Human Fertilisation & Embryology Authority

Authority meeting

Date and time: 23 September 2021- 1.00pm to 4.00pm

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

Agenda items	Time
1. Welcome, apologies and declarations of interest	1.00pm
2. Minutes of the meeting held 7 July 2021 **For decision**	1.05pm
3. Chair and Chief Executive's report **For information**	1.10pm
4. Committee reports **For information**	1.25pm
5. Performance report **For information**	1.35pm
6. Covid update **For information**	2.00pm
7. Developing the new approach to Inspection **For decision**	2.15pm
8. Licence fee proposals 2022/23 **For discussion**	2.30pm
Break	2.55pm
9. Multiple births **For decision**	3.05pm
10. Treatment add-ons next steps **For discussion**	3.30pm
11. Any other business	3.55pm
12. Close	4.00pm

Minutes of Authority meeting 7 July 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	23 September 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 7 July 2021 as a true record of the meeting		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☒ Low	☐ Medium	☐ High
Annexes			

Minutes of the Authority meeting on 7 July 2021 held at ETC.venues, One Drummond Gate, SW1V 2QQ and via teleconference

	In person	Via teleconference
Members present	Julia Chain, Chair Margaret Gilmore Gudrun Moore Alison Marsden Tim Child Jason Kasraie Catharine Seddon	Anita Bharucha Jonathan Herring Ruth Wilde Yacoub Khalaf Ermal Kirby Emma Cave
Apologies	Anne Lampe	
Observers by teleconference	Marina Pappa (Department of Health and Social Care - DHSC) Steve Pugh, DHSC Csenge Gal, DHSC	
	In person	
Staff in attendance	Peter Thompson Clare Ettinghausen Richard Sydee Catherine Drennan	Paula Robinson Debbie Okutubo Nora Cooke-O'Dowd Emily Tiemann Joanne Anton

Members

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

1. Welcome

1.1. The Chair opened the meeting by welcoming Authority members, observers and staff present both in person and online. She commented that this was the first in-person Authority meeting in 18 months due to the covid restrictions.

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 12 May 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 external stakeholders, as covid restrictions allowed.

3.2. The Chair commented that the HFEA was a UK wide organisation and she aimed to ensure she could visit licensed centres across the UK, including those within the devolved nations.

3.3. The Chief Executive commented on the annual accountability meeting with the Department of Health and Social Care (DHSC) sponsors. He noted that the HFEA was on target to meet the objectives within the business plan and had started to look at challenges ahead.

Decision

3.4. Members noted the Chair and Chief Executive report.

4. Committee Chairs' report

Audit and governance committee (AGC)

4.1. The AGC Chair (Anita Bharucha) presented this item to the Authority. The last formal meeting was on 22 June and the annual report and accounts were presented at the meeting.

4.2. The AGC Chair commented on the delay to the launch of PRISM which was because one of the major third-party API suppliers had asked for a significant delay to complete their work. It was noted that AGC will continue to meet monthly until the launch of PRISM.

4.3. The Authority Chair commented that it was frustrating that PRISM had been delayed.

Statutory Approvals Committee (SAC)

4.4. The SAC Chair (Margaret Gilmore) welcomed Jason Kasraie and Tim Child as new committee members and commented on the use of new PGD terminology (PGT-M) that was presented at the June meeting.

4.5. It was noted that there had been an increase in special direction applications.

4.6. The SAC Chair thanked committee staff for their support.

Scientific and Clinical Advances Advisory Committee (SCAAC)

4.7. The SCAAC Chair (Yacoub Khalaf) summarised the meeting held in June.

4.8. It was noted that an application had been considered to add Endometrial Receptivity Analysis (ERA) to the HFEA list of add-ons and SCAAC will give the add-on a RAG rating recommendation at the October meeting.

4.9. The Authority Chair thanked all Committee Chairs, members and staff and commented that the Licence Committee had not met in the relevant period. In terms of future committee meetings, it was noted that conversations were ongoing as some committees would keep meeting online while some would start to meet in person.

Decision

4.10. Members noted the Committee Chairs' reports.

5. Performance report

5.1. The Chief Executive commented on the recent internal audit of our performance scorecard and KPIs (key performance indicators), and that the auditor had identified a number of reporting errors from teams but that these were not material. Recommendations from the audit were being taken forward.

5.2. It was noted that on human resource issues, sickness levels were rising but were still within the target set. It was further noted that there was one staff member on sick leave who was suffering from long covid.

5.3. Staff turnover was also rising. It was believed that as the economy was improving and there were more job opportunities, some staff would be looking for promotion opportunities elsewhere. This could prove to be problematic, but we were keeping it under review.

5.4. In response to a question on reasons for the resignations, it was noted that there was no evidence from exit interviews that there was any single cause for people leaving.

5.5. Members asked if there was more that could be done to reduce staff turnover and if moving to Stratford was a factor. The Chief Executive responded that conversations were already happening with the other ALBs there in terms of mentoring staff. Also, that we have not been in Stratford long enough for us to measure the effect of moving there. Lastly, that the flexible home and work policy which we have would, we believe, be beneficial to staff.

5.6. In response to a question, it was noted that we have periodic reviews of the KPIs and that the regulatory efficiency indicator measured the performance of the organisation in relation to the end-to-end processing of items beginning with an inspection. This was an administrative measure of HFEA performance, rather than one that captured any sense of continuous improvements in the sector. Defining such a measure of sector improvement would need a wider discussion and consideration alongside our compliance and enforcement approach.

5.7. Regarding the PGT-M data, it was noted that the data presented was purely administrative. The Chief Executive commented that we had been outside the target for a while and we would be revisiting this to understand the reasons for the delay. In response to a question, it was noted that 75 working days was the current target and that it would be kept under review.

5.8. In response to a question, the Chief Executive said pressure on PGT-M was likely to grow as the HFEA licenses new conditions and that testing was getting faster, cheaper and more accurate. All of which suggested an increase in applications and since decisions are made by members, that in itself was limiting as there is only so much of members' time that can be allocated for SAC meetings.

5.9. The Chair of SAC responded that her committee had monthly meetings and asked why PGT-M targets were missed this month. The Chief Executive responded that we would look at the PGT-M KPI again.

5.10. The Authority Chair commented that PGT-M applications would increase as we go forward so modelling will need to be done to ensure that there is no adverse effect on patients.

Strategy and corporate affairs

5.11. The Director of Strategy and Corporate Affairs gave a summary of her area of work. It was noted that we were continuing to make progress against actions in the ethnic diversity in fertility treatment report including: The HFEA Research Manager presented the data to the European Society of Human Reproduction and Embryology (ESHRE) pre-conference which was received with great interest; and we were looking into further work with patients, with Fertility Network, and also through our own means.

5.12. The Patient Engagement Forum (PEF) would be launched very soon and this would be in addition to the existing Professional and Patient Stakeholder groups. It was noted that the purpose of the PEF was to encourage greater participation of, and feedback from, patients in our work.

5.13. It was noted that the Fertility Trends report was launched in May with good engagement and was of particular interest as it covered 30 years of data.

5.14. The Advertising Standards Authority (ASA) and Competition and Markets Authority (CMA) guidance was launched in June and would be discussed later in the meeting.

5.15. The final transition resulting from EU exit occurred at the end of June. All guidance was now up to date, the re-licensing exercise had been completed, and we were happy to report that no problems were encountered. Staff had worked hard for a long period of time on implementing the changes from EU exit and thanks were given to them, as well as those who had overseen a full re-licensing exercise of all HFEA licensed clinics resulting from changes to legislation relating to EU exit.

5.16. The Scottish Government had recently launched a campaign to recruit egg and sperm donors and it would be interesting to see how it develops.

5.17. In response to a question, it was noted that we would try and recruit as large a number as possible to the PEF (up to 100 people plus) as we want particular underrepresented groups to become more involved. There would therefore be targeted recruitment if needed.

Compliance and Information

5.18. The Director of Strategy and Corporate Affairs presented on behalf of the Director of Compliance and Information.

5.19. Members were advised that we were continuing with the risk-based approach for inspections which was combined with a desk-based assessment, but inspectors were also now conducting onsite inspections when needed.

5.20. It was noted that on average 12 inspections per month were carried out. A revised methodology was being worked on as the desk-based approach was very labour intensive and increased workload, which was in addition to onsite inspections. Members were informed that further information would be presented to the Authority in September.

5.21. The Chief Information Officer would be leaving the HFEA later this month and the Senior Management Team had decided to split the role into two – a Chief Technology Officer and a Head of Information, as it was felt that this would better meet the organisation's needs.

5.22. Dan Howard, Chief Information Officer was thanked for his work at the HFEA.

5.23. It was noted that two further temporary staff members had been recruited to the Open the Register Service (OTR) and would be starting at the end of July. There are over 500 applications outstanding and we were receiving 57 applications a month on average. The performance of the team was being monitored as we continue to train new staff members. Members were informed that work was underway on a plan to develop the service operationally so that it is able to meet demand, including how to process applications from 2023. Progress in the team is good and for the first-time last month more applications were processed than received.

5.24. The Authority Chair commented that she had received feedback that the hybrid model of carrying out inspections was working well and that the clinics she had visited had commented that they found it useful and felt that they had a better inspection.

5.25. The splitting of the role of the Chief Information Officer was also welcomed. When recruitment of new Authority members commences, to replace those whose terms of office come to an end in December 2021 or shortly thereafter, we would be looking for a member with experience in big data and information management.

5.26. The Chair commented that 2023 was not far away, and we therefore could not allow the backlog on OTR to get any longer.

5.27. The Chief Executive commented that we were on course to reduce the backlog on OTR and we would report back to the Authority in the Autumn on progress.

Finance and Resources

5.28. The Director of Finance and Resources informed Members that a discussion was held with the DHSC about the HFEA fee regime and the conclusion from it was that an increase in fees was within the remit of the Authority as long as the increase was within reason and the fee regime itself remained unchanged. We would therefore be working up the options for the Authority in the Autumn.

5.29. Regarding the new office, in line with government guidance, the office is open but retains social distancing and covid restrictions. Staff who had attended the new office had given positive feedback and we were looking to hold all our meetings in the new office when it was practical to do so.

5.30. The programme board involving all the arm's-length bodies (ALBs) at the new office would be meeting next week to decide what the next steps would be for staff if the government lifts all restrictions on 19 July.

5.31. Office based staff were being encouraged to attend the new office at least once between now and September 2021 and from September 2021 to attend the office at least one day a week.

5.32. We are also hoping to host the next Authority meeting in our Stratford office.

5.33. In response to a question, it was noted that we do not want to become a virtual organisation and we also needed to avoid isolating staff by continuing to work from home, and so we would continue to explore all possibilities.

5.34. The Director of Finance and Resources confirmed that in terms of commuting costs, the agreement was that we would pay for additional costs for three years to December 2023 for all staff, apart from inspectors who were home-based.

5.35. The Chair commented that it was important that as staff started to attend the office, there was sufficient support from senior staff members.

Decision

5.36. Members noted the performance report.

6. Covid update

6.1. The Director of Strategy and Corporate Affairs presented this item on behalf of The Director of Compliance and Information.

6.2. The summary of all cycles taking place by month in England from January to May in 2021 compared to 2019 was presented. Activity in both the private and NHS sector was good with the private sector being above activity levels compared to 2019 and NHS nearing previous activity levels.

6.3. In terms of NHS funded cycles in 2021 as a proportion of 2019 by nation, it was noted that Northern Ireland went through a downturn but since April 2021 it had started to rise but had not yet caught up with the other nations.

6.4. A revised General Direction 0014 (GD0014) was issued to allow licenced centres to recommence treatments from 11 May 2020. It was noted that the GD specified centres should have a strategy to set out how they would comply with specified guidance to ensure safe and effective treatment could be provided.

6.5. As government restrictions relating to covid change, GD0014 can be left in place as it would have different degrees of relevance for clinics.

6.6. In light of the recent announcement to remove covid restrictions in England from 19 July, we would review and update the information we provide to both patients and clinic staff through our frequently asked questions (FAQs).

Decision

6.7. Members noted the covid update.

7. Code of Practice update

7.1. The Head of Policy and Policy Manager presented this item.

7.2. Members were reminded that we had a statutory duty to produce a Code of Practice and ensure that it was fit for purpose and working effectively. It was noted that members had received drafts of the update in May 2021 and had provided useful comments.

7.3. The timeline of the next few months leading up to the publication of the new guidance was outlined.

7.4. It was noted that proposed changes had been grouped into legislative, least substantive and most substantive changes.

7.5. The legislative changes incorporated the changes in the law since the Code of Practice was last updated in 2019 and these had been communicated to the sector through Chair's letters.

7.6. The least substantive changes were smaller additions to our Code of Practice, mostly incorporating guidance previously communicated through our Clinic Focus newsletter.

7.7. The most substantive changes were amendments to guidance which would be added to the Code in order to build upon and clarify areas of existing guidance.

7.8. The Policy Manager explained that the Authority had adopted a policy which stated that donor gametes should not be used to create more than 10 families (or any lower limit specified by the donor). To respond to questions and for clarity, guidance had been added to guidance note 11 and guidance note 20.

7.9. In September 2019 a Clinic Focus article on e-consenting was issued which has further developed and put into guidance note 5. This included guidance on what we expect from clinics to ensure the e-consenting platforms they use were secure.

7.10. On legal parenthood, guidance note 6 was updated to include the various scenarios that could occur when patients returned to clinics as a single person or with a new partner and how clinics must record patients' status.

7.11. It was noted that guidance 18 had been amended which related to witnessing requiring three identifiers.

7.12. Medicines management was an area in which a high number of non-compliances on inspections are found. Additional guidance in guidance note 25 on the duty of clinics to comply with the relevant regulations and best practice was also updated.

7.13. Members commented that in terms of PGS and PGD and the recent change of terminology to PGT-A and PGT-M, there was a third type not mentioned, although it was recognised that the HFEA was not involved in its licensing. This was PGT-SR.

7.14. A member sought clarity on annex 8 – section 17 – storage of gametes and embryos and asked about the non-mandatory nature of the guidance.

7.15. The Head of Legal commented that a discussion would be held about whether it would be appropriate to change the terminology of parts of the Code from 'should' to 'must', to make it mandatory. Regardless of the wording, in practice clinics recognise the seriousness of cases in which legal action is a realistic prospect or is being threatened and in all cases that the Head of Legal had dealt with, the PR or clinic staff would either contact their inspector who would raise the matter with the Head of Legal, Director of Compliance and Information or the Chief Executive. Very often the clinic's lawyers or lawyers for the patient are involved and would approach the Head of Legal directly.

7.16. Members thanked staff for the very comprehensive piece of work. For legal parenthood there was a suggestion that paragraph 6.38 in the Code be made more prominent due to its complexity and importance.

Decision

7.17. Members approved the changes subject to the inclusion of the suggestions.

8. Fertility Trends

8.1. The Head of Research and Intelligence presented this item. It was noted that there was evidence of a significant increase in fertility treatments over the last 30 years. Birth rates in 2019 were three times higher than in 1991.

8.2. Frozen embryo transfer had increased over time and the use of donor eggs and sperm had increased significantly over the last 30 years.

8.3. There was substantial variation in IVF funding across the UK and we had started to see a decrease in NHS funded cycles among the younger age groups.

8.4. The multiple birth rate in 2019 was at 6%. However, multiple birth rates for patients of black ethnicities remained high.

8.5. Members discussed issues relating to the data and what they would like to understand further in relation to multiple births.

8.6. Members asked how the 10% multiple birth rate target was arrived at. The Chief Executive commented that the target was both realistic and aspirational and had been reduced over time to its present 10%. Progress in reducing multiple births was a combination of good engagement from clinics and the development of protocols from the professional bodies, which were updated and shared with clinics. Over the years, this had led to low multiple birth rates but higher success rates.

8.7. The professional members, when asked to comment on this, suggested that we needed to consider what the tipping point was between multiple birth rate and success rates and ensure that patients were not disadvantaged.

8.8. Also, that the changes still needed to be reviewed regularly. Clinics that were above the 10% target set should be targeted and asked for their minimisation embryo transfer policy to be reviewed as we need to understand why some centres are still not achieving rates of 10% and below.

8.9. We also need to pay close attention to patients that have more than one embryo transferred. We should consolidate around the 10% target and get those clinics who were still above the target to improve their practices.

8.10. Some members asked how the target can be maintained. Members were reminded that all licensed centres must have a multiple births minimisation strategy in place and GD 0003 sets out some basic requirements which need to be adhered to.

8.11. Some members commented that conversations with Black patients in particular would be helpful to understand why multiple births were predominantly in that group.

8.12. The Director of Strategy and Corporate Affairs suggested that a more detailed discussion would be held in the Autumn.

8.13. The Chair suggested that we do not need to alter the target, instead more analysis should be done using what we already know. There may be more work to do with those above the 10% target.

8.14. During the discussion in the Autumn, the paper to be presented should identify the risks of reducing and not reducing multiple birth rates, the weighting of risks in multiple births and in particular risks to any child born.

8.15. Members commented that it might be helpful to analyse data relating to unsuccessful treatments in particular relating to social and economic influences on fertility treatment. However, it was noted that we do not have access to this type of socio-economic data of patients in the Register.

Decision

8.16. To report back to the Authority in the Autumn with the details requested for further discussion.

9. Update on work with the Competition and Markets Authority (CMA) and the Advertising Standards Authority (ASA)

9.1. The Director of Strategy and Corporate Affairs presented this item. It was explained that the Competition and Markets Authority (CMA) set out to provide guidance to enable compliance by clinics and others with existing Consumer Law and the Advertising Standards Authority (ASA) set out to provide guidance to be used by those advertising services. The work had taken place over nearly two years and the HFEA had been closely involved in it. We welcome the work since, given the limitations of our powers in particular the absence of powers of enforcement, by working with other specialist regulators we can deliver benefits to patients.

9.2. It was explained that both the CMA and the ASA would allow time for clinics to review their information after June 2021 and make changes if needed.

9.3. After about six months, they will carry out reviews to see if clinics are compliant and if they found cases of non-compliance then they may take enforcement action.

9.4. In terms of the next steps for the HFEA, it was explained that the CMA and ASA would provide training for our inspectors in relation to the guidance. Even though HFEA inspectors would not review compliance with CMA or ASA rules or legislation, they need to be aware of any issues and know what to do if they spot something, or if a complaint is raised with them.

9.5. Memoranda of Understanding (MOU) and protocols with CMA and ASA would be developed.

9.6. We would also develop proposals on transparency as last discussed with the Authority in May 2021, relating to how others publish information, and we would return to the Authority later this year for further discussion.

9.7. In response to a question, it was noted that conversations were ongoing about the HFEA's role in the CMA and ASA guidance and that we would continue to bring this to the attention of patients.

9.8. In terms of how the guidance had been received by clinics, it was noted that there was initially a concern about how the guidance would be used and the effect of the enforcement powers by the either the CMA or the ASA. Broadly speaking, clinics were waiting to see how this developed.

9.9. Members commented that it was good that there was time for both sets of guidance to be embedded.

9.10. It was noted that the HFEA should continue to publicise the guidance enabling patients to understand that they have consumer rights and that the guidance could lead to a better working relationship between patients and clinics.

9.11. Members suggested that social media campaigns should be kept up by giving patients examples of practices that are not fair.

Decision

9.12. Members noted the CMA and ASA update.

10. Any other business

10.1. There was no other business.

Chair's signature

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

Signature

Chair: Julia Chain

Date: 23 September 2021

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:	23 September 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 July 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:

- 8 July – I observed the Licence Committee meeting
- 22/23/26 July – I chaired the Appeals Committee interviews to appoint new members to the panel
- 27 July – I observed an Executive Licensing Panel meeting
- 27 July – Peter and I had an introductory meeting with William Veineall – Director, NHS Quality, Safety, Investigations - our new senior sponsor at the Department of Health and Social Care (DHSC)
- 20 September – I attended HFEA legal training
- Throughout the period I have also been had numerous conversations with potential applicants to the Board

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

- 28 July – I attended a joint meeting with British Fertility Society (BFS) And Association of Reproductive and Clinical Scientists and HFEA
- 29 July – I attended the Audit & Governance Committee PRISM oversight meeting
- 12 August – I participated in the interview panel for our new Chief Technical Officer
- 12 August – I had an introductory meeting with the new CEO of the Nuffield Council on Bioethics
- 20 September – I attended along with the rest of the Senior Management Team the Quarterly Annual Accountability Meeting with our sponsor team at the DHSC
- Throughout the period I have also been involved in final preparations for the launch of PRISM. I will present an overview at the Authority meeting

Committee reports

Details about this paper

Area(s) of strategy this paper relates to:	The best care/The right information/Shaping the future
Meeting:	Authority
Agenda item:	4
Meeting date:	23 September 2021
Author:	Paula Robinson, Head of Planning and Governance
Annexes	Annex A – Licensing statistics

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. Annex A summarises licensing activity over the past 12 months.

2. Recent committee items considered

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

Meetings held	Items considered	Outcomes
Licence Committee:		
8 July 2021	1 Interim 1 Executive Update	Approved Noted
Other comments:	None	
Executive Licensing Panel:		
29 June 2021	2 Renewals 4 Interims	All granted
13 July 2021	3 Renewals 3 Interims 1 Variation of activities	All granted
27 July 2021	3 Interim 1 Extension of Licence	All granted
10 August 2021	1 Interim 1 Change of Person Responsible 1 Extension of Licence	All granted
24 August 2021	3 Renewals 1 Change of Person Responsible 2 Special Directions	All granted
7 September 2021	1 Renewal 1 Extension of Licence 2 Change of Premises 2 Chance of Centre Name	All granted
Other comments:	None	
Licensing Officer decisions:		
N/A	ITE certificates – 62 Changes of centre name – 7 Changes of Licence Holder – 1	All granted
Other comments:	The high number of ITE certificates is due to EU Exit.	

Meetings held	Items considered	Outcomes
Statutory Approvals Committee:		
24 June 2021	2 PGT-M Applications	All granted
29 July 2021	2 Mitochondrial Donation Applications 2 PGT-M Applications 4 Special Direction Applications	All granted 1 Approved, 1 Adjourned 3 Approved, 1 Adjourned
12 August 2021	3 Special Direction Applications	All granted
26 August 2021	6 PGT-M Applications 2 Special Direction Applications	Awaiting Final Sign-off
Other comments:	An additional meeting was held in August to manage additional applications for Special Directions that would otherwise have been delayed. There is currently a notably high number of Special Direction applications, possibly related to the Covid-19 pandemic (restricting travel options).	
Audit and Governance Committee:		
29 July	Prism oversight meeting	N/A
Other comments:	None.	
Scientific and Clinical Advances Advisory Committee:		
-	-	-
Other comments:	The Committee reported on its June meeting at the July Authority meeting and will next meet on 11 October 2021.	

3. Recommendation

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

Annex A – Licensing Statistics

The following is an annual picture of licensing throughput during the year August 2020 to July 2021.

Key:

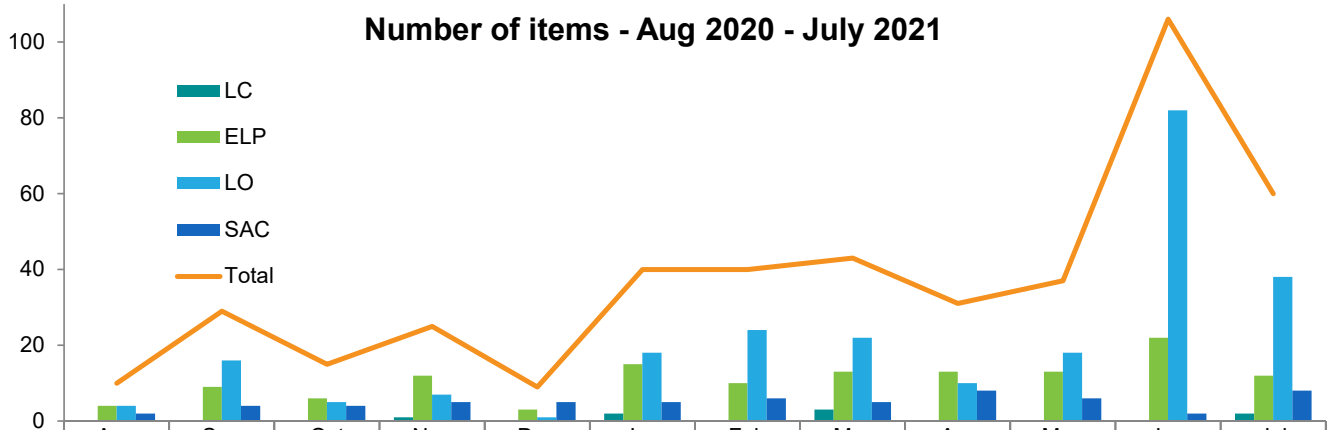
LC – Licence Committee

ELP – Executive Licensing Panel

LO – Licensing Officer

SAC – Statutory Approvals Committee

Overall throughput – by Committee



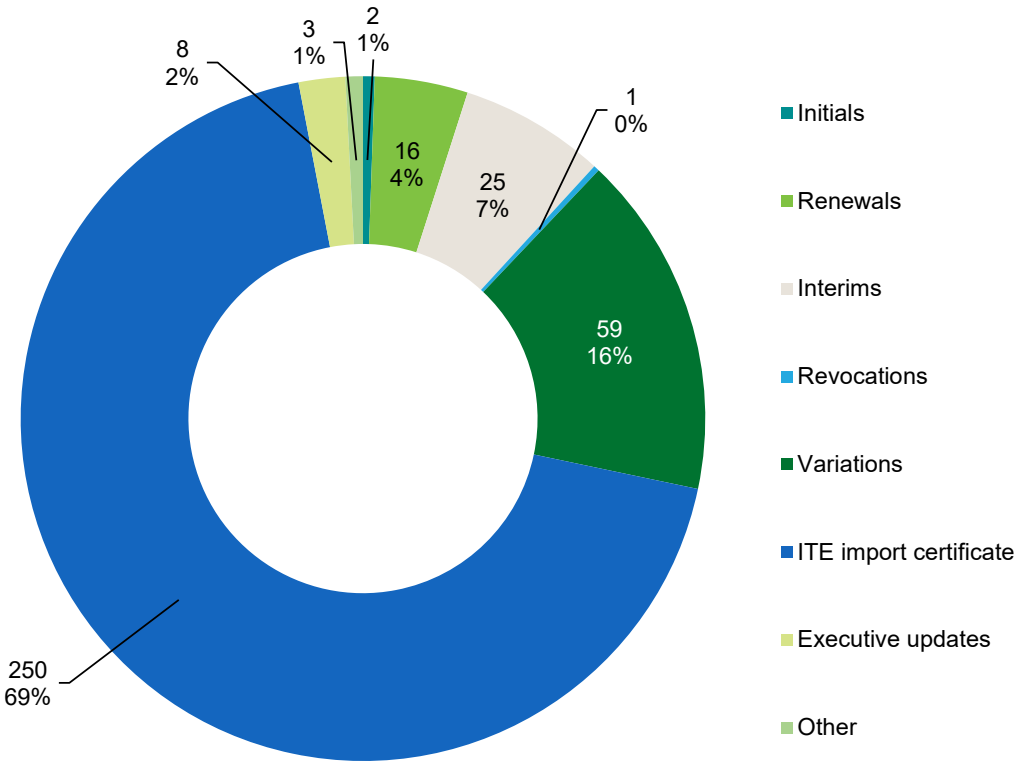
	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul
			2020			2021						
LC	0	0	0	1	0	2	0	3	0	0	0	2
ELP	4	9	6	12	3	15	10	13	13	13	22	12
LO	4	16	5	7	1	18	24	22	10	18	82	38
SAC	2	4	4	5	5	5	6	5	8	6	2	8
Total	10	29	15	25	9	40	40	43	31	37	106	60

The increase in licensing volumes since Covid restrictions were first eased can be seen in this graph, and a notable peak in Licensing Officer activity in June and July. This relates mainly to the issuing of high numbers of importing tissue establishment certificates to clinics at the end of the EU Exit transition period.

The relicensing project was conducted in addition between December and July.

Apart from ITE certificates, the commonest licensing item types during the past year were licence variations and interim and renewal inspection reports. This is illustrated by the pie chart below. Apart from the surge in ITE certificates, this is a typical distribution of item types.

Licensing item types



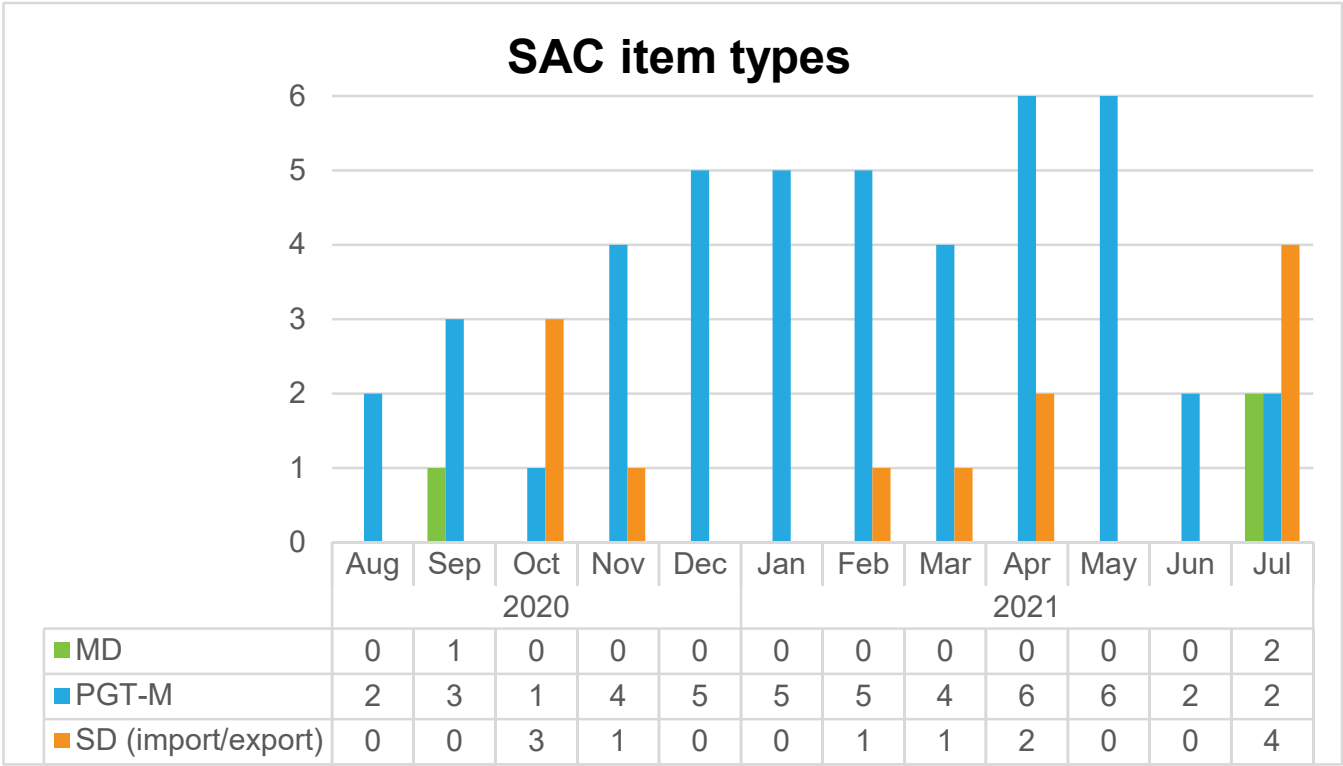
Statutory Approvals Committee item types

Key:

MD – Mitochondrial donation

PGT-M – Preimplantation genetic testing for monogenic/single gene defects

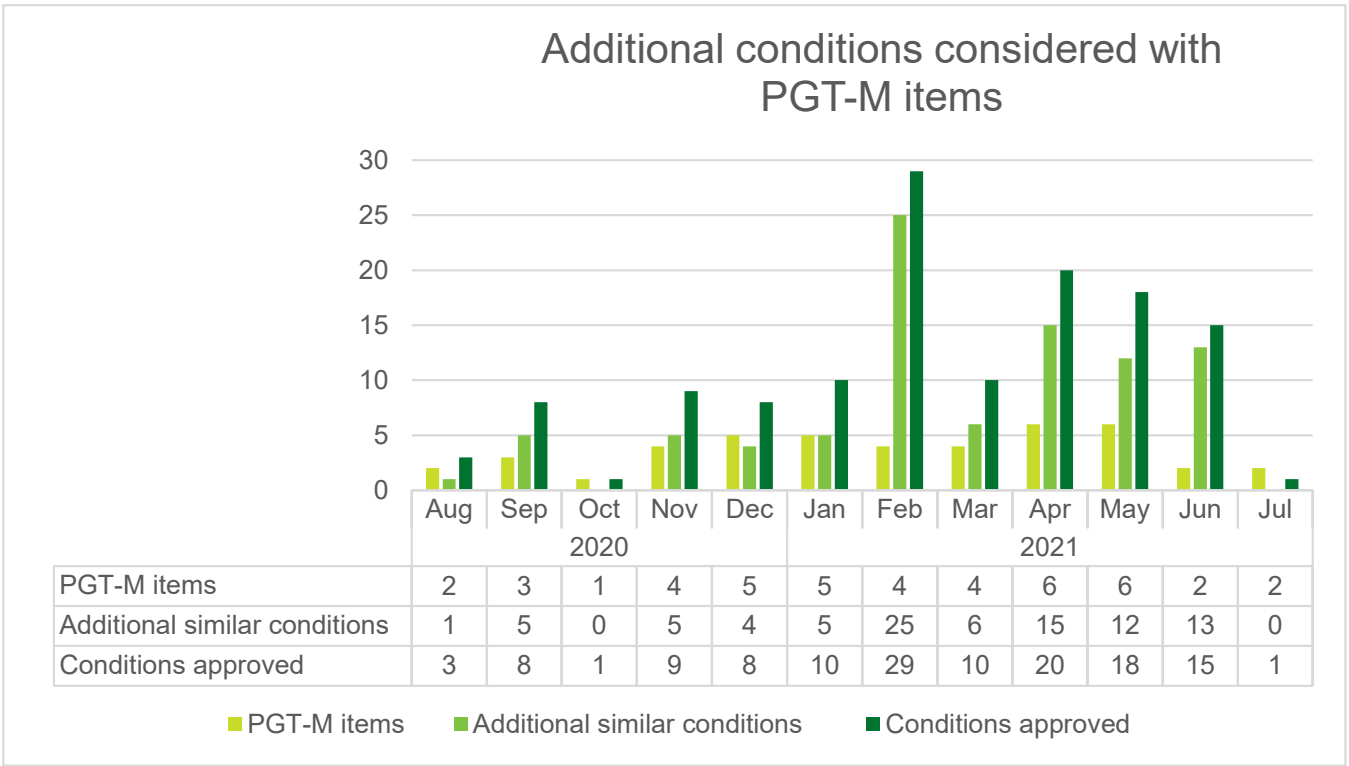
SD – Special directions for the import or export of gametes or embryos



	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul
	2020					2021						
MD	0	1	0	0	0	0	0	0	0	0	0	2
PGT-M	2	3	1	4	5	5	5	4	6	6	2	2
SD (import/export)	0	0	3	1	0	0	1	1	2	0	0	4

The volume of PGT-M applications has increased gradually since Covid restrictions were first eased, and currently remains at a volume comparable to most previous years. Applications for special directions for the import or export of gametes and embryos have increased recently. It is not yet known if this will become a trend.

It is also worth noting that many PGT-M applications include consideration of additional similar conditions:



	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul
	2020					2021						
PGT-M items	2	3	1	4	5	5	4	4	6	6	2	2
Additional similar conditions	1	5	0	5	4	5	25	6	15	12	13	0
Conditions approved	3	8	1	9	8	10	29	10	20	18	15	1

The graph shows how variable the number of additional similar conditions is, with no predictable pattern. The views of the peer reviewer and the committee's expert adviser are taken into account when considering whether to approve additional similar conditions, as relevant.

Performance report

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	5
Meeting date:	23/09/2021
Author:	Helen Crutcher, Risk and Business Planning Manager
Annexes	Annex 1: Performance scorecard Annex 2: Financial management information Annex 3: High level KPIs

Output from this paper

For information or decision?	For information
Recommendation:	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 until July 2021

1.2. Performance was reviewed by SMT via email in August.

2. Key trends

2.1. In July performance was generally good. There were two red indicators in both June and July.

Red indicators - June

2.2. The indicators classed as red are as follows:

- HR1 - Sickness absence
- II1 - Internal Incidents

Red indicators - July

2.3. The indicators classed as red are as follows:

- R2 - Register data errors
- C4 - Mitochondrial donation

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. At its last meeting, Authority members raised some concerns about PGT-M processing performance. At its meeting in July, SMT reviewed trends as at the end of the first quarter, and this included PGT-M end to end processing performance. SMT compared performance against the previous year. In 2020-21 performance was very good, the average across all months reported was 73 working days, green, within target performance.

3.2. Performance so far this year by contrast is amber overall. There have been fluctuations in some months, where processing times have missed our targets and we have on a couple of occasions had a ‘red’ indicator for this KPI, typically because of the added complexity of items, or due to agendas which were full, leading to items being scheduled later. We are keeping this under review and discussions are ongoing to effectively horizon-scan about likely volumes and complexity of PGT-M items in the future, to ensure that the HFEA’s approach continues to enable these complex decisions to be made in the considered, thorough and timely way that they are currently and that our performance targets reflect the reality of the delivery context.

Annex 1 HFEA Performance scorecard and management commentary – July data

Breakdown of total Red, Amber, Green and Neutral Indicators

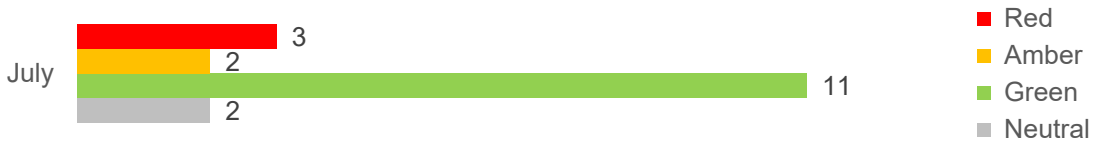


Figure 1 - Fewer red indicators this month

RAG	Area	Trend and key data
Amber – above target	**People -** Employee turnover Target: between 5%-15%	16% turnover 3 leavers
Amber – performance just below 100% target	**Regulatory efficiency -** Time for end-to-end inspection and licensing process Target: 100% in 70 working days or less	94% within target. Average of 69 wds (items beginning with an inspection)
No target – similar level to last month	**Engagement -** HFEA website sessions	61,816 sessions (62,485 in same month last year)

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

Type	Actual in YTD £'000s	Budget YTD £'000s	Variance Actual vs Budget £'000s	Forecast for 2021/22 £'000s	Budget for 2021/22 £'000s	Variance Budget vs Forecast £'000s
Income	**2,417**	**2,315**	**102**	**7,291**	**7,048**	**243**
Expenditure	**(2,112)**	**(2,328)**	**216**	**(6,765)**	**(7,043)**	**278**
Total Surplus/(Deficit)[1]	**305**	**(13)**	**318**	**526**	**5**	**521**

Commentary on financial performance to 31 July 2021

Year to date, we have a surplus against budget of £318k. This is largely due to our income for the first four months being higher than budgeted (£102k). Our expenditure is under budget (£216k) as explained in the detailed commentary.

The adjusted forecast position is currently a surplus against budget of £521k which will be reviewed again in quarter two when activity levels are expected to increase, and a full review of Directorate plans has been undertaken. [1]Figures differ from detailed accounts due to rounding.

Management commentary

In July performance is generally good. We had 3 red indicators. July saw our turnover rate creeping up to nearly 16%, compared to the target of between 5% and 15%, this performance is rated amber. This was expected as Covid-19 restrictions were lifted and the public sector jobs market reopened. We have seen a number of resignations and the completion of several fixed term-contracts. This trend is expected to continue, and it seems likely that this KPI may become red in the coming months.

We were just outside the target on end-to-end inspection and licensing in June, with performance at 94% (amber rated) and average processing within the target days (average of 69 working days). The DBA process, coupled with two new inspectors, a maternity leave and not being able to use external inspectors, put extra stress on the inspection team. The new Compliance and Enforcement Policy has also come into force, which means although it is a more robust process it also takes time to follow and document. There have also been a few complex inspections which have required management review processes. These conditions are being managed carefully by the compliance management team to ensure that where possible we continue to meet our high targets for performance.

In July and August, very few OTR applications have been able to be processed as there was only one fully competent member of the team due to turnover. However, two new starters have been recruited and once they are fully trained, delivery volumes will increase and OTR processing efficiency can again start to be tracked.

Red indicators in July:

Information

- **R2** - **Register data errors** – After a significant reduction in June, we saw the number of errors nearly double (compared to a target of a greater than 5% reduction) in July, or around 3,000 unexpected additional errors. Unfortunately, the increase is real and a coincidence that we have seen a large rise at the same time across approximately seven clinics. This has been investigated by the Register team, who identified the sources of this spike in errors and proactively followed this up with the affected centres. Guidance was provided on how to correct errors as a matter of urgency given the EDI switch off and engagement undertaken with staff at affected centres. Assurances were provided by centres that they would resolve these errors but on reviewing the data, only a small improvement has been made overall as at end August. The clinics each have the list of errors to fix and they have all given undertakings to correct them (and have begun doing so). Whilst EDI is switched off no data will be coming into us, but corrections can still continue being made in the sector. The register team will still have access to the archive of the old register and can continue to offer advice on what caused the errors in the old database.

Compliance

- **C4 - Mitochondrial donation** – Two applications (which had been paused by the centre earlier and restarted) were due for completion in July, but could only go to the July SAC, they were completed in 98 working days compared to a target of 100% being processed in 90 working days.

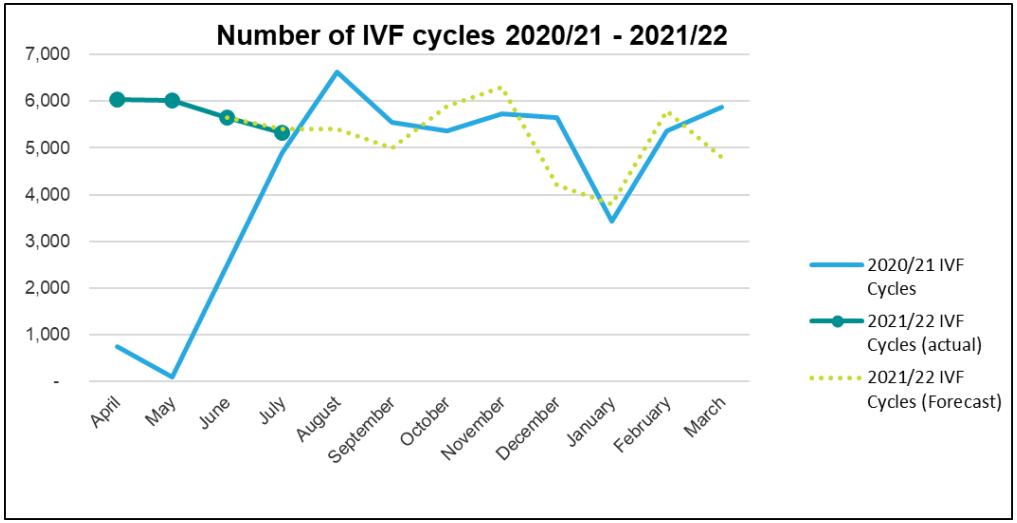
June red indicators:

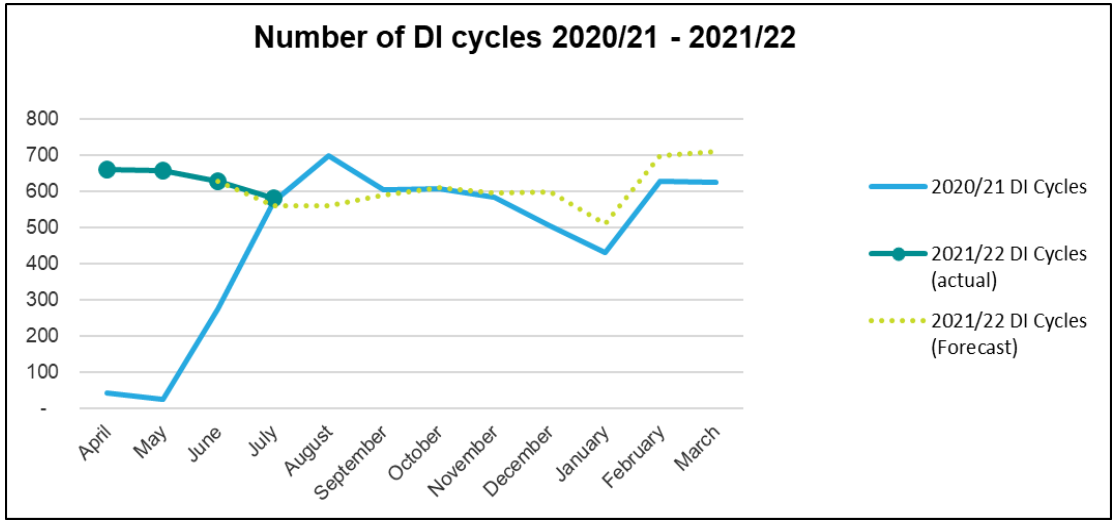
- **HR1 - Sickness absence.** In June, sickness rose to 4.37% compared to a less than 2.5% target. This was composed of one long-term and 18 short-term sickness absences for various reasons. By July, sickness had returned to within target.

- **II1 – Internal Incidents.** In June, the average was very significantly over the target at 158 working days, compared to the target of 30 working days between an incident being raised and closed. Performance was significantly impacted by one incident which was held open for remaining tasks. Our policy is to leave incidents open until all identified actions are taken, but this can delay closure when completion of these takes time. In July, performance was Amber,

with an average of 35 working days for the incidents closed. For context, Internal incidents are those within the HFEA, such as errors in internal processes, they **do not** relate to patient safety or clinical incidents. In both months, performance was hampered by ten working days where the Risk and Business Planning Manager was on sick leave, which affected prompt administrative follow up and closure of these incidents. Crucially, this did not affect the actions taken on the internal incidents, which were taken in a prompt way. We have reminded staff of the importance of providing prompt updates on closure actions, so that the administrative closure takes place swiftly once action is taken. There is obviously room to improve the implementation of the process, but it remains a valuable source of learning and improvement for the organisation. The Risk and Business Planning Manager will be reviewing the process prior to leaving the organisation in October.

Annex 2 Financial management information





IVF Cycles	YTD		YE Position	
	Volume	£	Volume	£
2020/21 IVF Cycles	8,197	655,760	51,795	4,143,600
2021/22 IVF Cycles (actual)	23,031	1,842,480	64,231	5,138,480
Variance	14,834	1,186,720	12,436	994,880

DI Cycles	YTD		YE / Forecast	
	Volume	£	Volume	£
2020/21 DI Cycles	913	34,238	5,598	209,925
2021/22 DI Cycles	2,528	94,800	7,403	277,613
Variance	1,615	60,563	1,805	67,688

IVF cycles continue to exceed those of the previous financial year as expected. If the trend continues, we could see our income levels return to 2018/19 volumes.

As with IVF volumes, DI treatments are up on the same period last year. If this trajectory continues, we could see DI income reach £278k.

Overall, should the current trend in treatment activity continue we could expect to exceed our income forecast by c 4%.

HFEA Income & Expenditure Jul-21

	Year to Date				Full Year		
	Actual £'000	Budget £'000	Variance £'000	Variance YTD %	Forecast £'000	Budget £'000	Variance £'000
Income							
Grant-in-aid	234	275	41	0	1,098	1,098	-
Non-cash (Ring-fenced RDEL)	172	172	-	-	516	516	-
Grant-in-aid - PCSPS contribution	33	33	-	-	100	100	-
Licence Fees	1,943	1,749	(193)	-11%	5,431	5,188	244
Interest received	0	1	0	1	1	2	(1)
Seconded and other income	35	85	50	59	145	145	-
Total Income	2,417	2,315	(102)	**(4)**	**7,291**	**7,048**	**243**
Revenue Costs							
Salaries (excluding Authority)	1,572	1,591	19	1	4,576	4,447	(129)
Staff Travel & Subsistence	12	18	6	31	62	73	11
Other Staff Costs	31	30	(1)	(3)	108	111	3
Authority & Other Committees costs	71	78	7	9	234	234	(0)
Facilities Costs incl non-cash	171	241	70	29	658	954	297
IT Costs	139	213	74	35	576	642	65
Legal / Professional Fees	83	99	16	16	326	339	13
Other Costs	33	58	25	44	226	244	18
Other Project Costs	(1)	-	1	-	-	-	-
Total Revenue Costs	**2,112**	**2,328**	**216**	**9**	**6,765**	**7,043**	**278**
TOTAL Surplus / (Deficit)	**305**	**(13)**	**318**		**526**	**6**	**520**
Adjusted for non-cash income/costs	**203**	**(57)**	**260**		**236**	**6**	**229**

Management commentary

Income.
At the end of period 4 (July 2021), our income remains above budget (11%) by £193k. This relates to the continued increase in treatment fee income. The small variance within our Grant-in-aid is due to budget profiling and will be rectified by March 2022.

Expenditure by exception.
Year to date we are under budget by £216k.

Salary costs - are under budget (£19k), a reflection of the vacancies we carry which are being filled towards the autumn.

Staff Travel and Subsistence - the underspend of £6k reflects the slow return to onsite inspections.

Authority & Other Committee costs - the underspend here relates to the Members' travel and subsistence which are under budget due to many meetings conducted virtually. This does include the cost of the Authority meeting held earlier in July.

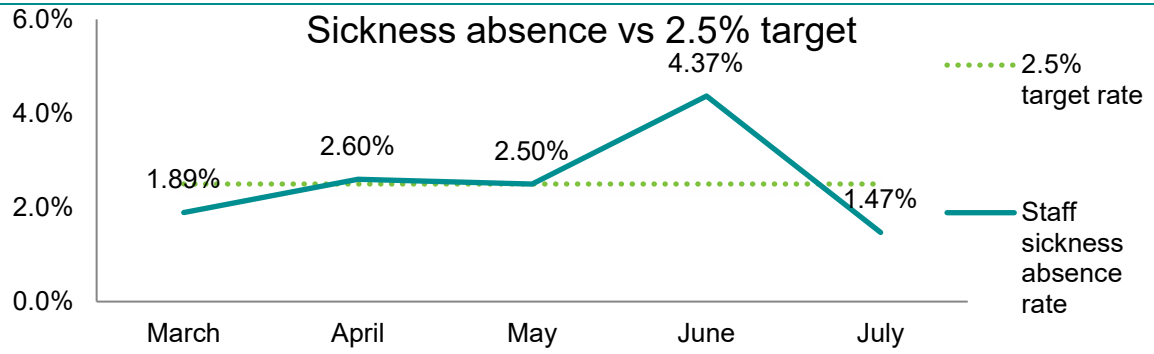
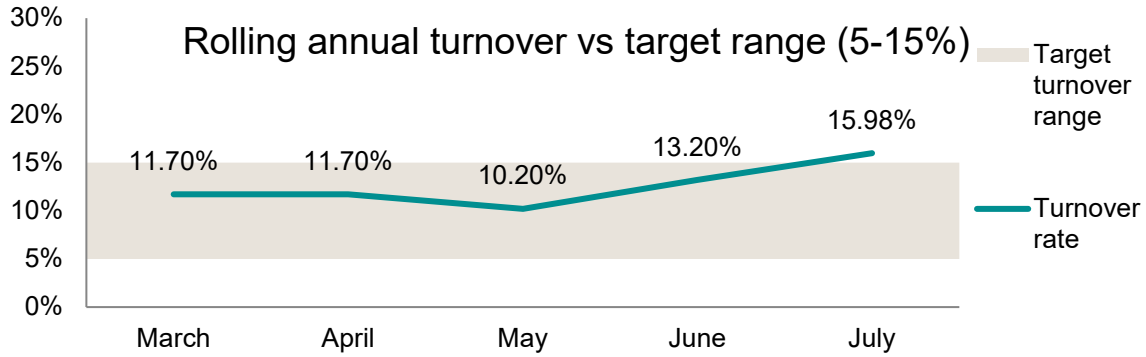
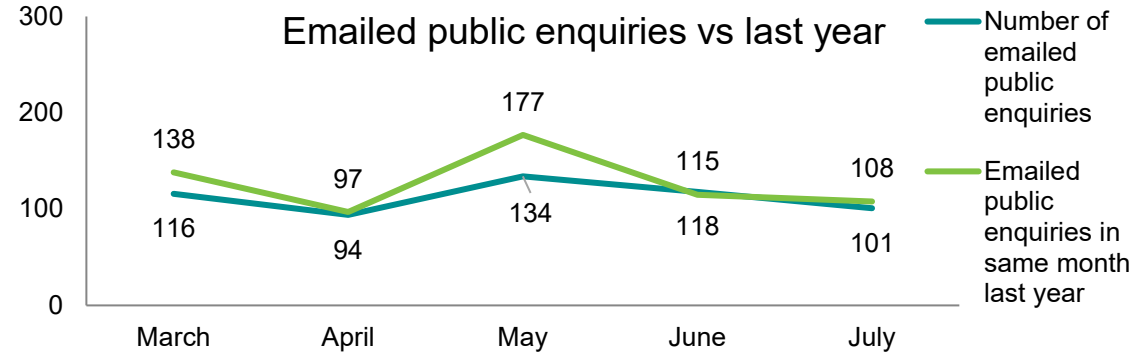
Facilities costs - underspent by £70k the majority (£43k) relates to our accommodation costs for 2 Redman Place. We have yet to be billed by DHSC for these costs. The budget was based on provisional costs provided by DHSC. In addition we have an underspend (£22k) within our non-cash costs. The majority of the underspend relates an asset that has come to the end of its useful life, which reduces our monthly charge by £20k. The budget has been re-profiled to reflect the amortisation of PRISM costs from Q2 when PRISM goes live.

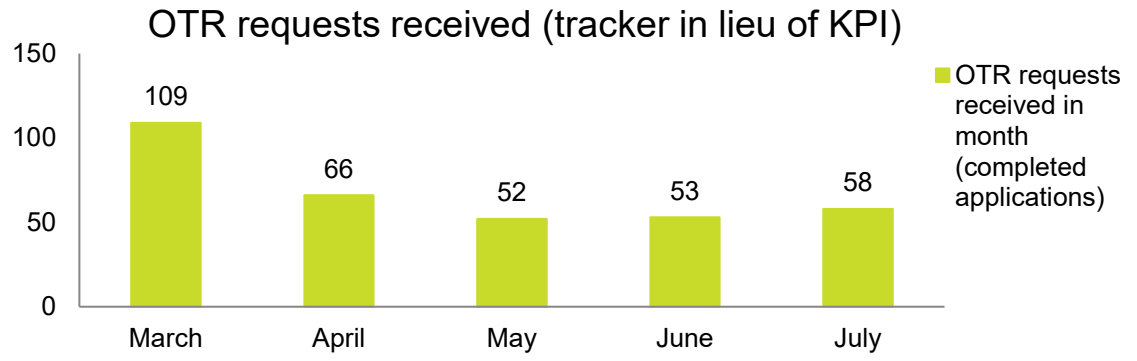
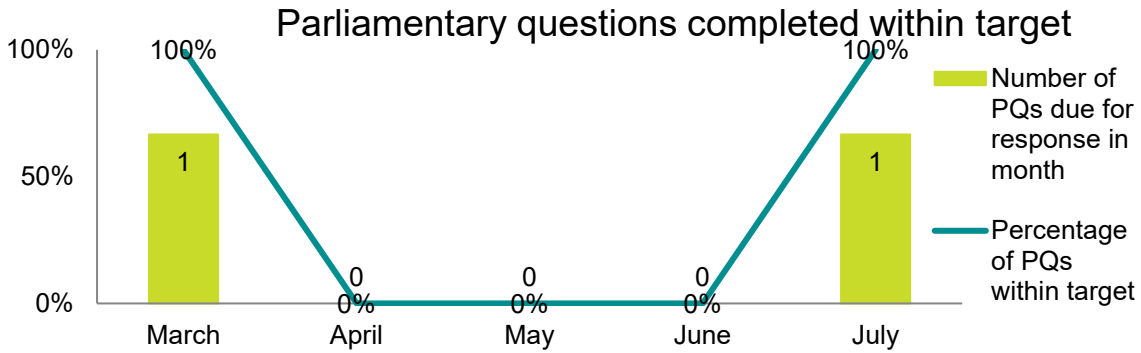
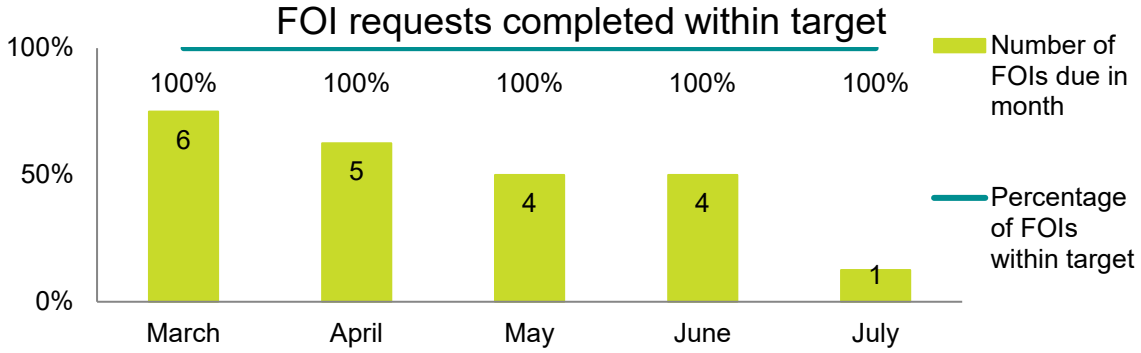
IT Costs - underspent by £74k. The main underspends are within our Telephone and Photocopier costs £8k, Support costs £34k and IT Subscriptions £26k, Internet £7k and Low value assets £1k. Offsetting these is an overspend on consumable of (£2k).

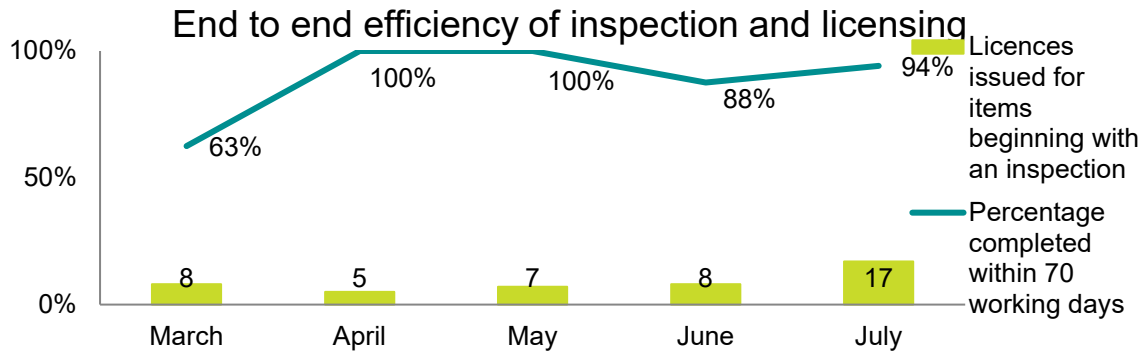
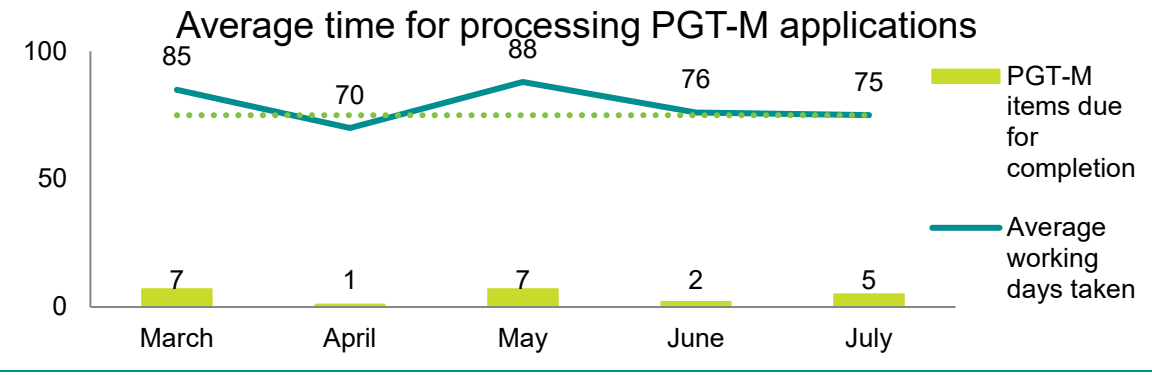
Other Costs - underspend of £25k, the significant variances relate to: Compliance Other which covers the costs of OTR (£9k), Discretionary training (£3k), In addition to the above are underspends within the Strategy and Corporate Affairs directorate, the main item being £4k underspend within the Stakeholder Engagement costs. There are smaller variances across other cost lines.

Forecast.
As at 31 July 2021, we are forecasting a surplus against budget excluding our non-cash costs of £229k.This assumes that our income remains consistent and there are no unexpected costs. A more detailed review will be conducted at quarter two.

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 has stabilised, although one employee remains on long term sick leave.	Green
HR2 - Turnover **Target**: between 5 and 15% turnover for the rolling year.		68 - Headcount 68 - Establishment (posts) Turnover is increasing, 3 leavers this month, although two were end of fixed term contracts.	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.**		We're not currently reporting against a target this is now a tracker – as agreed at Authority October 2020.	Neutral
RI1 – PQs responded to within deadline set (Based on deadlines agreed with DHSC) **Target:** 100% within deadlines set.			Green
RI2 - FOIs responded to within deadline **Target:** 100% within statutory deadlines.			Green

Key performance indicator name and description	Graph showing performance trend for last 5 months	Commentary (if any)	RAG rating
C1 - Efficiency of end-to-end inspection and licensing process. **Target:** 100% within 70 working days (wds). % processed in 70 working days, for items where minutes were sent in month. Measured from inspection date to date minutes sent.		Average working days taken 69 Most days taken: 91 working days Least days taken: 21 working days	Amber
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: 92 working days Least days taken: 66 working days	Green

Developing the new approach to Inspection: Learning from the experience of Covid update

Details about this paper

Area(s) of strategy this paper relates to:	The best care
Meeting:	Authority
Agenda item:	7
Meeting date:	23 September 2021
Author:	Rachel Cutting, Director of Compliance and Information. Sharon Fensome-Rimmer, Chief Inspector.
Annexes	Annex A: HFEA Virtual Inspection Feedback Survey Annex B: Average number and costs for an inspection year.

Output from this paper

For information or decision?	For information
Recommendation:	That members note the continued use of a hybrid approach to inspection and the modifications which have been made to the process. To note the completed actions from the GIAA audit.
Resource implications:	N/A
Implementation date:	
Communication(s):	N/A
Organisational risk:	Medium

1. Overview

1.1. In response to the Covid-19 pandemic the Authority decided that the inspection schedule should be suspended from March 2020. A further decision was taken in August 2020 to resume inspections from November 2020.

1.2. The HFEA has a statutory duty to inspect licensed clinics at least every two years, and moreover that the inspection should involve a visit to the licensed premises. The extraordinary circumstances of the pandemic meant that our decision to not conduct onsite inspections was justified during the first lockdown, but as restrictions lifted new thinking was required of how to meet our statutory duty in a safe and effective manner. This paper sets out the key changes in the inspection methodology used for inspections post November 2020.

1.3. To assess the robustness of the process the new inspection methodology was audited by our internal auditors, the Government Internal Audit Agency (GIAA) in January and February 2021. Their overall finding was 'substantial' (the highest rating that can be awarded), but the GIAA recommended that we should conduct a retrospective evaluation exercise on both internal and external users and conduct an assessment of cost savings.

1.4. The result of that evaluation exercise is set out in sections 5, 6 and 7. Section 8 summarises how the methodology has been refined to ensure the new hybrid inspection process maintains robustness and drives compliance forward in licenced centres.

2. How inspections were conducted pre-Covid-19 and during lockdown

2.1. In considering how to move forward it is helpful to review how inspections were conducted pre Covid-19 and how we modified the process during lockdown to maintain compliance oversight of the sector and to ensure clinics maintained their licence.

2.2. The inspection cycle involves three types of inspection: initial, interim and renewal. Most clinics are usually issued with a four year licence, which reduces work for both clinics and the HFEA given the statutory requirement to inspect at least every two years, although the Act allows for a licence of up to five years. Clinics where significant concerns are raised have more targeted and focussed inspections and may receive a licence for a period shorter than four years if significant problems are identified at a renewal inspection.

2.3. The initial and renewal inspection involves a review of compliance against all requirements of the Human Fertilisation and Embryology Act 1990 (as amended) (the Act) as set out in Licence Conditions, Directions, the Code of Practice, and all applicable statutory provisions. An initial inspection to determine if a centre should receive a licence pre Covid-19 involved 2-3 inspectors for one day, while a licence renewal inspection involved 2-3 inspectors over two days. Less time is required on site for an initial inspection because treatment has not yet started, and more information can be reviewed in the pre-inspection period.

2.4. An interim inspection is normally conducted at the half-way point of a licence, which in the case of a four-year licence is after two years. This type of inspection pre Covid-19 was typically

unannounced and focused on certain elements of the regulatory requirements, involving two inspectors for one day.

2.5. Having decided to suspend inspections from March 2020 a risk-based approach (RBA) was developed for inspections which were due between 18 March and 31 August 2020. This included the fact that the Act, as noted above, allows a licence of up to five years so we could ensure that no clinic was unlicensed.

- **Renewal Inspections**: for centres with a four-year licence with no concerns, the recommendation to the licensing committee was that the licence be extended by one year. For centres with a four-year licence with significant concerns, or with a licence for less than four years, a desk-based analysis (DBA) was undertaken to review the risks of extending the licence by a further year. If extension was deemed inappropriate, it was noted that an inspection should be scheduled when inspections recommence.
- **Interim Inspections:** no interim inspections were to be conducted at clinics with a four-year licence and no concerns. Where inspectors had concerns, the recommendation was for an inspection to be scheduled at the earliest opportunity once it was safe to do so.
- **Initial Inspections:** if appropriate, a DBA of the licence application and virtual inspection were conducted.

3. Key changes in inspection methodology after inspections resumed in November 2020

3.1. In August 2020 the Authority approved the inspection resumption strategy which consisted of a modified approach, incorporating, and adapting, pre-existing inspection techniques. Part of the inspection process requires a significant review of clinic documentation including standard operating procedures, policies, competency assessments and audits. Given the restrictions still in place, it was agreed that there should be a greater use of DBA to allow for offsite review of compliance.

3.2. The process involved sending a modified inspection notebook to PRs 12 weeks prior to the scheduled inspection date. Documented information was then sent electronically to inspectors for review against the requirements specified in the inspection notebook, which consists of guidance and audit templates that aid in assessing compliance.

3.3. A DBA highlights areas of compliance as well as the risks to compliance. The need to further investigate these risk areas dictates the inspector resources allocated to an onsite inspection. During the period from November 2020 to March 2021 when Covid restrictions were in place inspections were conducted virtually where no areas of concern were found from the DBA. Centres where it was deemed further investigation was necessary were visited on site.

4. Findings and recommendations from the GIAA Audit

4.1. In January 2021, the HFEA were audited by the GIAA. The following scope was agreed between the HFEA and GIAA:

- The cyclical inspection process which has operated during 20/21 and the impact of COVID -19, including the introduction of desk -based inspections and the scale of inspections that were undertaken during the year.

- The development of a virtual inspection process which will operate in 2021. The assurance arrangements in place to ensure quality and consistency of inspection activities across licensed establishments, when transitioning from physical to virtual inspections
- The management and reporting of any residual regulatory inspection risks, including any changes to the risk appetite due to COVID -19.

4.2. The result of the audit was a 'substantial' rating (the highest rating awarded); a testimony to the planning and hard work that went into the resumption of inspections. However, the report identified one recommendation 'that HFEA complete a retrospective evaluation exercise when the pandemic is over to establish the extent to which the revisions to the process have been a success and where adjustments may be required. This should include an assessment of cost savings and other efficiencies (medium priority)'.

4.3. This evaluation exercise was conducted in May 2021. The exercise included the following.

- A questionnaire (via survey monkey) of all clinics inspected using the DBA/RBA Virtual inspection approach.
- Individual inspector feedback sessions with the Director of Compliance and Information
- A retrospective evaluation of the cost savings achieved by the implementation of the DBA/RBA virtual inspection approach.

5. PR Feedback

5.1. Overall, the survey results were very positive with most users reporting they had sufficient time to prepare for the inspection along with sufficient communication (15 PRs were asked for feedback. Responses were received from 11).

5.2. Expectations were well managed with users clearly understanding how the new methodology would differ from previous inspections and advice and guidance were clearly disseminated.

5.3. In general, the modified approach has been seen as an improvement with over 80% stating that the new process helped the centre improve the way it worked and achieve better compliance.

5.4. The survey feedback is outlined in Annex A.

6. Inspector Feedback

6.1. Inspectors were invited to arrange individual feedback sessions with the Director of Compliance and Information.

6.2. The majority of inspectors found some challenges in the new approach to inspection. This was mainly around increased workload due to the amount of documentation to review in advance. There was a large degree of variation in the quality of documentation received by inspectors, and this strongly influenced the length of time the DBA took.

6.3. Having multiple inspection notebooks to coordinate at the same time was difficult to manage and when PR engagement was poor it involved multiple emails from inspectors which was again time consuming and inefficient.

6.4. The inspectors who provided feedback all stated that the new approach has multiple benefits. The DBA allows a more in-depth review and allows more specific information to be added into the notebook. An upfront review provides focus and informs further lines of questioning at the inspection.

6.5. The overarching feeling was that the process adds robustness to the inspection process and work is underway to agree a consistent approach across inspectors to manage workload such as utilising the inspectors audit tools so that information is received by inspectors in a consistent format.

7. Cost Benefit Exercise

7.1. A cost benefit exercise was conducted by the Finance and Compliance teams. Using the pre Covid-19 inspection model a typical annual inspection schedule costs upwards of £120k (taking into account travel and accommodation). The annual costs for the hybrid approach are around £82k making a cost saving of approximately £38k. The cost benefit is realised from a reduction in days onsite and travelling. Further details and precise costings can be found at annex B.

8. Current Inspection hybrid approach

8.1. Using the feedback gained from both PRs and inspectors a hybrid approach has been developed to ensure it is both robust and workable in the future.

8.2. The hybrid model will utilise the findings from the DBA to determine inspector resource on site. For centres where there are no major areas of concern inspectors will be able to reduce site time to a single day.

8.3. Now restrictions have been lifted, we will fulfil our statutory duty wherever possible to undertake an onsite visit within a two-year period. However, it is important to note that as deferred inspections are being scheduled into this year it may be justifiable to recommend that a licence is extended to a five year licence where an RBA has deemed a clinic low risk and where we have no concerns to accommodate inspections which must be carried out. This will only be recommended with Director approval.

8.4. The methodology has been recently improved to include the following

- A reduction and refinement in the number of documents and audits requested in advance.
- An emphasis on the PR to engage with the lead inspector. Failure to produce the documents at the necessary time will result in the inspection reverting to an onsite inspection.
- Use of external inspectors to support inspectors with DBA work and inspections (external inspectors have always been used for inspections)

9. For discussion

9.1. Members are asked to note the following:

- Continued use of the DBA and further refined inspection methodology.
- To note that the GIAA actions have been completed.

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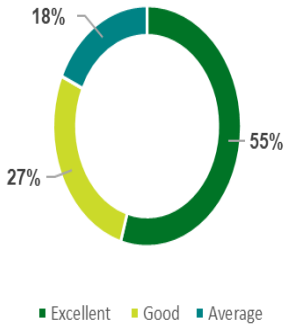
10. Next steps

10.1. It is essential that the inspection process continues to develop and improve. Future focus will involve:

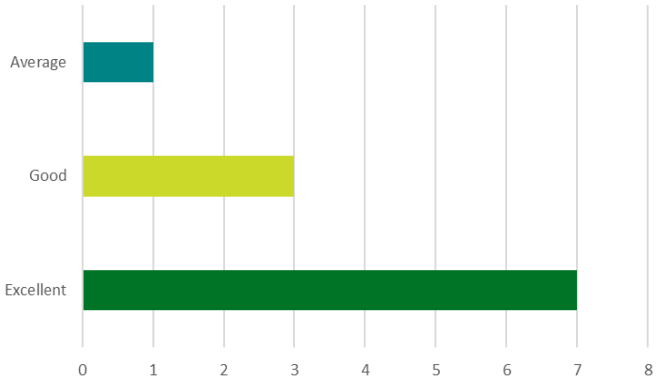
- Further refinement of the documents and audits requested in advance.
- Development of audit tools which will allow clinics to complete audits in advance and submit to inspectors which will ensure documentation is consistent and easier to scrutinise.
- Further implementation of the hybrid approach for interim inspections.

Annexe A- HFEA Virtual Inspection Feedback Survey

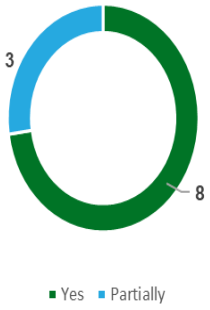
Please rate the notification period provided to you (e.g. was there enough time to prepare for the virtual inspection?)



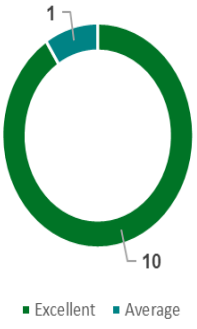
Please rate the advance communications provided to you (e.g. was there enough information to prepare for the virtual inspection?)



Did you understand the expectations for the DBA / virtual inspection, and how the structure would differ from a site visit inspection?



Please rate the approach used by your inspector (e.g. was it open and transparent, was the advice and guidance useful?)



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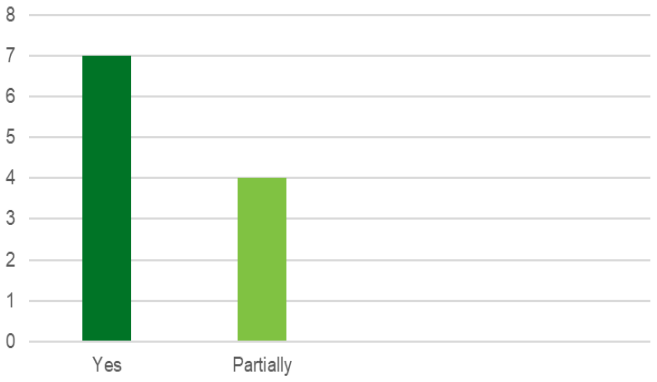
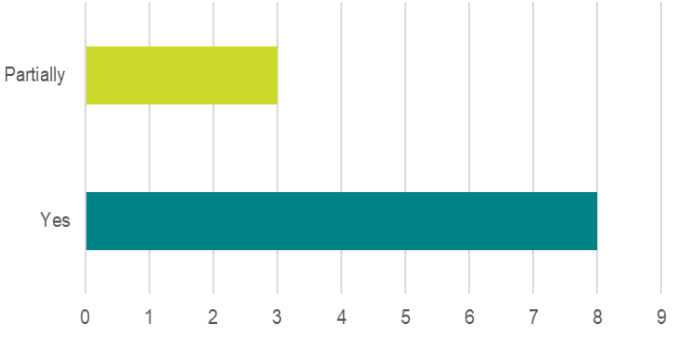
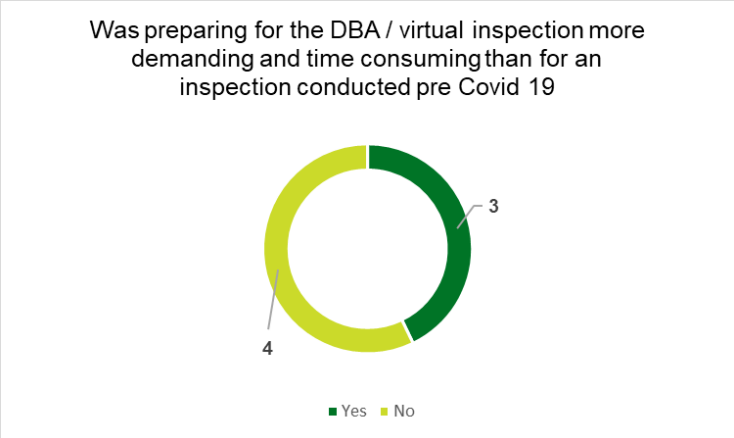
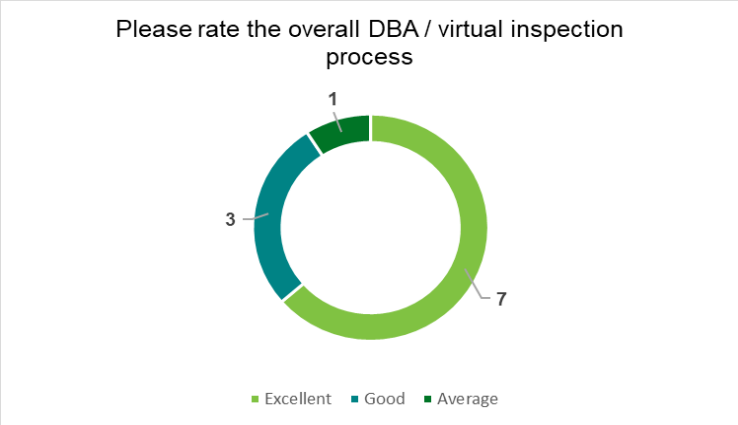
Were you given enough time for the requested documents to be returned to the inspector?

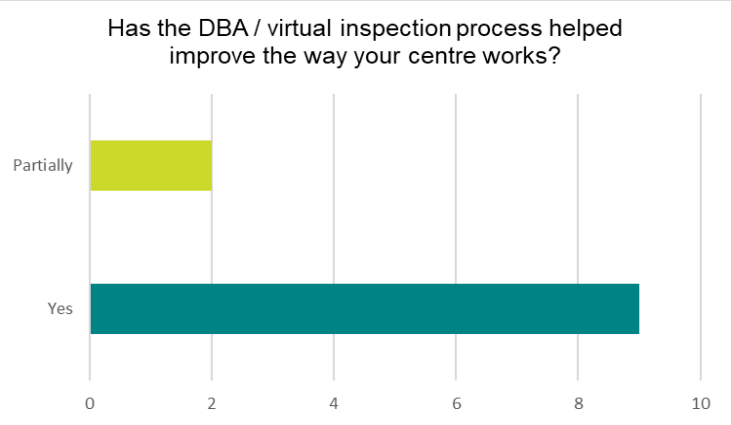


Did the information presented in the feedback meeting provide you with a clear understanding of the DBA / virtual inspection findings?









Annex B- Average number and costs for an inspection year.

Average number of inspections per year	
Total number	99
Treatment & Storage renewals	30
Treatment and Storage interims	37
Treatment and Storage initials	2
Additional inspections	16
Research renewals	4
Research interims	7
Research initials	2
Research variation of premises	1
Average total cost	£119,347.68
*Forecast of costs for an average inspection year using a DBA/RBA hybrid process	£82460

- *An average inspection year using a DBA/RBA hybrid approach will cost £82460. This amount has been forecasted to include a contingency of 30% to allow for targeted, deferred, and initial inspections.
- *This calculation is based on the average cost of a renewal inspection using the previous methodology of 2-3 inspectors for 2 days with a reduction of 50% due to the reduced costs associated with travel and accommodation. There is no change to the cost for interims due to the same allocation of inspectors and days. A contingency of 30% has been included in the costs for when a 2 day inspection may still be appropriate due to lack of PR engagement or concerns over compliance.

Licence fee proposals 2022/23

Details about this paper

Area(s) of strategy this paper relates to:	
Meeting:	Authority
Agenda item:	8
Meeting date:	23 September 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 in principle to increase the HFEA's licence fee
Resource implications:	N/a
Implementation date:	N/a
Communication(s):	Engagement with Licensed Centres and Patient Groups will follow over the Autumn
Organisational risk:	High

1. Introduction

1.1. Following a paper on proposals for a review of the HFEA licence fee structure at its May meeting the Authority requested a further, more detailed paper outlining proposals for an increase in its licence fee from April 2022. Although the Authority agreed in principle that any fundamental reform should be delayed, they were keen to explore the resourcing pressures facing the HFEA over the next two years and the likely impact and benefit that a modest increase in fees would provide.

2. Background & Resource Pressures

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. 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 – both increased demand and the change in the law in 2005 that will increase demand further from early 2022
- 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.

There are other pressures on our horizon that will also need to be managed, but these are not currently fully formed.

2.4. We have taken an increase to both our IT staff and OTR staff at risk for 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 what has been over the opening 4 months of this business year higher than anticipated treatment activity.

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. Annex A set out in more detail the staffing requirement, but in total it is estimated that £250k will be required in 2022/23 if the HFEA is to achieve its BAU regulatory oversight and improve its data provision and responsiveness to stakeholders.

2.6. In the May 2021 meeting the Authority acknowledged the need to revisit our licences fee model to better reflect the cost and drivers of regulation in the future. This will not be rushed and there will be further modelling of regulatory drivers and license fee models through this strategic period.

However, given the emerging pressures you were keen to understand how an immediate increase in the HFEA licence fee might fund your priorities.

3. Proposals for an increase in the existing licence fee

3.1. Annex 2 sets out prospective yields based on activity and price increase scenarios. For illustrative purposes an increase in the Licence fee for an IVF cycle of £5 (moving the licence fee from £80 to £85 and representing a 6.25% increase in the fee) would, based on our forecast activity level for 2021/22 of 64,231 treatment cycles, yield additional licence fee income of £321k.

3.2. Any proposed increase should be considered in the context of general economic growth and price inflation over the same period, as previously outlined the CPI has increased by 10.8% over the past 5 ½ years whilst HFEA fees have remained static.

3.3. Our licence fee is charged to clinics providing fertility treatment and not to patients, although we acknowledge it is likely that a number of private treatment providers would look to pass this cost through to patients in the fees they charge. In terms of the impact of a £5 licence fee increase on the full cost of a privately funded IVF cycle this would represent an increase of 0.15% percent on a cycle costing £3500 and less than 0.1% on treatment cycles costing above £5000.

3.4. Any proposed licence fee increase is complicated by the volatility in treatment activity. Prior to the pandemic we had started to see a small decrease in activity that attracts a licence fee, but activity over the past 9 months has been above the levels we saw in 2019/20. In broad terms a 1% increase in licensable activity would generate increased income comparable to a £1 increase in the IVF licence fee.

4. Spending Review 2021 & Reserves

4.1. The Chancellor of the Exchequer recently announced that SR 21 would conclude in November 2021. As part of this process the HFEA have made a submission to its sponsor department for continued GIA at existing levels and for funding for additional pressures relating to dual regulation. We have not included the pressures outlined in section 2 in our SR submission as they do not fall within the envelope of activity funded by GIA. Once our GIA allocation for 2022/23 and beyond is confirmed through this process we will adjust the level of pressure we model in our budgets.

4.2. 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. Should the Authority decide to propose a fee increase a submission would be made to DHSC and HMT for agreement with the intention of returning to the Authority in November for a final decision. This is not a given and any case presented to HMT would need to demonstrate both that it would not be possible to reprioritise deliverables and resources within our current funding envelope and that we would not simply be passing our financial pressure on to the NHS.

4.3. The HFEA continues to hold significant cash reserves, we have outlined previously the Government accounting rules that prevent us from unilaterally accessing these reserves. As in previous years we have raised a desire to access these funds with DHSC colleagues, with a specific aim of utilising our reserves to fund IT infrastructure improvements that will directly support the better use of data for regulation and as information to stakeholders and patients.

4.4. Our preference would always be for greater flexibility in access to our cash reserves, to allow us smooth out the variations in income over a strategic period. The HFEA requires a permanent increase in its staffing levels in order to respond to increased demand, this could be affordable if treatment activity increases and remains at 2-3% points higher than 2019/20 levels, but this is not certain. The ability to plan expenditure on this assumption but with flexibility to utilise our cash reserves to balance our income position should activity fall below forecast levels would negate the need for a fee increase ahead of a review of our fee model.

5. For discussion

5.1. Members are asked to:

- consider the proposals for an increase HFEA License Fees from 2022/23
- confirm whether they wish the executive to proceed to discussions with DHSC and HMT on a fee increase.

Annex A – Additional Staffing requirement 2022/23

Compliance Directorate

Technology

Head of Information Technology (Split of CIO role into Head of IT and Head of Information)

Junior Developer

Donor Information Team

2 x Donor information Officers

Strategy & Corporate Affairs Directorate

Data and Intelligence Team

Research Manager

Annex B – Additional licence fee income, IVF treatment cycles by £1 increments

		Number of Treatment Cycles							
		10,000	**20,000**	**30,000**	**40,000**	**50,000**	**60,000**	**70,000**	**80,000**
£ increase	**£1**	10,000	20,000	30,000	40,000	50,000	60,000	70,000	80,000
	£2	20,000	40,000	60,000	80,000	100,000	120,000	140,000	160,000
	£3	30,000	60,000	90,000	120,000	150,000	180,000	210,000	240,000
	£4	40,000	80,000	120,000	160,000	200,000	240,000	280,000	320,000
	£5	50,000	100,000	150,000	200,000	250,000	300,000	350,000	400,000

Multiple births: update on what has been achieved and looking ahead to the future

Details about this paper

Area(s) of strategy this paper relates to:	The best care/The right information
Meeting:	Authority
Agenda item:	9
Meeting date:	23 September 2021
Author:	Niamh Marren, Regulatory Policy Manager Amanda Evans, Research Manager
Annexes	Annex A: Demographic differences Annex B: International comparison of multiple birth trends Annex C: Multiple births Minimisation strategy

Output from this paper

For information or decision?	For decision
Recommendation:	Members are asked to discuss the options identified in the paper regarding the future of the multiple birth policy: • Maintain the 10% multiple births policy and continue to monitor on inspection • Review General Directions and Code of Practice guidance and consideration of other regulatory levers that could be engaged to promote compliance with the target with a view to tightening the requirements placed on those clinics which do not meet the target • Open discussions with key stakeholders, patients and clinics, with the aim of reviewing the 10% target (given that is now 6% nationally) and having a lower target at some future point • Encourage clinics to be mindful of their multiple birth minimisation strategy in relation to patients from ethnic groups

Resource implications:	Depending on the option(s) agreed by the Members this work would require input from policy, intelligence and compliance teams. This would require availability of these resources.
Implementation date:	Depending on the option(s) agreed
Communication(s):	Clinic Focus/Chairs letter/Website updates and information for patients - depending on what option(s) are agreed by the Members
Organisational risk:	Medium

1. Introduction

1.1. Over the last 30 years the multiple birth rate (MBR) from IVF treatment in the UK has decreased significantly, from around 28% in the 1990s to an average of 6% in 2019. This success is due to the now standard practice of transferring a single embryo during treatment, which was encouraged by the 'One at a time' campaign led by the HFEA and the professional societies from 2007. Success rates have also continued to rise while the MBR has fallen.

1.2. The reduction in multiple births from IVF has been a huge public policy success in relation to the health of mothers and babies and the reduction in costs to the NHS of multiple pregnancies and any follow up health issues.

1.3. This paper provides an overview of the development and implementation of the multiple births policy and looks to what the future of that policy should be now that the MBR target of 10% has been surpassed.

1.4. Section 2 briefly provides some background to the medical impact of multiple births; section 3 sets out the history of policy development in this area in the UK; section 4 looks at monitoring and compliance with the policy; section 5 looks at some of the demographic differences in multiple births; and section 6 outlines some options going forward.

1.5. A detailed statistical overview will be presented to Authority at the meeting which looks at the changes over time and is outlined in Annex A.

2. Background

2.1. Multiple births remain a health risk for IVF patients and babies, resulting in increased maternal and childhood morbidity. A multiple pregnancy increases the risk of stillbirth, neonatal death and disability. Compared with singletons, twins are four times more likely to die in pregnancy, seven times more likely to die shortly after birth, ten times more likely to be admitted to a neonatal special care unit and have six times the risk of cerebral palsy. Maternal morbidity and mortality are also increased due to late miscarriage, high blood pressure, pre-eclampsia and haemorrhage[1].

2.2. Care of pregnancies leading to twin or higher order births is almost three times as expensive for the NHS as the cost of care for singleton pregnancies.

3. History of the multiple birth policy

3.1. As noted above, in the 1990s the multiple birth rate in the UK from IVF was around 28%. The risk of a multiple birth is in large part determined by the number of embryos transferred back during IVF treatment. In the 1990s, three embryos were put back in more than half of IVF cycles, and a majority of the remaining transfers involved two embryos. In 1991, just 13% of

[1] Braude, P. (2006) One child at a time: Reducing multiple births after IVF *Report of the Expert Group on Multiple Births after IVF* http://www.hfea.gov.uk/docs/MBSET_report_Final_Dec_06.pdf

cycles had one embryo put back (known as single embryo transfer or SET). Annex A shows in more detail changes to the UK multiple birth rate over time.

3.2. The HFEA was concerned about the risks of multiple births from the early 2000s, culminating in the introduction of restrictions on triple embryo transfer in 2003, which banned the use of triple embryos in younger women.

3.3. In the early 2000s, the HFEA looked at what other countries had done to reduce their MBR and commissioned a group of fertility and public health experts to report on the risks of multiple births from fertility treatment culminating in the publication in 2006 of the **One child at a time report**. The HFEA then ran a consultation on how we could regulate the MBR in 2007.

3.4. The 'One at a time' campaign encouraged clinics to transfer back one embryo and freeze any remaining embryos for good prognosis IVF patients. The combination of these policies and concerted efforts across the fertility sector led to fewer double and triple embryo transfers, and fewer multiple births as a result.

3.5. As part of the 'One at a Time' campaign, a consensus statement with the fertility sector's key stakeholders was established and the HFEA introduced a multiple birth target in 2009 which licensed clinics were expected to meet (subject to statistically significant variation). Clinics were also required to develop their own SET policies (what were termed multiple births minimisation strategies) to ensure that they could meet the multiple births target given their local circumstances. This collaboration between the HFEA and the sector encouraged the sharing of best practice and developing professional guidance, publishing information for patients and professionals about multiple births and SET and improving NHS provision of fertility treatment.

3.6. The multiple birth rate target introduced in 2009 was progressively reduced over time. The current of target of 10% has been in place since 2012 and was achieved for the first time in 2017. Since then, the rate has fallen further, to just 6% in 2019. Notably, the continued decline in the multiple birth rate has not had a negative effect on the pregnancy rate which has continued to increase. Despite this, there are still concerns among some clinicians that putting back multiple embryos is necessary to give the best chance of success.

4. Monitoring and compliance

4.1. Most HFEA licensed fertility clinics have embraced the policy to reduce the MBR and have changed their practices over time. They understand that SET is an effective policy and will discuss the risks of multiple births with their patients. However, when the MBR target was initially implemented it was not welcomed by everyone working in the sector. As noted above, some believed that SET would reduce the birth rate and that patients wishing to have a multiple birth would be unhappy and seek treatment elsewhere.

4.2. HFEA inspectors monitor each clinic's progress and give them early warning if they are likely to miss the target. In addition, multiple birth rates are reviewed at every clinic inspection and reported on in every inspection report, which is published on our website. The clinic's multiple birth rate is also a headline indicator on the Choose a Fertility Clinic section of our website.

4.3. In 2019, of all clinics with more than 150 cycles, 80% of clinics had a MBR below 10%, with 24 clinics at less than 5% and 41 clinics between 5-9%. Just four clinics have a MBR that is considerably above the target at above 15%. Although HFEA inspectors are actively engaging with clinics who have non-compliances with relation to multiple births, we are 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.

4.4. The requirement on clinics to have a multiple births minimisation strategy is contained in General Directions 0003 and guidance in our Code of Practice (December 2019). There is an example of a multiple birth minimisation strategy from the Centre for Reproductive and Genetic Health in Annex C which can be used to show best practice.

4.5. Part of the success of the policy to reduce multiple births rests on the use of regulatory 'soft power' alongside limited 'hard' rules. We have worked with clinics over the years by providing best practice examples, facilitating multiple birth workshops, as well as updating the inspection process and code of practice guidance when required.

5. Demographic differences

5.1. There are two principal demographic influences on multiple birth rates: age and ethnicity. The figures in Annex A sets out the differences in detail:

- Multiple birth rate has decreased over time
- Single embryo transfers are increasing
- Multiple births decreased most for youngest and oldest ages
- Multiple birth rate is highest among younger patients receiving double embryo transfer (DET)
- 18% of IVF cycles for patients under 35 used double embryo transfers
- Multiple birth rates higher with donor eggs
- Multiple birth rates are higher for patients of Black ethnicities
- Multiple embryo transfers more common among Black patients
- Multiple births higher in some regions
- 80% of clinics had multiple birth rates below 10% in 2019
- Younger patients had higher multiple births with private funded cycles
- Multiple embryo transfers in younger patients did not increase birth rates

5.2. In the UK, the MBR in each age group decreased across all groups from 2007 to 2019 to under 10% target. In 2019, the 38-42 years age group had the highest proportion of multiple births. The MBR was greater among the younger patients who received a DET.

5.3. The HFEA's report on Ethnic diversity in fertility treatment highlighted that the multiple birth rate varied by ethnicity. Between 2014-18, Black patients experienced higher than average multiple births. Black patients had the highest rate of multiple embryo transfer (46% of cycles) over that same period, while White patients had the lowest (38%). Patients of Other ethnicities had the second highest rate of multiple embryo transfers at 45% of cycles, followed by Mixed patients at 41% and Asian patients at 39% of cycles.

5.4. While all clinics should have a multiple birth minimisation strategy in place, clinics should be mindful of the higher multiple birth rate in certain ethnic groups and complete a review of their multiple birth policy where necessary. Black patients are typically a bit older that other patients when they first start treatment and this may explain in part why Black patients receive more multiple embryo transfers than other ethnic groups during that period.

6. Looking ahead

6.1. The policy to reduce multiple births has been a great success. Initial views from the sector are that the policy works well at present and a newer lower target is not required to drive further progress. However, looking ahead, the Authority is asked to discuss the following options regarding the future of the multiple birth policy

A) Maintain the 10% multiple births policy and continue to monitor on inspection
B) Review General Directions and Code of Practice guidance and consideration of other regulatory levers that could be engaged to promote compliance with the target with a view tightening the requirements placed on those clinics which do not meet the target
C) Open discussions with key stakeholders, patients and clinics, with the aim of reviewing the 10% target (given that is now 6% nationally) and having a lower target at some future point
D) Encourage clinics to be mindful of their multiple birth minimisation strategy in relation to patients from ethnic groups.

Annex A: Demographic differences

Figure 1. Average multiple birth rate, 1991-2019

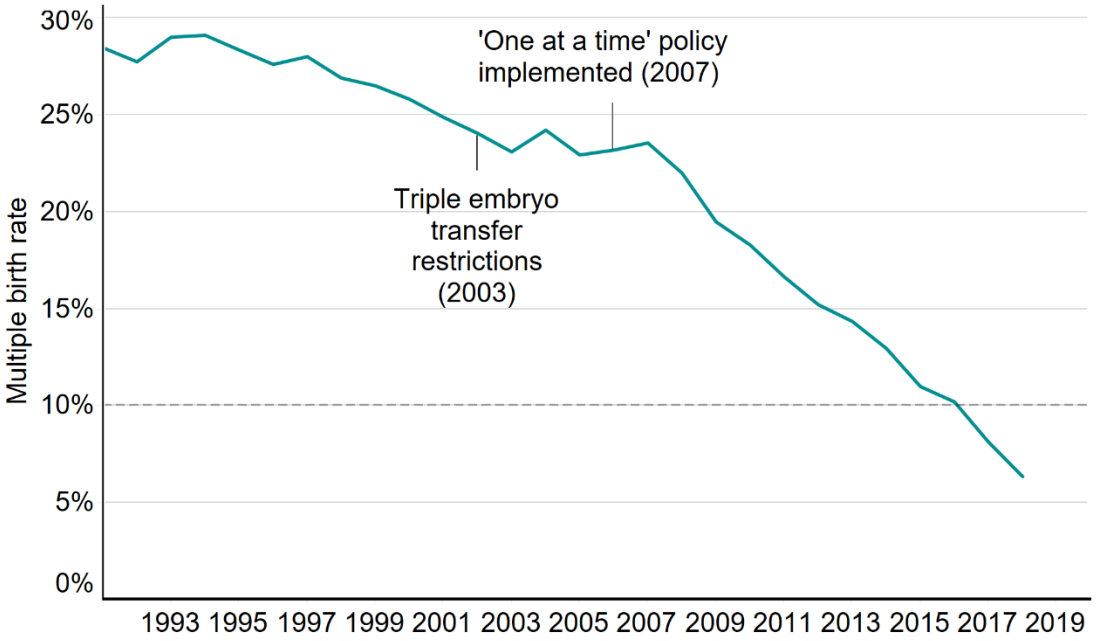


Figure 2 Proportion of single, double and triple embryo transfers, 1991-2019

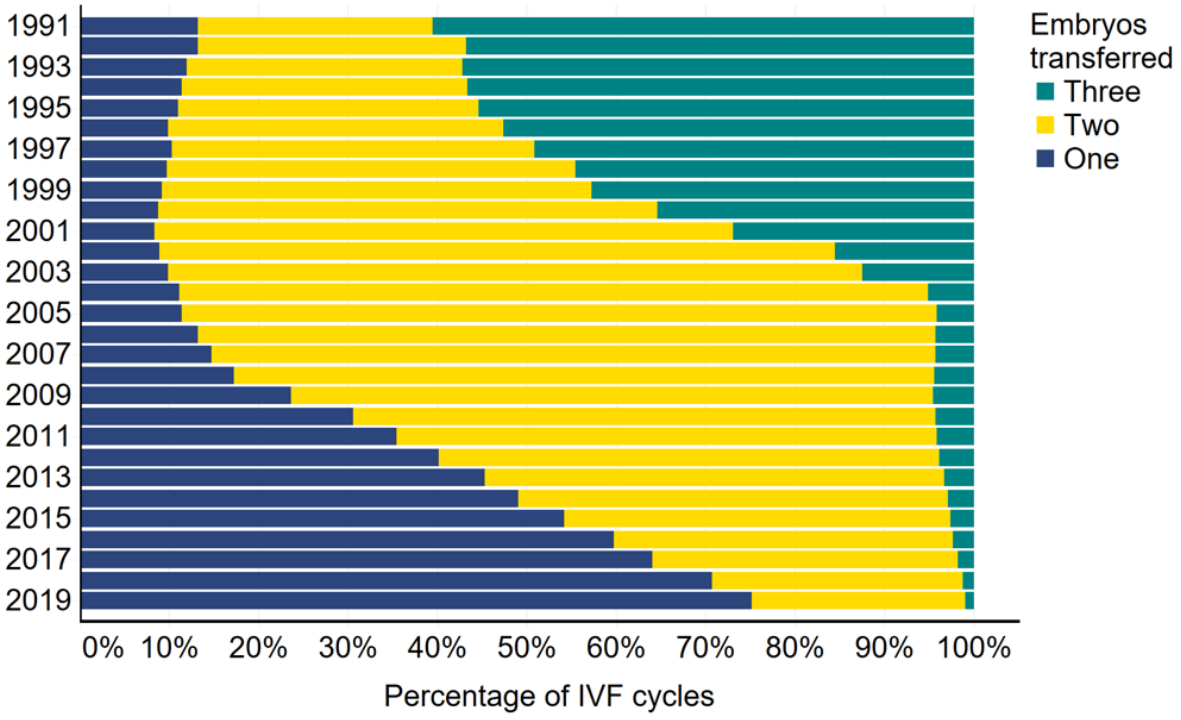


Figure 3. Average multiple birth rate by age, 2019 compared to 2009

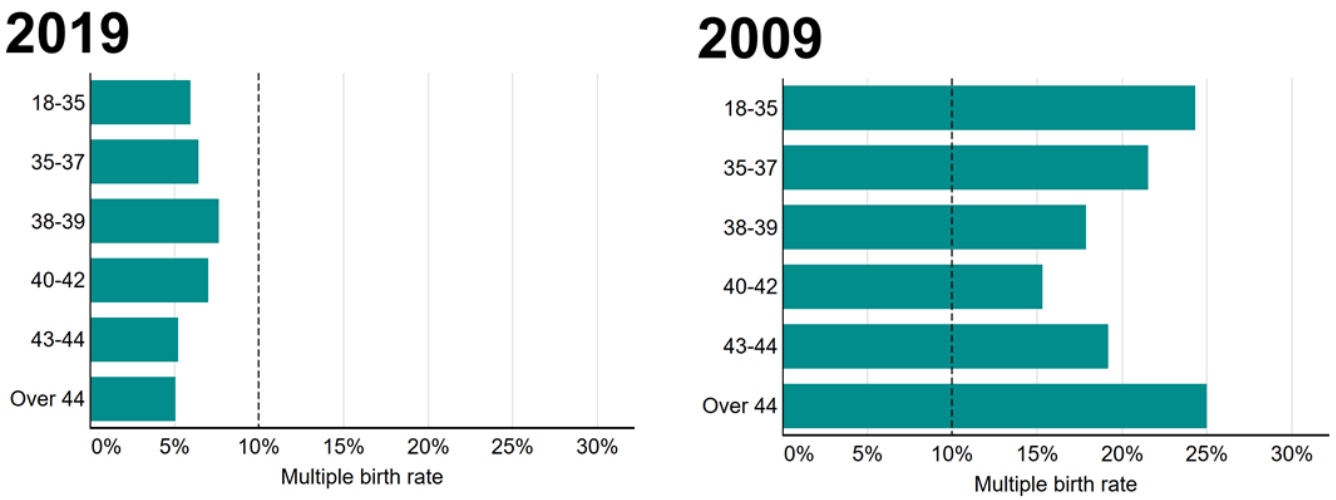


Figure 4 Multiple birth rate by patient age and embryos transferred, 2015-2019

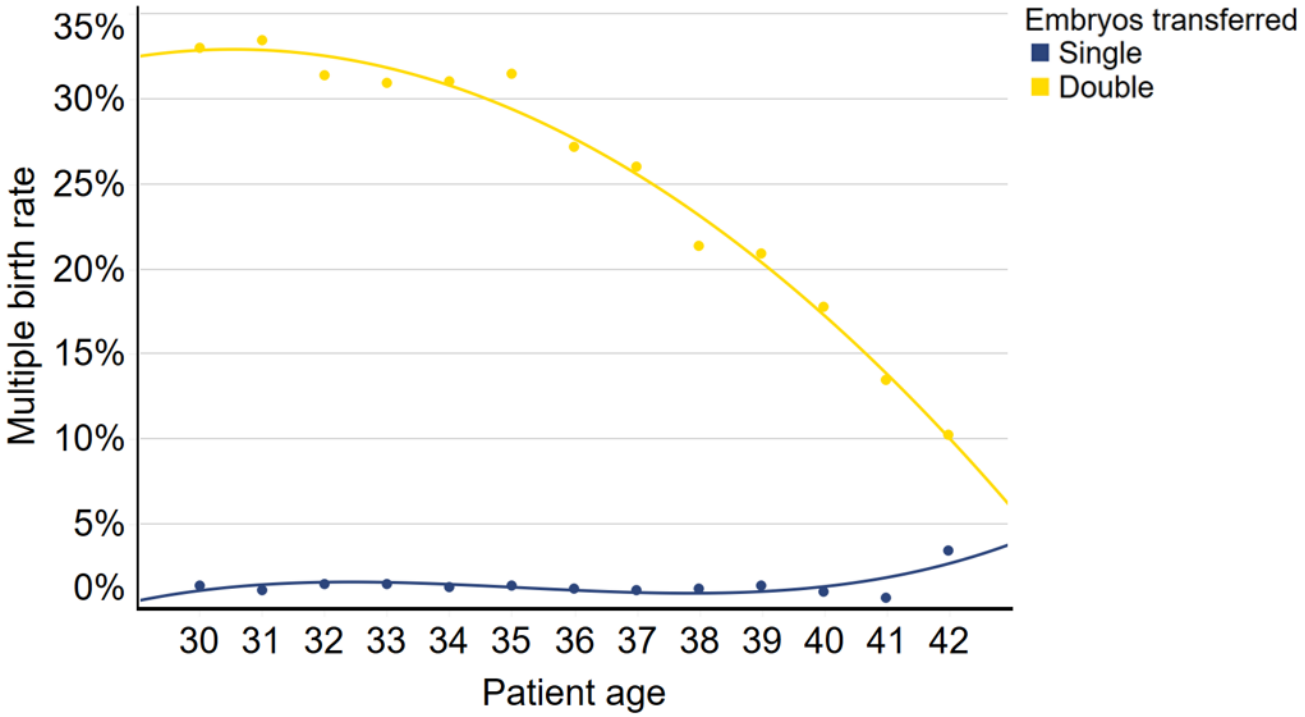


Figure 5 Embryos transferred by patient age, 2019

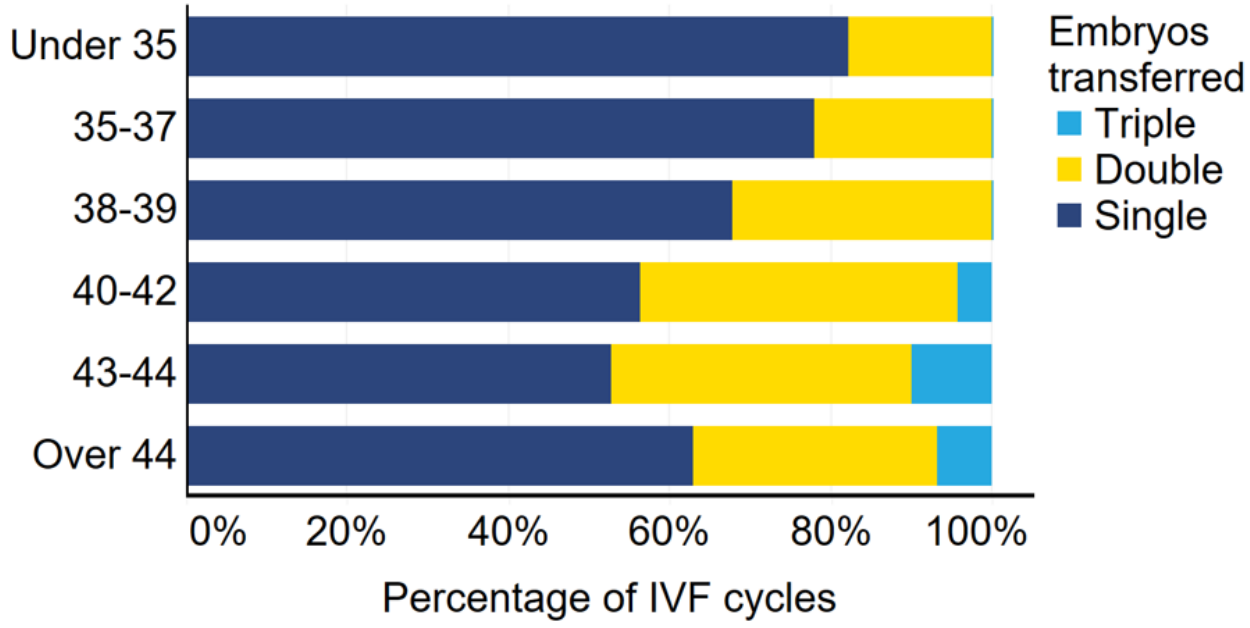


Figure 6 Multiple birth rate by age, egg source and embryos transferred, 2017-2019

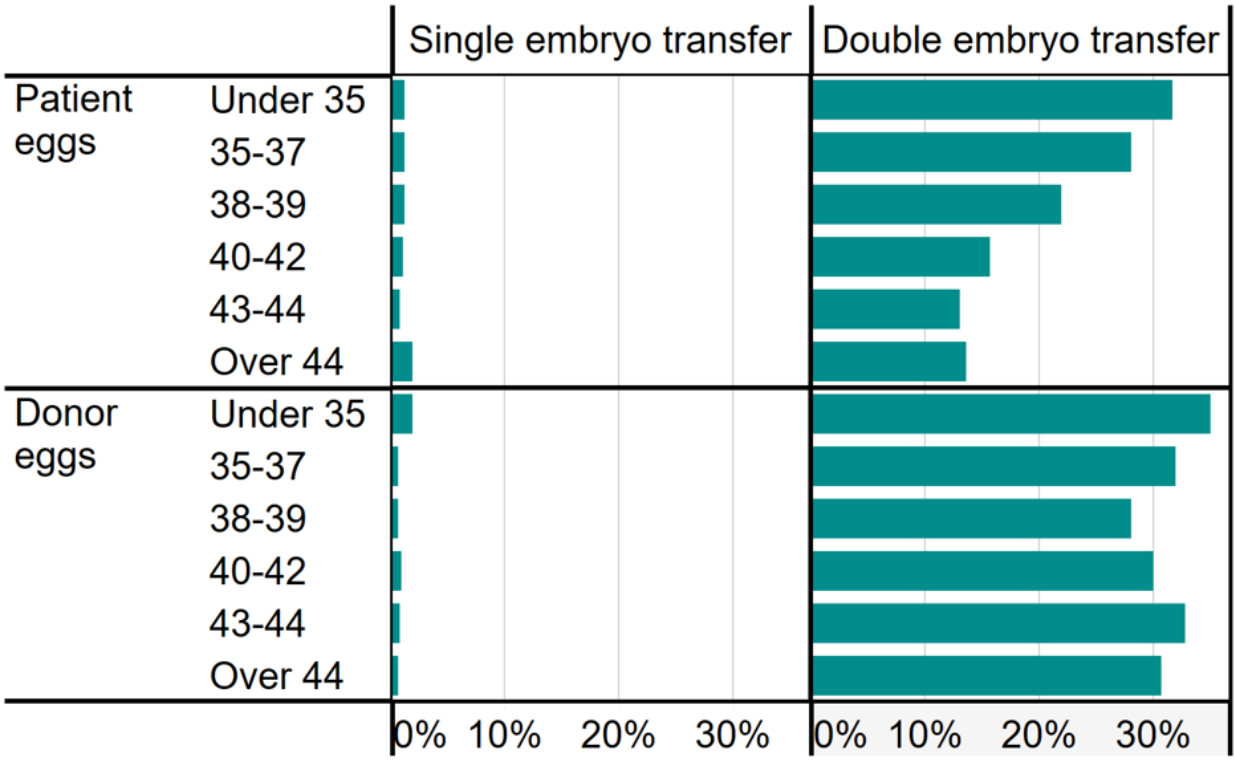


Figure 7 Multiple birth rate by patient ethnicity, 2014-2018

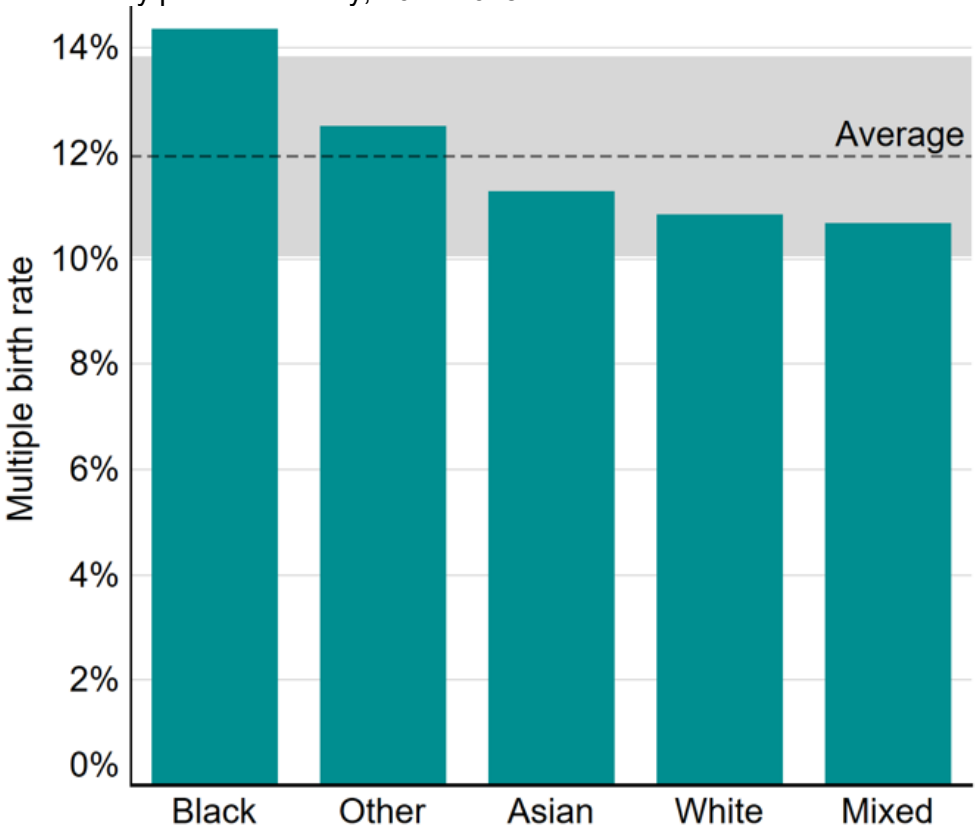


Figure 8 Proportion of embryo transfers by patient ethnicity, 2014-2018

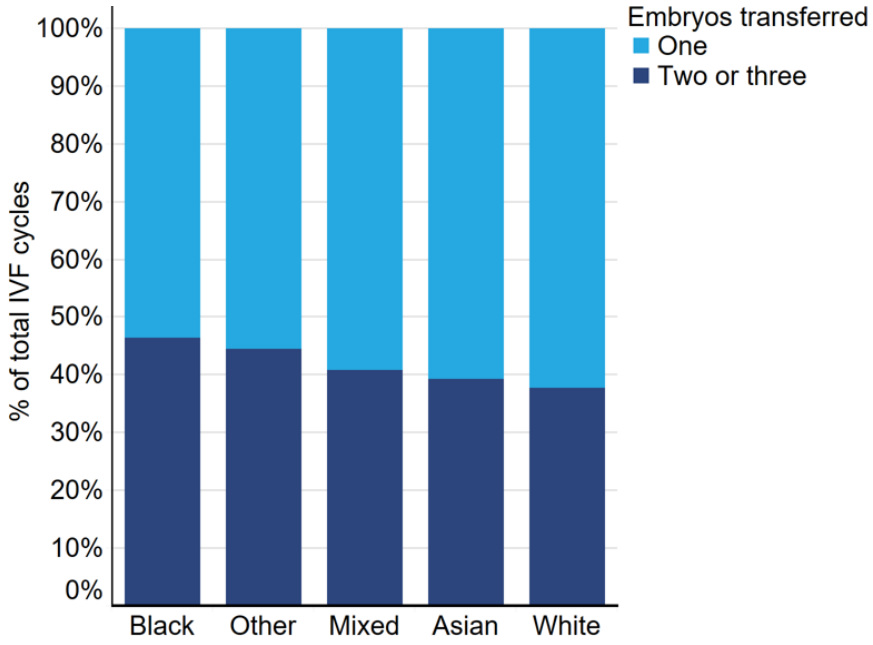
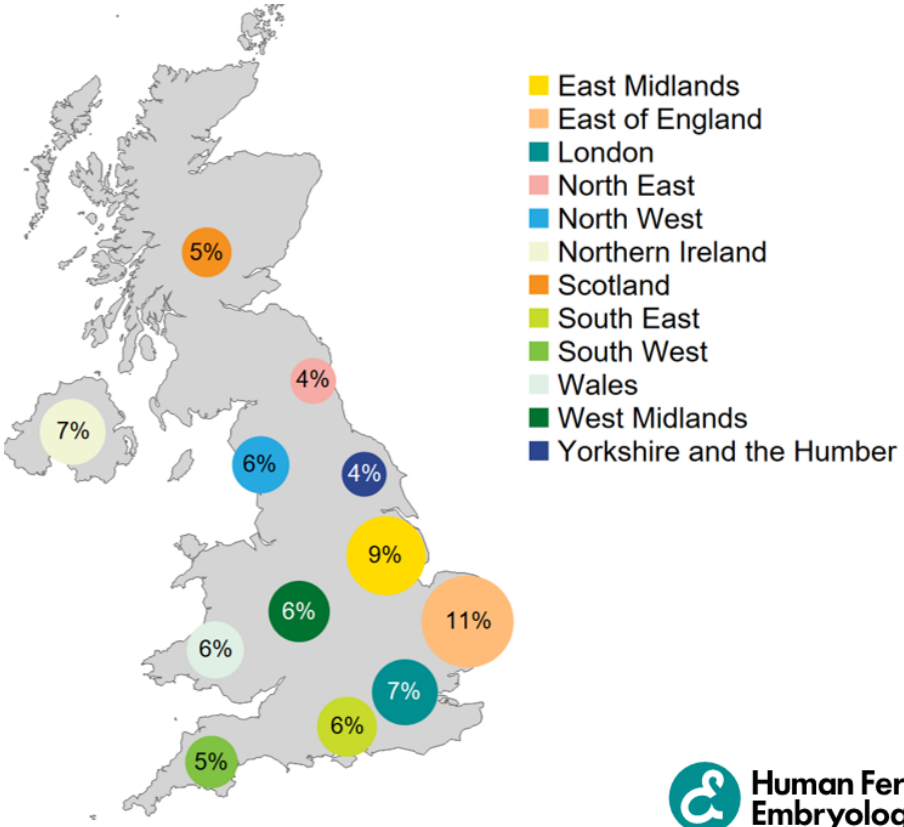


Figure 9 Multiple birth rate by nation and English regions, 2019



Note: This data includes treatment cycles and IVF only. It excludes cycles where pregnancy was recorded but not outcome.

Human Fertilisation & Embryology Authority

Figure 10 Count of clinics by multiple birth rate ranges, 2007 and 2019

Multiple birth rate	2007 clinics	2019 clinics
<5%	0	24
5-9%	1	41
10-14%	3	10
15-19%	11	2
≥20%	52	2
All clinics >150 cycles	**67**	**79**

Figure 11 Proportion of embryo transfers and multiple birth rate by funding type, 2019

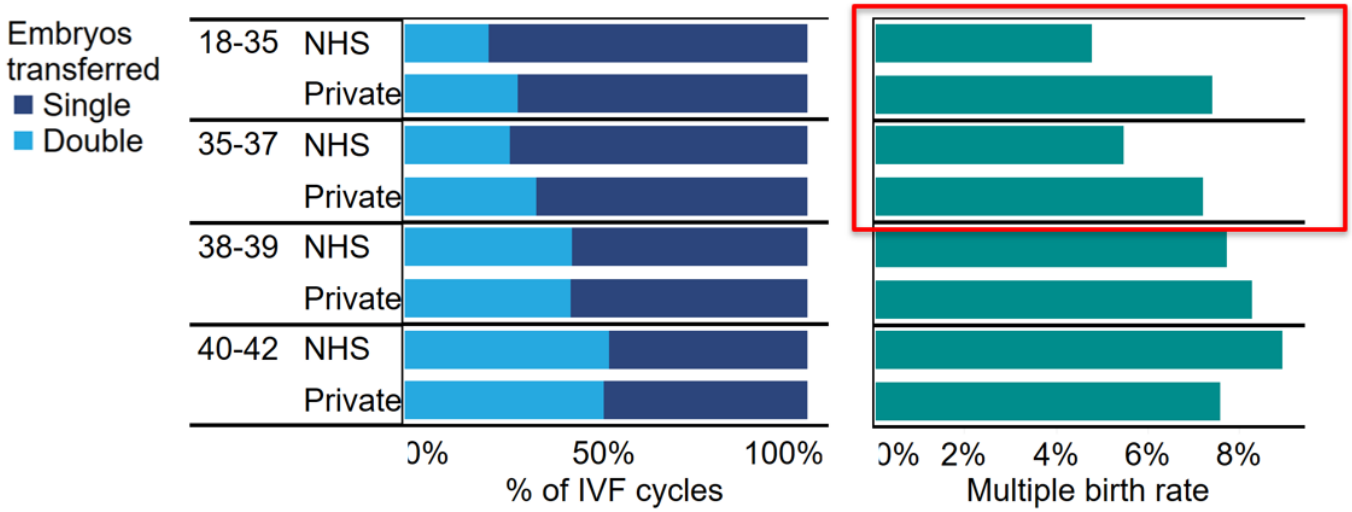
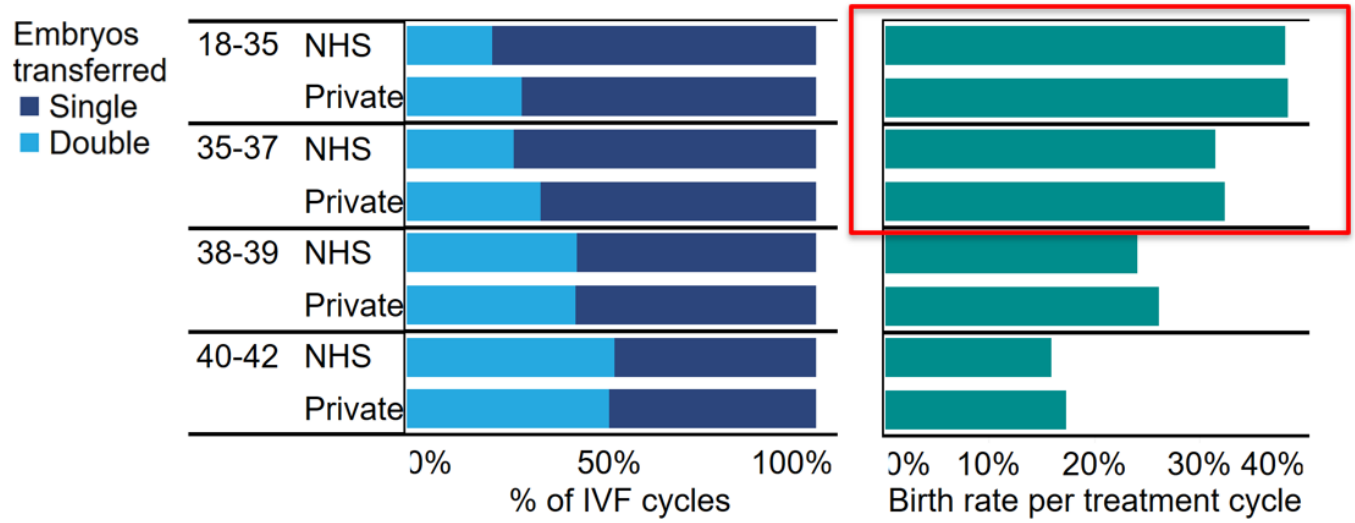


Figure 12 Proportion of embryos transfers and birth rate by funding type, 2019



Annex B: International comparison of multiple birth trends

7.1. In considering whether we should look again at the UK MBR target, it may be helpful to look at the experience of other countries, particularly those that have also successfully reduced their MBR. However, it is difficult to directly compare the MBR from assisted reproductive technology (ART) between countries because the legislation, funding, policies and practices can vary, as well as when or how the data was reported. This annex briefly summarises data from Australia, New Zealand, Japan, Sweden and Belgium.

7.2. Table 1 shows a comparison of the MBR, SET, in different nations based on the year specified*[2]

	Year	MBR	SET
Australia/New Zealand	2014 to 2018	4.9% to 3.2%	29.2% to 90.6%
Japan	2015	3.1%	80%
Sweden	1992 to 2003	30% to 5%	
Belgium	2003 to 2010	27% to 11%	50%

7.3. The success in **Australia** and **New Zealand** has been achieved by clinicians and patients changing to SET. Each ART unit must minimise the incidence of multiple pregnancy and provide evidence of their policies and procedures that ensure a regular audit of multiple pregnancy rates and their corrective actions to continue to reduce the MBR. They must recommend SET for the first treatment cycle for women aged 35 years or less, no more than two embryos transferred for women under the age of 40 and if a woman is using donor gametes no more than two embryos can be transferred regardless of the recipient woman's age and any gestational surrogate can only have SET.[3]

7.4. In 2008 in **Japan**, The Japan Society of Obstetrics and Gynecology (JCOG) recommended restricting the number of embryo transfers to one in order to prevent multiple pregnancies. However, DET is allowed in certain circumstances, such as for women older than 35 years or women who have had recurrent implantation failure.[4]

7.5. **Sweden** was one of the first countries to adopt a policy in favour of SET, and they too have been able to reduce their MBR to a lower figure than the UK. The majority of IVF cycles in Sweden are state funded, therefore implementation of the SET policy is easier. In 1993 advice was published by the National Board of Health and Welfare restricting the number of transferred embryos and in 2002 a rule was set that only one embryo could be transferred but if the risk of a multiple pregnancy was small, two embryos could be transferred.[5]

7.6. In **Belgium**, a legal restriction in 2003 on embryo transfer was introduced resulting in an increase in SET to around 50% in 2010.[6] The legal restrictions on embryo transfer are related

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[2] *The data in the table are from different years and from multiple sources.

[3] Code of Practice for Assisted Reproductive Technology Units, Fertility Society of Australia, October 2017 Guidelines for RTAC (fertilitysociety.com.au)

[4] https://doi.org/10.1002/rmb2.12074

[5] B. Källén, O. Finnström, A. Lindam, E. Nilsson, K.-G. Nygren, P. Otterblad Olausson, Trends in delivery and neonatal outcome after *in vitro* fertilization in Sweden: data for 25 years, *Human Reproduction*, Volume 25, Issue 4, April 2010, Pages 1026–1034, https://doi.org/10.1093/humrep/deq003

[6] D. De Neubourg, K. Bogaerts, C. Wyns, A. Albert, M. Camus, M. Candeur, M. Degueldre, A. Delbaere, A. Delvigne, P. De Sutter, M. Dhont, M. Dubois, Y. Englert, N. Gillain, S. Gordts, W. Hautecoeur, E. Lesaffre, B. Lejeune, F. Leroy, W. Ombelet, S.

to the age of the recipient irrespective of the age of the donor. The legal regulations implemented for the number of embryos that can be transferred are:

- for women younger than 36 only one embryo is transferred during the first and second treatment.
  Only in exceptional cases may two be transferred during the second attempt.
  For the third and other attempts maximum two;
- from the age of 36 two embryos may be transferred at attempt no. one and no. two, and three from attempt no. three;
- from the age of 40 there is no limitation in the number of embryos that can be transferred. The number is determined by you and your doctor.[7]

Perrier D'Hauterive, F. Vandekerckhove, J. Van der Elst, T. D'Hooghe, The history of Belgian assisted reproduction technology cycle registration and control: a case study in reducing the incidence of multiple pregnancy, *Human Reproduction*, Volume 28, Issue 10, October 2013, Pages 2709–2719, **https://doi.org/10.1093/humrep/det269**

[7] **UZ Brussel Fertility clinic CRG - Brussels (Jette) - Does ART treatment increase the chance of multiple pregnancies? (brusselsivf.be)**

Annex C: Multiple births minimisation strategy

The Centre for Reproductive & Genetic Health

CRGH Clinical Department

Standard Operating Procedure for Multiple Births Minimisation Strategy

Document Name and Reference Number:	Multiple Births Minimisation Strategy CP111
Latest Version No:	8
Release Date:	July 2021
Author	S. Cawood
Approved by:	P. Serhal
Review due:	July 2022
Total pages*:	4

Version/revision control

Version	Changes	Updated by	Approved by	Released date
6	Original	N/A	Medical Director	March 2017
7	Update to eSET policy for those undergoing fresh ET	S.Cawood	Medical Director	January 2018
8	Updated	S.Cawood	Medical Director	July 2021

*Excluding control sheet

The Centre for Reproductive & Genetic Health

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The Centre for Reproductive & Genetic Health

Purpose

1. The purpose of the SOP is to minimise the incidence of multiple births for patients treated at The CRGH in accordance with General Directions Ref 0003.

When to apply this procedure

2. This procedure should be used whenever a patient has fertility treatment which could result in a multiple birth.

3. Patients should be counselled from initial consultation all through to embryo transfer/IUI procedure regarding the risks of multiple pregnancy and how we can avoid this risk.

Responsibilities

4. The Medical Director has overall responsibility for ensuring compliance with this procedure.

5. It is the responsibility of the Senior Clinical Managers to ensure that all staff members are aware of the risks of multiple pregnancy.

6. All clinical staff members should counsel patients appropriately regarding risks of multiple pregnancy and inform patients of any ways in which we can reduce this risk through elective single embryo transfer.

Step by Step guide to procedure

7. CRGH is committed to providing our patients with the best care possible. This involves optimising our protocol to ensure the best success rates we can give our patients whilst reducing our multiple birth rate.

8. Our criteria for recommending elective single embryo transfer (eSET) will be continually reviewed an audited to ensure we are not jeopardising the success rate for our patients nor are we seeing too high a multiple pregnancy/live birth rate.

9. We recommend elective single embryo transfer to the following patient groups:
   a) For those patients undergoing **fresh cycles**:

Inclusion Criteria

- First IVF attempt/no history of failed IVF treatments.
- Age 36-37 or under having a fresh day 5 blastocyst transfer with at least 1 top quality blastocysts AA, B+A or AB+ if level of expansion level > 2.
- Age 35 or under having a fresh day 5 blastocyst transfer with at least 1 top quality blastocysts B+B+ if level of expansion level > 2.
- If patient is an egg recipient or have undergone PGD/PGS, then 1xd5 embryos at B+B+ qualifies for eSET.
- Endometrium between 7-13mm.

Exclusion Criteria

- AMH of ≤ 10 in addition to ≤ 5 eggs collected
- Endometrial thickness of less than 7mm
- Testicular sperm ICSI cycle

Patients should meet all inclusion criteria with none of the exclusion criteria present in the medical history.

   b) For those patients undergoing **frozen embryo transfer**:

c) If patients had a live birth in the immediate previous cycle, the patients fulfil the criteria for an elective single embryo transfer in the subsequent cycle. This is regardless of embryo number transferred in previous cycle, age of patient, embryo quality etc.
d) If the patient has had one failed embryo transfer (fresh/frozen) or has yet to have an embryo transfer, the patient only fulfils eSET IF she was ≤37* at the time of embryo creation and has one embryo in storage of B+B+ quality (d5/d6).

*In the case of PGS, the age restriction is removed from this part of the criteria. i.e. In the case of a euploid embryo, the patient fits eSET if embryo quality is ≥B+B+ and number of failed ETs is ≤1.

10. The following are being performed in order to comply with legislation:
- Patients are provided with information from the outset at open evening where information including risks of multiple pregnancy and the option of single embryo transfer is provided via a presentation.
- All patients are counselled on the risks of multiple pregnancies at consultation before embarking on a treatment cycle and a note of such made in the patient file on IDEAS.
- Further information is provided throughout the treatment cycle via information sheets, consent forms and verbal discussion.
- On the day of transfer all patients fitting the criteria are strongly recommended to transfer only one embryo and are further counselled regarding the risks of multiple pregnancies by the clinician and an embryologist. Statistics of the pregnancy and multiple pregnancy rates for patients meeting eSET criteria and either accepting or refusing eSET will also be discussed with the patient. In this way, an informed decision can be made.
- CRGH policy allows patients to refuse eSET in favour of 2 embryos. Any refusal is logged on IDEAS with a clear explanation of the reason for transferring two embryos (compliance to sections 3c, 4 and 7a and b).
- All patients having an embryo transfer (regardless of type of treatment/criteria) sign a consent form documenting they have had sufficient time and information regarding risk of multiple pregnancy to make their decision on the number of embryos.

All patients regardless of age, type of treatment and medical history have the option of eSET in order to minimise the risk of multiple pregnancy and birth.

Glossary

AMH	Anti Mullerian Hormone
CRGH	The Centre for Reproduction and Genetic Health
eSET	elective single embryo transfer
HFEA	Human Fertilisation & Embryology Authority
PGD	Pre Genetic Diagnosis
PGS	Pre Genetic Screening
MBR	Multiple Birth rate
MPR	Multiple Pregnancy Rate
SOP	Standard Operating Procedure

Treatment add-ons next steps

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	23 September 2021
Author	Dina Halai, Scientific Policy Manager
Annexes	None

Output from this paper

For information or decision?	For decision
Recommendation	The Authority are asked to consider and agree the proposed directions: • 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.
Resource implications:	Within budget
Implementation date:	With immediate effect
Communication(s):	Clinic focus articles and engagement with the sector and patients/public where necessary
Organisational risk:	Medium

1. Introduction

1.1. Addressing treatment add-ons has long been a priority issue for the HFEA. We introduced an evidence rating for selected add-ons in 2017, a World first, and add-ons are a key feature of our organisational strategy for 2020-24. The Authority last discussed add-ons in March 2021 and noted the progress made:

1.1.1. A second substantial update to the information for patients on treatment add-ons on the HFEA website (the last big update was in August 2020) went live in February 2021.

1.1.2. The HFEA worked with Fertility Network UK (FNUK) to develop a list of questions that patients could ask their clinicians when discussing add-ons, this went live in April 2021. A patient guest blog and FNUK-hosted webinar were published in association.

1.1.3. All professional guidelines relevant to treatment add-ons can now be found on a single page on the HFEA Clinic Portal.

1.2. Taken together, this work means that patients have access to clearer information on our website, enabling them to better understand the evidence and risks and potential benefits for each add-on. Significantly, information on each add-on is now framed within a reminder that for most patients, routine IVF is an effective treatment. We have also made important progress towards strengthening patients' position when discussing add-ons with their clinic.

1.3. Since the last Authority discussion:

1.3.1. The Treatment Add-ons Working Group (TAG)[1] met in May 2021 and the BFS, RCOG, SING and ARCS published articles highlighting the HFEA's new information on add-ons.

1.3.2. We continue to promote our add-ons information on our various social media platforms.

1.4. Our work on add-ons continues and the remainder of the paper sets out proposed future activities in relation to two key elements:

1.4.1. Evolving the presentation of the rating system for treatment add-ons

1.4.2. Broadening the evidence base reviewed to inform our add-ons ratings and information

2. Evolving the presentation of the rating system for treatment add-ons

2.1. We currently employ a traffic-light rating system consisting of three colours (red, amber and green) that indicate whether the evidence, in the form of high-quality RCTs, shows that a treatment add-on is effective at improving the chances of having a baby for most fertility patients.

[1]The membership of the TAG is made up of the 11 professional and patient bodies that are signatories of the consensus statement - Association of Biomedical Andrologists (ABA), Association of Clinical Embryologists (ACE), British Andrology Society, British Fertility Society (BFS), British Infertility Counselling Association (BICA), European Society of Human Reproduction and Embryology (ESHRE), Fertility Network UK (FNUK), Human Fertilisation and Embryology Authority (HFEA), Royal College of Nursing (RCN), Royal College of Obstetricians and Gynaecologists (RCOG) and Senior Infertility Nurses Group (SING)

2.2. Since its introduction there has been considerable debate about the merits of the traffic light ratings and the information on the HFEA website about treatment add-ons. Some professionals like the traffic light ratings; others think they run the risk of being too simplistic. While that expert debate is healthy, what matters most is the response of patients. At the November 2020 Authority meeting, we reported that we had conducted user testing to determine patients' understanding of the then new information around treatment add-ons and the traffic light ratings, and that findings from the survey showed that, four in five (83%) participants found the content easy to understand. A similar proportion (80%) thought that the content was helpful for patients who are thinking about, or are going through, fertility treatment (including fertility preservation) in making an informed choice about treatment add-ons. However, it is also clear that some of the subtleties are not always understood and that although we do not need to start from scratch, that there is more we could do to develop the information.

2.3. Given that much research is still required, it is premature to have a discussion now about how the rating system might develop but two issues illustrate the complexity:

2.3.1. First, the absence of a green rated add-on in the current ratings has led to a debate about whether this may mean that some patients look more favourably than the evidence suggests they should on add-ons rated as amber, seeing them as the 'best' add-on available. Therefore, it may be appropriate to consider the suitability of alternative rating systems eg star ratings, 5-point rating scale etc.

2.3.2. Second, add-ons may be offered for reasons other than to improve the chances of having a baby. In some circumstances there may be a justifiable medical reason for using the add-on as part of fertility treatment. Some treatment add-ons show benefits in certain groups of patients for outcomes other than improving live birth rate. For example, there may be evidence that a treatment add-on could reduce the chance of having a miscarriage or reduce the risk of ovarian hyperstimulation syndrome (OHSS). Therefore, it may be that a red or amber rated add-on could be used appropriately for specific clinical cases after careful discussion with a clinician. In these circumstances, it may be appropriate to have multiple ratings per add-on to indicate the different possible outcomes. However, we would need to keep in mind that the evidence that supports the use of add-ons in specific cases might not be as high quality as the RCTs used to decide the current traffic light ratings.

2.4. We therefore propose carrying out consultation work to gather the thoughts of patients/public and the sector/experts on how best to evolve the rating system for our add-ons information and to consider whether the traffic light ratings are still the most appropriate way to indicate the strength of the evidence base for each add-on. **It is important to note that we are not starting from scratch to develop a whole new rating system and previous discussions about the rating system will be considered.**

2.5. The proposed direction is to:

2.5.1. Carry out some scoping work on the extent to which the current rating system could evolve and improve (eg do we stick with RAG or move to star ratings, 5-point rating scale etc) and/or introduce multiple ratings per add-on (eg for various outcomes for each add-on).

2.5.2. We will come back to a future Authority meeting to report the outcome of that scoping work and set out a proposed consultation strategy.

2.5.3. We will then come back to an Authority meeting in 2022 with a recommendation on how best to evolve/change the rating system based on consultation findings.

2.5.4. Any changes to the rating system will need to be agreed 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.

2.6. The Authority is asked to agree the proposed direction to evolve the presentation of the rating system for treatment add-ons.

3. Considering broadening the evidence base

3.1. Traffic light ratings are allocated by SCAAC based on the evaluation of the evidence base in the form of randomised controlled trials (RCTs), and advice from an independent expert in systematic reviews and evidence assessment.

3.2. When reviewing the effectiveness of treatments, well-designed RCTs provide the most reliable source of evidence. Unfortunately, there are many situations where RCTs have not yet been carried out, and this is particularly the case for treatment add-ons. The reasons for this are many and varied, including funding and the difficulty of sufficiently large sample sizes, but as things stand it is likely that many treatment add-ons will not have a well-designed RCT for the foreseeable future.

3.3. In addition, at the event for fertility clinic leaders (person's responsible or PRs) in 2019 and at the HFEA's Annual Conference that same year, some argued that the HFEA should consider if it should continue with an approach which uses RCTs as the sole determinate of the allocated rating or if it should try to accommodate other types of evidence (notably retrospective studies of large data) into that assessment. The issue is further complicated by an increasing proportion of the sector relying on their own experiences and analysis of live birth rates and patient outcomes within their own clinics, to make claims relating to the effectiveness of certain add-on treatments for patients.

3.4. The SCAAC, along with invited experts, considered broadening the evidence base that the HFEA consider when assigning traffic light ratings to add-ons in October 2019 and agreed that, with intelligent use, large data can complement RCTs but cannot replace them.

3.5. Sticking with a traffic light rating based on RCTs ensures that our assessment is based on the highest quality studies but risks being overtaken by other publicly available research data; whilst accommodating data from other less robust sources risks diluting the objective quality of that assessment. It is therefore essential to consider the appropriateness of alternative evidence in these circumstances.

3.6. The proposed direction is:

3.6.1. SCAAC and expert(s) in systematic reviews and evidence assessment to consider the quality of other evidence types and to recommend whether any should be included, in addition to RCTs, in

the HFEA's annual review (currently using the GRADE methodology[2]) of evidence for treatments add-ons.

3.6.2. We will come back to the Authority in early 2022 with a recommendation on whether we should expand the evidence base reviewed annually for allocation of ratings to add-ons and how.

3.6.3. Any changes to the evidence base reviewed will need to be agreed by July 2022 so that the required work to inform the October 2022 SCAAC meeting (at which evidence is reviewed as part of their annual review) can be undertaken.

3.7. The Authority is asked to agree the proposed direction to consider broadening the range of data that the HFEA consider when assigning ratings to treatment add-ons.

4. Looking ahead

4.1. As noted earlier, the HFEA was the first regulatory body in the World to publish information for patients on the efficacy of treatment add-ons. There are signs that this picture is now changing, and we will continue to monitor new sources of reviewed evidence to ensure that HFEA resources continue to respond to UK patients' needs. For example, in October 2020 a Cochrane Special Collection review looking at some of the same add-on treatments, and which also includes some patient-facing content, was published. This Cochrane Special Collection review will be updated regularly.

4.2. We will also continue to monitor the potential for any collaborative opportunities in future, in order to make the clearest high-quality information offer to patients and the best use of HFEA resources. We are currently in discussion with the Victorian Assisted Reproductive Treatment Authority (VARTA) in Australia, who have similar concerns around the offering of add-ons and are considering developing their own evidence-based information for patients.

[2]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.