system** as it would be difficult to know intuitively what each colour meant and so would be difficult for patients to understand.
- **Option 4 (i.e. stars) would not be an improvement from the current rating system** as it would be too much of a change from the current rating system which is already useful to patients and could cause confusion.
- **Option 5 (i.e. symbols) would not be an improvement from the current rating system** as it would be a change from the current rating system and could provide too much information in one go which could cause confusion or misunderstanding if patients are looking at the rating system quickly.
- **Option 6 (i.e. wording), option 7 (i.e. letter grading) and option 8 (i.e. number rating) were not an improvement from the current rating system** as they are all too texted based and the lack of colour makes it difficult to see trends quickly potentially leading to accessibility issues.
- **Option 9 (i.e. additional outcomes) was seen as a useful improvement from the current rating system** as it would provide more information and detail about the add-ons to patients. They suggested that **additional patient groups may also be useful but should be included in addition to the information on additional outcomes**.
- **Option 10 (i.e. splitting the impact and evidence and rating them separately) was not seen as a useful improvement from the current rating system** because it would be too confusing for patients and not simple for them to understand quickly.

Annex C - LCP and POSG's preferred options

- We have developed options based on the discussions from LCP an POSG. Some of these options may be hybrids or slightly different to our suggested options in Annex A which we presented to LCP and POSG members.
- Please note that the options below cannot be taken as fact and don't reflect the true current situation on add-ons.

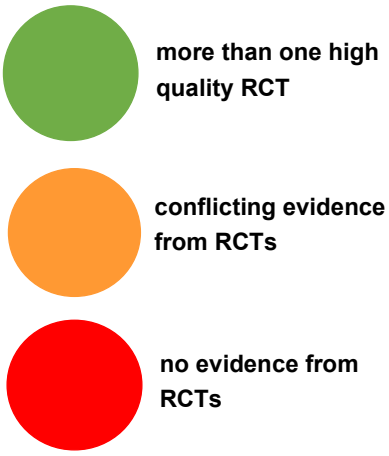
1. The Current rating system

1.1. Both LCP and POSG members suggested that the current rating system was useful for patients as it was easy for patients to understand quickly.

1.2. This would mean that there is no change to the current RAG (red, amber, green) rating system on our website.

1.3. POSG suggested that patients do want more information and that this should be provided through, for example, drop downs or layered/clickable information.

1.4. It was noted by POSG members that the current system may not be useful for patients with colour blindness and so potentially adding 'red', 'amber' and 'green' inside the dots to make it clear what the colour is could be useful. This should be considered further.



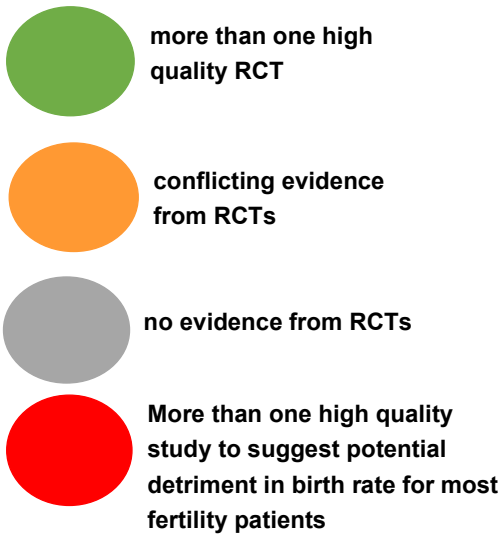
2. The GRAG rating system

2.1. Both the LCP and POSG members thought that the GRAG option, or something similar, could be an improvement to the current rating system.

2.2. Red would change to mean that there is potential detriment (or negative effects).

2.3. Grey would mean that there is no evidence (i.e. what red currently means).

2.4. Some LCP members felt that the grey should change to another colour such as yellow. **We will be able to review different variations of this option through our further scoping work.**



2.5. It was noted by POSG members that the use of colours may not be useful for patients with colour blindness and so potentially adding 'red', 'amber' and 'green' etc. inside the dots to make it clear what the colour is could be useful. This should be considered further. **We will be able to consider this and develop the best way to ensure that the ratings are accessible through our scoping work.**

2.6. Based on the suggestions from the LCP members, the colours would go in order from best (i.e. green) to worst (i.e. red).

3. Additional outcomes

3.1. Both LCP and POSG members thought that including additional outcomes would be useful to patients.

3.2. The additional outcomes to live birth rates included in this example are: reduction in miscarriage, time to conception and OHSS risk, however, any outcome could be considered. **We need to continue our scoping work to know if this is option is preferred and which patient groups would be preferred.**

Treatment add-on	Outcome			
	Successful birth	Reduction in miscarriage	Reducing the time to a positive pregnancy test	Ovarian Hyperstimulation Syndrome
Artificial egg activation calcium ionophore				
Assisted hatching				
Elective freeze all cycles				

3.3. This example uses the GRAG rating system, also used in the example shown in option 9 of Annex A. **Any rating system could be used and we will need to continue our scoping work to know which rating system is preferred.**

3.4. It would be possible for some additional outcomes to have green ratings for increased live birth rate as this would not necessarily mean that the add-on itself would be used in standard IVF treatment.

3.5. It is unlikely that it would be possible for live birth rates to be rated green because if they were rated green then the add-on would be used in standard IVF treatment.

3.6. Although LCP liked the addition of additional outcomes, they suggested having **additional patient groups** rather than outcomes may be more useful to patients (see options 4 in Annex C below).

3.7. POSG members suggested that rating the add-ons for additional patient groups would be useful information, but this should be provided in addition to additional outcomes.

4. Additional patient groups

4.1. LCP members suggested that rating add-ons for additional patient groups rather than for additional outcomes may be more useful to patients.

4.2. POSG members suggested that rating the add-ons for additional patient groups would be useful information for patients but this **should be provided in addition** to additional outcomes.

Treatment add-on	Patient Group			
	For most fertility patients	Patients who have suffered from multiple miscarriages	Patients who are over the age of 35	Patients at risk of Ovarian Hyperstimulation Syndrome
Artificial egg activation calcium ionophore	●	●	●	●
Assisted hatching	●	●	●	●
Elective freeze all cycles	●	●	●	●

4.3. Similar to option 9 presented in Annex A but, based on the suggestions from LCP members, rather than rating additional outcomes other than live birth rates, we would rate live birth rates for additional patient groups rather than only for 'most fertility patients'.

4.4. The patient groups we have included here are patients who have suffered from multiple miscarriages, patients who are over the age of 35, patients who are at risk of Ovarian Hyperstimulation Syndrome (OHSS). **We need to continue our scoping work to know if this is option is preferred and which patient groups would be preferred.**

4.5. This example uses the GRAG rating system. **Any rating system could be used, and we will need to continue our scoping work to know which rating system is preferred.**

4.6. As this is a newly suggested option. **We will need to further look into the feasibility of rating add-ons for additional patient groups to ensure that it is possible.**

4.7. If this option is feasible, it would be possible for some patient groups to have green ratings for increased live birth rate as this would not necessarily mean that the add-on itself would be used in standard IVF treatment.

4.8. If this option is feasible, it is unlikely that it would be possible for live birth rates for 'most fertility patients' to be rated green because if they were rated green then the add-on would be used in standard IVF treatment.

Transparency and Publication – next steps

Area(s) of strategy this paper relates to:	The best care/The right information
Meeting:	Authority
Agenda item:	11
Meeting date:	24 November 2021
Author:	Clare Ettinghausen. Director of Strategy and Corporate Affairs
Annexes	Annex A: Publishing information: What we do now Anne B: Publishing information: What we could do

Output from this paper

For information or decision?	For decision
Recommendation:	The Authority are asked to review the options for next steps with this work outlined in the paper
Resource implications:	Input required from across the organisation, particularly from communications, licensing and compliance.
Implementation date:	To be decided
Communication(s):	Communication plans to be developed depending on which option is agreed.
Organisational risk:	Medium

1. Background

1.1. The Authority considered some broad issues relating to transparency and regulation at its May 2021 meeting. In this context we use the term 'transparency' to mean, the clarity of our regulatory information and the ease with which patients and others can access it on our website.

1.2. It was noted at the May 2021 meeting that the HFEA publishes information relating to the regulation of HFEA licensed clinics, principally in the inspection reports available on the **Choose a Fertility Clinic** (CaFC) function on the HFEA website. These reports are written primarily to support licensing decisions and, from a transparency perspective, can be hard to find on our website. Our recent work with the Competition and Markets Authority (CMA) and Advertising Standards Authority (ASA), both of whom publish enforcement actions on their websites, suggested that the HFEA should consider whether and, if so how, we should publish this information too. Lastly, it was noted that although the HFEA publish clinic non-compliances on our website by putting inspection reports online, other regulators do so in a manner and format which is more visible and therefore of greater use to those that they regulate and the wider public.

1.3. The minutes of the May 2021 Authority meeting note that:

- Increasing transparency (in the general sense referred to above) around our compliance work was in the best interests of patients and was therefore very welcome;
- Raising transparency goes to the heart of our duty to provide information to patients;
- Patients being able to access information readily was very important;
- While collaborative work with the sector was important that should not prevent the HFEA drawing attention to non-compliances;
- Improvements should be made to the information that we already publish on CaFC with the aim of making it easier to find and it was noted that inspection reports needed to be seen in context as the narrative within them needed to be told in full;
- Whatever we publish must be within the legal powers of the HFEA.

1.4. The Authority asked for more detailed options to be brought back for decision. This paper looks at how our compliance decisions could be better published and publicised.

1.5. Given other priorities within the current strategy, it is useful to assess whether the HFEA might be out of step and why this might be an opportune moment to consider these issues.

1.6. In thinking about these issues, it is also useful to note the statutory duty on information provision in the Human Fertilisation and Embryology Act 1990 and why transparency is fundamental for modern regulators, especially in providing information to those who need our information most – in this case patients.

1.7. Section 2 below gives a short introduction to the issues; section 3 looks at what information we publish now and its effectiveness for clinics and patients; section 4 looks at what we could do differently; section 5 considers what may happen when other regulators publish information relating to HFEA licensed clinics; and section 6 provides three broad options for the way forward.

2. Introduction

2.1. As noted above, at the May 2021 Authority meeting an overview was given of a range of issues relating to 'transparency and regulation'. The specific issues discussed in this paper are more suitably described as 'transparency and publication' as they relate to the regulator's duty to be transparent and how we make more easily available some of the information that is within inspection reports and meeting minutes for patients and licensed clinics.

2.2. When this issue was discussed in May, it was noted that transparency can be used as regulatory incentive and, indeed, is by many other regulators. Examples were given of publication by other health and non-health regulators where publicly naming entities that have been considered for regulatory action is commonplace. This paper looks at how we could make more easily available the information we already publish, rather than how publication can be used as a regulatory tool.

2.3. The Human Fertilisation and Embryology (HFE) Act 1990 (as amended) gives us a statutory duty to provide information and the regulatory principles set out in the Act also require us to be transparent and to consider whether our current process of publication fulfils these objectives effectively.

2.4. According to the HFE Act 1990:

The Authority shall—
(b) publicise the services provided to the public by the Authority or provided in pursuance of licences,
(c) provide, to such extent as it considers appropriate, advice and information for persons to whom licences apply or who are receiving treatment services or providing gametes or embryos for use for the purposes of activities governed by this Act, or may wish to do so,

And in carrying out its functions:

> The Authority must, so far as relevant, have regard to the principles of best regulatory practice (including the principles under which regulatory activities should be transparent, accountable, proportionate, consistent and targeted only at cases in which action is needed).

2.5. In looking at what we currently publish, it is worth considering whether we make available *all* the information that the *most* relevant people can access easily.

2.6. Any decision to change the way we publish information must ensure it is made so that it is most useful to patients and therefore, if the Authority decide to move forward with this work, then an important step will be to gather patient feedback on a number of options.

2.7. The Authority has previously been cautious about some levels of publication – for example, anything that would end up in a 'league table' or similar, because of the complex nature of how clinics offer treatment, the impact on patient decision making, and the competitive and litigious nature of some HFEA licensed clinics. Any decision to change this might therefore increase the risk of legal action being taken against the HFEA.

3. Publishing HFEA information – what we do now

3.1. Information on clinic performance is largely found on a clinic-by-clinic basis in Choose a Fertility Clinic (CaFC), in part through the publication of clinic inspection reports, in part through key measures or statistics drawn from the HFEA Register or licence decisions, and in part from voluntary survey information submitted by patients. We also publish national level performance data in the form of quarterly or annual publications.

3.2. While the national patient survey taking place in November/December 2021 will provide us with some first-hand information about how patients use the HFEA website and CaFC information, we know that these webpages are the most popular on our website.

3.3. The different types of information on CaFC include the inspection 'star' rating, the patient ratings, statistical information about each clinic's success rates and comparison to the national average, and the detailed inspection reports and licencing committee minutes for the last few years.

3.4. Annex A outlines the main pieces of information published on our website with an indication of its effectiveness.

3.5. At present there is no way of knowing when regulatory action may have been taken without reviewing every inspection report. This is in marked contrast with many other regulators.

3.6. Of the information we do publish relating to clinic performance, some of this can be tricky to understand. For example, the inspection 'star' rating given to clinics is determined by the length of licence a clinic is given by a licensing committee, with most clinics having a four-year licence. This reflects the clinic's compliance with legal requirements following any inspections that have been undertaken and is informed by an assessment by the inspectors of information provided and responses to any non-compliances identified.

3.7. The most recent clinic inspection reports are also published on our website. These provide a detailed assessment of clinic performance against a range of measures. However, they are for a licensing committee to make regulatory / licensing decisions; although they contain much useful information about the clinic, they are not written with patient audiences in mind.

3.8. Some work has been carried out to review what a revised front cover of the inspection report could look like to make it more 'patient friendly' and this is likely to continue during 2022.

3.9. Feedback from the Patient Organisation Stakeholders Group was sought, and members made some important points:

- Most patients are not interested in inspections but focus on different success rates rather than detailed inspection findings
- The information we have already is relevant for patients, but some patients do not know about it or are unaware of the HFEA
- Any review of CaFC information should look at how patients can distinguish which clinics are better for them based on their own circumstances, for example, which are the clinics who excel at surrogacy?
- The HFEA should rate, for example, the counselling support that patients receive so they can make more informed decisions
- Clinics should be required to say they have a HFEA licence by having a badge or icon on their homepages linking to their most recent HFEA inspection report

- A lay summary of the inspection report for patients and current/ongoing issues should be published alongside inspection reports
- League tables could be useful for patients and would enable better patient choice
- It would be useful if there was a rating (like CQC or Ofsted) of, for example, 'good', 'fair', 'outstanding' etc to enable clearer understanding of the differences between clinics
- It is important that any decisions by the CMA or ASA are reflected for patients when they look at clinic information on the HFEA website.

4. What we could do

4.1. If we were to publish more clearly where compliance or enforcement action has been taken, then we would need to decide three questions: what threshold would we apply to publicising regulatory action? When would such information be published? And in what form would publication take?

4.2. Reference to the Compliance and Enforcement Policy Regulatory Action Table is useful starting point here and the differing risk scores may provide a framework for deciding what and when to publish.

Risk score 1-4	Risk score 5-9	Risk score 10-12	Risk 15-16	Risk 20 - 25
Level 1 action(s) requiring response within reasonable timescales.	Level 1 action(s) requiring more intensive scrutiny or shorter response timescales (e.g., additional audits, seeking legal advice).	Level 1 and/or Level 2 action(s) requiring urgent and/or immediate interventions or actions.	Level 1 and/or 2 action(s) requiring immediate interventions or actions.	Level 3 action
4-year licence	3- or 4-year licence with or without additional conditions	2-year licence with or without additional conditions	1-year licence with or without additional conditions	Recommendation not to grant a licence, or revocation or immediate/ongoing suspension of licence

4.3. Publication could be as simple as an excel chart that links back to full the inspection report in CaFC and says whether action has been taken or not.

4.4. For example: on risk scores 1-4, where actions are required within a reasonable timescale and have been taken – this would simply note – full 4 year licence. For risk scores 10-12 where urgent and/or immediate interventions or actions is required – the information be published on a and linked to the Licence Committee (or Executive Licensing Panel) report and note that there

are outstanding actions and/or additional conditions on the licence. At risk level 20 plus where level 3 action is taken potentially resulting in a licence not granted, revoked or suspended – a press statement and social media activity may be considered more appropriate.

4.5. The timing of publication would depend on the severity of the issue. Generally, it would make most sense to publish such information at the end of the licensing process. That is, after the period in which a licensing decision may be appealed. This would mean that the regulatory action is settled and would not need to be updated. However, in instances where regulatory action needed to be taken quickly for reasons of patient safety, resulting in say the suspension of a service or licence, there is a case for making such information public while the licensing process is ongoing.

4.6. Further consideration could also be given to publishing other information that we hold, for example:

- We could publish the inspection schedule of planned inspections
- We could publish the schedule of what items are going to which committee giving greater transparency to when inspection reports are being reviewed.

4.7. In a future Code of Practice amendment, we could also consider amending paragraph 25.11 which currently states:

- The centre should display a copy of its Certificate of Licence where it can easily be read by current and potential patients and donors.

This could be amended to something that would need to be added to clinic websites linking directly back to HFEA inspection/compliance publication.

5. Publishing another regulator's information

What we do now

5.1. We rarely publish details of another regulator's information unless it is directly relevant to our own HFEA inspection work. An example of this is when we inspect centres (for example those that store ovarian cells for future use) when there is also a Human Tissue Authority (HTA) inspection regime. We refer to the HTA inspections in our inspection reports and note if there have been non-compliances against the HTA regime.

What we could do

5.2. Following recent work by the Competition and Markets Authority (CMA) and Advertising Standards Authority (ASA), there is possibility of HFEA licensed clinics coming under another regulator's compliance regime. We should consider how to make patients and other clinic's aware of when another regulator has taken enforcement action. This could be done on the individual clinic page on CaFC, on a separate web page, and / or publicised via social media (which the CMA and ASA already do when taking regulatory action). We would need to ensure we had strong relationships with other regulators to enable us to know when action has been taken against an HFEA licensed clinics so keep our published information up to date.

6. For decision

6.1. Members are asked to consider the issues outlined above and discuss the following options:

6.2. Do nothing – keep publishing inspection reports and licensing decisions as now

6.3. Develop the options outlined in section 4 above to return to a future Authority meeting with more detailed plans following feedback engagement with clinics and patients.

6.4. Only consider options relating to publishing other regulator's decisions (section 5) and return to Authority with options for decision

Annex A: Publishing information: what we do now

Information on clinics is largely found on CaFC, in part through the publication of clinic inspection reports, in part through key measures or statistics drawn from the HFEA Register or licence decisions, and in part from voluntary survey information submitted by patients. We also publish national level performance data in the form of quarterly or annual publications.

What	How	For clinics	For patients
CaFC – inspection rating	Rating is out of 5 and determined by the length of licence. Any clinic (currently x out of x) that has a full 4 year licence has a 5 rating. Text says it is based on inspector's assessment	Most clinics have a 4 year licence and therefore a 5 star rating makes it may make it difficult for high performing clinics to differentiate themselves.	It suggests to patients that most clinics are of an appropriate and similar standard. While that is true, it is difficult for patients to identify high performing clinics, particularly as a single rating does not distinguish between the different elements of a clinic's performance that might guide patient choice. The problem is compounded by the fact that patients may not understand the link between length of licence and levels of compliance.
CaFC – patient rating	Patient feedback and free text	Most clinics conduct their own surveys and the limited number of questions asked on CaFC provide clinics with very little useful additional information	At its best the feedback on CaFC provides an independent source of patient views about a particular clinic, but it is only useful if substantial numbers of patients take part from a broad range of clinics

What	How	For clinics	For patients
CaFC – birth rates in comparison with national average	Tick if consistent with national average	Allows clinics to demonstrate that they are as good as their peers	Provides patients with reassurance that a particular clinic is as good as the national average but detailed statistics can be difficult to make best use of.
Clinic inspection reports	On a clinic by clinic basis	Used to inform a licensing decision, identifies areas of good practice and areas for improvement	A detailed assessment against the standards required to make a licensing decision but very difficult for a lay reader to follow and interpret.
Minutes of every ELP/LC	On a clinic by clinic basis	Effective – as a record of the licensing decision	A record for the licensing decision only; a patient would learn little useful information about the performance of clinic
Publication of overview of common non-compliances	Quarterly non-compliance report published in Clinic Focus	Information targeted at clinics. Drives compliance as clinics can use this as a resource to audit own practices to determine where improvements need to be made	Not visible to patients
Publication of State of the Sector	Annual review of compliance across clinics	Overall picture of sector	Only overall picture of sector, would not enable patients to find any information about clinics
Publication of compliance action such as change in length of licence, suspension or	Through Licence Committee papers	Only specific clinic would see this information	Patients would not necessarily see this information unless they looked through all the

What	How	For clinics	For patients
revocation of licence or change of PR			committee papers on each clinic CaFC page

Annex B: What we could do

What	For who	How	When
Revised inspection report front cover	Written for patients Assessment according to agreed criteria	Clearer for patients Easier to compare between clinics	12 months – to include patient and clinic consultation
CaFC star rating	Could be reviewed to be more nuanced to go with a revised inspection report front cover	Clearer and more meaningful Would take time and money Require consultation? Could be a thematic rating linked to revised inspection report.	Year 3 of current strategy 2023-24 or in future strategy
Categories of non-compliances	Could be easier to understand and compare Tables according to themes in inspection report front cover.	Clearer for patients Easier to compare between clinics Possibly linked with inspection report front cover Or website pages – expanded version of quarterly non-compliance report but on clinic level?	12 months – to include clinic consultation linked to front page of inspection report
Details of enforcement action by the HFEA in accordance	Explain LC decisions in lay language e.g. why length of	If published in easy to find place or on clinic page on CaFC then effective	12 months to include details of actions by LC

What	For who	How	When
with the Compliance and Enforcement Policy	licence reduced, why conditions placed on licence etc	Time lag between decision and publication? Other regulators publicise enforcement action on social media – would we e.g. today HFEA LC reduced the length of clinic X licence because we found x, y and z	
Publicising when enforcement action is being considered in accordance with the Compliance and Enforcement policy	Social media and website information when concerns have been raised	Clear for patients and others to get almost real time information about concerns but could raise worries unnecessarily?	Up to 12 months to consider impact and consultation
CaFC patient ratings	To increase patient feedback, we will be introducing a new process via using our social media channels. This will be done prior to a clinic's renewal inspection. Posts will be put out on social media 4-6 weeks prior to the renewal inspection to encourage patients to provide feedback via CaFC on their experience.	This feedback can be used by the inspectors to gain a greater insight into a patient's experience of using the clinic for the treatment and can also be access by other patients from CaFC.	Autumn 2021