Human Fertilisation & Embryology Authority

Authority meeting

Date and time: 7 July 2021- 1.00pm to 4.00pm

Venue: ETC.venues – One Drummond Gate, SW1V 2QQ

Agenda items	Time
1. Welcome, apologies and declarations of interest	1.00pm
2. Minutes of the meeting held 12 May 2021 **For decision**	1.05pm
3. Chair and Chief Executive's report **For information**	1.10pm
4. Committee Chairs' report **For information**	1.20pm
5. Performance report **For information**	1.35pm
6. Covid update **For information**	2.00pm
Break	2.15pm
7. Code of Practice update **For decision**	2.30pm
8. Fertility trends next steps **For discussion**	3.00pm
9. CMA/ASA update **For information**	3.30pm
10. Any other business	3.50pm
11. Close	4.00pm

Minutes of Authority meeting 12 May 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	7 July 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 12 May 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 12 May 2021 held via teleconference

Members present	Julia Chain, Chair Margaret Gilmore Anita Bharucha Jason Kasraie Catharine Seddon Emma Cave	Jonathan Herring Gudrun Moore Ruth Wilde Yacoub Khalaf Ermal Kirby Alison Marsden Tim Child
Apologies	Anne Lampe	
Observers	Marina Pappa (Department of Health and Social Care - DHSC) Steve Pugh, DHSC Csenge Gal, DHSC	
Staff in attendance	Peter Thompson Clare Ettinghausen Richard Sydee Rachel Cutting Catherine Drennan	Joanne Triggs Paula Robinson Debbie Okutubo Helen Crutcher

Members

There were 13 members at the meeting – eight lay and five professional members.

1. Welcome and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members, observers and staff present online. She commented on it being her own, and Alison Marsden's, first Authority meeting as Chair and an Authority member respectively.

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. The Deputy Chair (Margaret Gilmore) extended a warm welcome to the new Chair on behalf of the Authority. She praised the staff and Authority members for inspirational work over the years as the HFEA became a leader among regulators in recognising where scientific and technological advances could benefit patients. She commented that the new Chair would enable the HFEA to continue to flourish in this vein and offered her support and the best wishes of the members in her new role. The Chair thanked Margaret for her comments.

1.4. 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 24 March 2021 were an accurate record and could be signed by the Deputy Chair (Margaret Gilmore) since the Chair was not in post at the last meeting.

3. Chair and Chief Executive's report

3.1. The Chair summarised the numerous meetings she had had over the last six weeks since she became Chair, including visiting two licenced centres and speaking to the persons responsible (PRs). Her impression was that the sector held the HFEA in high regard. The Chair also paid tribute to the previous Chair, Sally Cheshire, for ensuring the Authority was viewed in such a positive light.

3.2. The Chair said that she and the Chief Executive had begun to look at the expertise required on the board as there were up to six members with terms of office coming to an end this year. She outlined that it was a risk to the Authority with so many experienced members stepping down and that starting the recruitment process to replace them was being looked at as a matter of urgency. The Chair also noted that 3 members were up for reappointment and that the DHSC had been asked to confirm these reappointments.

3.3. The Chair set out her priorities:

- Modernising the Act. The Chair stated that she believed that this was a key strategic aim. While parts of the Act had held up very well over time, some aspects were now out of date.
- The use of data. There would be opportunities in the future to use our data more effectively, building on the launch of PRISM this summer. It was important that we used our data to help patients, clinics and to facilitate research.
- Inequalities. While this had been particularly highlighted in the recent report on ethnic diversity in fertility treatment, the Chair was keen to look further at these and other inequalities in particular inequality in access to treatment.

3.4. The Chair commented that the themes and priorities that she had listed would be discussed with Lord Bethell at their introductory meeting taking place later in the month.

Chief Executive

3.5. The Chief Executive and Directors had the quarterly accountability meeting with the Department of Health and Social Care and reported that the meeting went well. It was noted that despite the pandemic we were meeting our commitments in the business plan and that we continued to recognise challenges ahead.

3.6. The Chief Executive had spoken at a roundtable discussion on the contribution of Mary Warnock to fertility regulation.

3.7. Members were advised that the Chief Executive would be attending a Regulatory Horizons Council meeting to speak about the role of the HFEA in encouraging innovation.

Decision

3.8. Members noted the Chair and Chief Executive report.

4. Committee Chairs report

Audit and governance committee (AGC)

4.1. The AGC Deputy Chair (Margaret Gilmore) reported back to the Board. At the 28 April meeting, the committee received a paper and reviewed options for a revised PRISM go live date, slightly delayed due to Covid-19 pressures. They were pleased with the progress made on PRISM in the last few weeks.

4.2. The three criteria the committee would consider before authorising the go-live of PRISM in mid-June, were: patient security, clinic usability, and HFEA business processes.

4.3. At the last meeting the Committee received assurances that PRISM cut-over was on target, data quality issues were resolved and simulations showed a high level of accuracy.

4.4. The team were frequently in-touch with clinics and the majority were on track for launch, with an appropriate communications strategy in place.

4.5. RITA, the internal reporting system for HFEA staff was also ready for launch.

4.6. The AGC Deputy Chair reported that an internal audit was carried out on PRISM and a lessons learned report which the committee had requested was being compiled. This would be shared with the AGC and the Authority Chair once finalised.

4.7. The committee heard that there was still a risk that a lot of knowledge and technical knowhow lay with contracted staff, but to mitigate this, there was a handover programme in place to transfer the knowledge to permanent HFEA staff.

4.8. Training for clinics and support continued and the committee was assured that the programme spend remained in line with the reviewed forecast.

Statutory Approvals Committee (SAC)

4.9. The Chair of SAC (Margaret Gilmore) addressed the Authority. The committee continued to meet monthly and had considered a large number of PGD applications since the last Authority meeting. The committee had also regularly considered Special Direction applications. Many of these were Covid-19 related and concerned people unable to travel to or from a country where they intended to have treatment, due to travel restrictions. They therefore requested permission for gametes to be imported or exported in cases where this could not necessarily be compliant with UK general directions (GD).

4.10. The SAC Chair reported that cases coming before the committee were increasingly complex and challenging and she expressed her thanks to committee members for the depth of their discussions and to staff for supporting the committee. She pointed out the decisions reached would be life changing for the patients involved.

Decision

4.11. Members noted the Chairs' updates.

5. Performance report

5.1. The Chair invited the Chief Executive to introduce the report. It was noted that there are currently three red indicators, which were set out in the report. The indicators on staff turnover and sickness were currently classed as green. The mental health and wellbeing of staff remained paramount and there were a number of initiatives in place to support staff.

5.2. Members were advised that the earliest staff would be formally returning to the office was 21 June – dependent on the lifting of wider Covid related restrictions - and that conversations would be held with staff about return to an office setting.

5.3. The Chair commented that a framework should be developed to ensure arrangements provide direction from the SMT on office attendance and flexibility, rather than simply having a series of ad hoc individual working arrangements for each member of staff.

Strategy and Corporate Affairs

5.4. The Director of Strategy and Corporate Affairs gave a brief overview on ongoing work in the directorate.

5.5. It was noted that since the Authority last met, a number of actions relating to treatment add-ons had progressed including publishing for the first-time information on holistic and alternative therapies. The patient questions on what to ask about add-ons, which we worked on with Fertility Network, had also been published. The work on EU exit continued and the team was compiling the annual fertility trends report to be published later in May.

5.6. As noted at the last meeting, following the publication of our report on ethnic diversity in fertility treatment in March, we will be updating Authority on progress against the actions in the report. The report received a great deal of media and social media coverage. Since publication we have also discussed with some of our stakeholder groups and presented the findings to the NHS Health Race Equality Observatory Maternal Health group. We are now planning further work on the actions in the report and will continue to update Authority on this.

5.7. A member commented that there were concerns that counsellors in clinics could become marginalised and suggested that the HFEA should engage in dialogue with licensed centres to ensure that post Covid-19, counsellors were not a casualty of cost-cutting exercises. Members were advised that the British Infertility Counselling Association (BICA) had raised concerns about this. Members were informed that some these issues were staffing concerns for individual clinics. However, where there were wider issues, we would work with BICA to see if there were any further actions we could take.

5.8. A member updated the Authority that a few arms-length bodies (ALBs) in the health sector had recently come together to discuss diversity and inclusion and the conclusion from the meeting was that more needed to be done on inclusion.

Compliance and Information

5.9. The Director of Compliance and Information gave an overview. The inspection schedule was busy and we continue to inspect via a risk based approach with desk-based analysis (DBA) / virtual technology (as restrictions have eased site visits are resuming). An unannounced inspection was undertaken with a clinic where we had concerns. We have sent a survey monkey questionnaire to centres who have gone through the DBA/virtual inspection to gather feedback. So far feedback

has been very positive from PRs but, there is the challenge of extra paperwork for inspectors to assess, but this is under review. The PR and inspector feedback will help to inform how inspections will be conducted once all restrictions have been lifted.

5.10. Members were reminded that during the pandemic the decision to close the opening the register (OTR) service led to an increased backlog. There had also been a rise in applications since the service resumed. To mitigate this, an additional member of staff has been appointed. A wider review of the service is also planned.

5.11. Members asked if there were plans to train other existing staff members as a way of reducing the backlog as the waiting times listed were not acceptable. It was noted that this would be difficult to achieve due to the expert nature of the role and length of time to train, but more resources were being sought.

5.12. Members asked if the red indicator on regulatory efficiency was still appropriate. The Director of Compliance and Information responded that it related to inspectors having backlogs owing to workload pressures, but that we would continue to work on this.

5.13. A member asked about whether the internal incidents red indicator was patient safety related. The Director of Compliance and Information confirmed that this was not and that it related to incidents within the HFEA, not clinics. More work had been done to increase reporting and learning from such occurrences.

5.14. The Chair commented that the additional resource for the Register team formed part of a larger conversation on succession planning that she was having with the Chief Executive and with the DoH.

Finance and Resources

5.15. The Director of Finance and Resources presented to the Authority. It was noted that one of the red indicators related to debt collection but commented that he had every confidence that the debt would be collected. It was noted that a large part of the underspend was from the Legal budget as it was not fully used in the last financial year.

5.16. Members asked about the project cost for EU transition and if there were increased known risks. The Director of Finance and Resources responded that there were no financial risks incurred. The Director of Strategy and Corporate Affairs commented that operational risks had been mitigated as no work had been delayed by the HFEA, since we continued to follow the government timelines.

5.17. It was noted that the financial data presented were unaudited and the audit work would be starting at the end of May 2021.

Decision

5.18. Members noted the performance report.

6. Covid-19 update

6.1. The Director of Compliance and Information presented to the Authority. It was noted that privately funded cycles saw an increase in 2021 compared to 2019.

6.2. In terms of clinic activity, private clinics are working at higher activity levels compared to NHS clinics.

6.3. The Director of Compliance and Information commented that concerns had been raised about delays in patients accessing primary care and that there were difficulties in recruiting donors and sourcing products. There were also concerns that NHS patient cycles were being capped.

6.4. Professional members on the board commented that they had also experienced delays in patient referrals both from primary and secondary care. NHS funded IVF patients could also be seeing delays because there were more patients seeking fertility treatment in the UK while travelling abroad was restricted.

6.5. The Chair commented that we needed to keep an eye on this especially if there was evidence that NHS patient intake and cycles were being capped.

Decision

6.6. Members noted the Covid-19 update.

7. Strategic risk register

7.1. The Chair invited the Risk and Business Planning Manager to present this item. Members were advised that the risk register was revised last year to reflect our current strategy. The AGC continued to provide assurance to the Authority that the executive was managing risk effectively as they reviewed the register at every AGC meeting.

7.2. Members were advised that we had one above tolerance risk, C2, which related to our board and senior management team (SMT) capability. This followed a reassessment and reframing of the risk in April following a discussion with AGC at their March meeting.

7.3. Members were advised that the executive intended to review the wider risk management approach, including the risk policy and strategic risk register in the coming months.

7.4. The AGC deputy chair commented that legacy planning was important at SMT level.

7.5. The Chair responded that as a small organisation it would always carry some element of risk in relation to this, and that Authority members and leadership team turnover required good succession planning to be in place to the extent possible.

7.6. There was a suggestion from members that under risk I1, information provision, we needed to capture a new risk cause that the HFEA could be perceived as less consumer-focused or out of step with other regulators in terms of the transparency of information about regulatory action.

7.7. Members asked if there was robust evidence that patients knew about us and what we do as a regulator and if there was a way of gathering evidence of what was known about us.

7.8. Professional members on the Authority commented that some patients knew about the HFEA, but more could still be done as only a few would have interacted with the HFEA or be aware of our remit.

7.9. The Chair commented that the relative lack of enforcement powers was an issue, we therefore needed to rethink how we let patients know about what we do.

7.10. The Chief Executive commented that some of the work that we had to reschedule for later at the start of the pandemic would have raised awareness - an example was how we link in with GP practices which would have given patients more early information about the HFEA.

7.11. The Director of Strategy and Corporate Affairs responded that staff would revisit risk I1 and have a further discussion internally.

7.12. Members asked about P1 – positioning and influencing, and whether we were influencing optimally. Also, if there was scope for developing a role whereby we became a sector leadership convenor on certain matters. Further interdependencies could perhaps also be reflected over time.

7.13. Under C1 – capability, it was hoped that we could act swiftly to facilitate mentoring and other such arrangements, jointly with the other ALBs we will be sharing space with at our new premises.

7.14. Members commented that going forward good messages and good impacts could be built on further. We could use PRISM to promote and raise the transparency of some aspects of our work and also use our data to educate as required. Research carried out could be tagged on the website.

7.15. The Chair concluded the discussion by stating that prioritising was key and that the Executive would take the comments away, revisit and report back at a future Authority meeting.

Decision

7.16. Members noted the strategic risk register.

8. Licence fee review project – timing and next steps

8.1. The Director of Finance and Resources presented this item to the Authority. The Authority last received a paper on the fees review work at its meeting in June 2020. The Director of Finance and Resources commented that it was important to note that as a regulator we did not charge patients.

8.2. Following the June 2020 meeting further work was undertaken on modelling the potential impact of the agreed options. It also became apparent that it would be difficult to continue this work to a successful conclusion with the full engagement of the sector given the pressures of operating through the ongoing Covid-19 pandemic.

8.3. Members were advised that subject to the agreement of the DHSC, we were looking to delay this work to 2022 with the intent of introducing any new fees from the start of the 2023/24 financial year.

8.4. Members were invited to comment, and stated that in reality, increases to fees would be passed on to patients by clinics but if it were a small increase, it might be absorbed by centres and asked if the Director of Finance and Resources had considered charging for the storage of frozen embryos.

8.5. There was the suggestion of having the option of a flat fee and making it clear to clinics that it was not for a specific treatment, but it was a flat fee linked to the size and activities of clinics.

8.6. Members commented that the current charging structure needed to be reviewed as it was out of date compared to current treatment trends, but we must not lose sight of anything that would make people on a low income lose out on affordability grounds.

8.7. Members cautioned that the data available in this financial year was for the last six months since clinics reopened and that its accuracy could be questioned especially if was to be used to model future charges. Members suggested that strategic risks needed to be carefully evaluated. They

commented that going from an underspend this financial year to an increase in fees could appear to be out of step and requested that the executive think carefully about this.

8.8. The Director of Compliance and Information reminded members that the charge was to cover the cost of regulation and reiterated that as a regulator we did not charge patients.

8.9. The Chair commented that looking at the challenges ahead, we would need more resources. Some of the good ideas put forward included charging for some treatment types that we did not currently charge for or adding a small increase to the current charge given the fact that the existing fee had not been uprated for inflation for several years. Any option proposed would require us to be able to demonstrate to the DHSC and the Treasury that this was a fair assessment of our actual regulatory costs. Also, once agreed, we would need to implement any new charges speedily.

8.10. The Chief Executive commented that Authority members had shown that they had an appetite for further discussion. We would therefore work on the suggestions put forward, approach the DHSC and in time the Treasury, and keep Authority members informed.

8.11. The Chair stated that the Executive would do some re-modelling and bring it back to the Authority.

Decision

8.12. Members noted the licence fee review project and that further information would be provided to the Authority in due course.

9. Transparency and Regulation

9.1. The Director of Strategy and Corporate Affairs presented this item. Members were advised that this was an initial discussion to frame future work about the transparency of our regulatory information.

9.2. Members were reminded that inspection reports and licensing committee minutes were published for every clinic on Choose a Fertility Clinic (CaFC) but that these could be hard to find and were written primarily for the purposes of making a licensing decision.

9.3. Members were also reminded that the work we were doing with the Competition and Markets Authority (CMA) and the Advertising Standards Authority (ASA) had shown that both regulators routinely published enforcement actions on their websites and in future, if enforcement action by the CMA or ASA was taken against an HFEA licensed clinic, we should consider whether to publish this information too, for patients to find easily.

9.4. It was noted that some other regulators published enforcement actions in different ways and clearer visibility was given to non-compliances, and so the HFEA should consider whether our approach was now out of step with other modern regulators. Regardless of the outcome of this discussion, we should continue to ensure consistency with the Compliance and Enforcement Policy.

9.5. Members commented that increasing transparency around our compliance work was in the best interests of patients and was therefore very welcome. Raising transparency goes to the heart of our duty to provide information to patients. Patients being able to access information readily was very important.

9.6. Members also commented that while collaborative work with the sector was important that should not prevent the HFEA drawing attention to non-compliances. Also, the CMA and the ASA publishing enforcement actions gave us a good case also to make more visible our own enforcement actions.

9.7. Members commented that we already published information but since it was contained within each clinic's CAFC page, it was not easy to find. This needed to be worked on.

9.8. Comments were made on the merits of the publication of 'league tables'. While this recognised 'good' or 'poor' clinic performance, there was the potential for patients to be excluded from some clinics to drive up success rates which could have a wider negative effect on patient care.

9.9. Some members cautioned that inspection reports needed to be seen in context as the narrative within them needed to be told in full. We also should note that whatever we publish must be within the legal powers of the HFEA.

9.10. The Chair noted that there was a will to progress some of these matters further and more detailed options would be brought back to the Authority for discussion and decision in due course.

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: 7 July 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:	7 July 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 May 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:

- 13 May - meeting with our internal auditors to discuss our KPI's on board performance management
- 19 May – introductory meeting (with Peter) with Lord Bethell to discuss our strategic aims for the next few years
- 24 May - annual accountability meeting (with Peter) with our sponsors at the Department of Health and Social Care (DHSC)
- 24 May - introductory meeting with Jane Denton
- 25 May - attended the Treatment Add-ons Group
- 2 June - visited Oxford Fertility Centre, with thanks to Tim Child and his team for giving up time to show me around
- 7 June - observed the Scientific and Clinical Advances and Advisory Committee meeting
- 8 June - introductory meeting with Katherine Mathieson, CEO of the British Science Association.
- 17 June - introductory meeting with Celine Lewis, Senior Research Associate in Genomics NIHR Advanced Fellow, UCL
- 21 June - visited CARE Nottingham (with Rachel Cutting), with thanks to David Burford, Simon Fishel and all their team for giving up their time
- 22 June - observed the Audit & Governance Committee meeting
- 29 June - observed an Executive Licensing Panel meeting
- 6 July - introductory meeting with Stephen Lightfoot, Chair of the MHRA

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

- 19 May – meeting (with Julia) with Lord Bethell
- 24 May - annual accountability meeting (with Julia) with our sponsors at the DHSC
- 25 May - chaired the Treatment Add-ons Group meeting
- 7 June - attended the Scientific Clinical Advances and Advisory Committee meeting
- 22 June - attended the Audit & Governance Committee 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
Paper number:	4
Meeting date:	7 July 2021
Author:	Paula Robinson, Head of Planning and Governance Committee staff
Annexes	None

Output from this paper

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

1. Committee reports

1.1. In the past we have conveyed some Committee information verbally at meetings, via the Committee Chairs. We had also previously commenced the occasional reporting of licensing statistics. However, during the Covid pandemic, we largely paused this type of reporting.

1.2. It now seems appropriate to recommence reporting. It is hoped that providing a simple paper will give a framework within which Chairs can draw attention to the key issues raised in their Committees, without the need to read out statistics such as the number of items considered at each meeting.

1.3. We will add some licensing statistics to the next report in September.

1.4. Members' views on the report are welcome.

2. Recent committee items considered

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

Meetings held	Items considered	Outcomes
Licence Committee:		
6 May 2021	None	N/A
Other comments:	Meeting cancelled because there were no items.	
Executive Licensing Panel:		
18 May 2021	2 Renewals 2 Change of Person Responsible 1 Variation of Premises	All granted
1 June 2021	2 Renewals 1 Extension of Licence 1 Change of PR	All granted
15 June 2021	1 Renewal 3 Interims 2 Change of Person Responsible	All granted
Other comments:	None.	
Licensing Officer decisions:		
N/A	58 ITE Certificates 1 Change of Centre Name 2 Change of Licence Holder 1 Voluntary Revocation	All granted
Other comments:	High volumes of ITE certificates for the past few months.	

Meetings held	Items considered	Outcomes
Statutory Approvals Committee:		
29 April 2021	6 PGD applications 2 Special Directions for import/export	All granted
27 May 2021	6 PGD applications	All granted
24 June 2021	2 PGD applications	Minutes in progress.
Other comments:	At the May meeting, the committee also received an update on EU Exit and a briefing on the use of new PGD terminology (PGT-M).	
Audit and Governance Committee:		
21 May	Prism oversight meeting	N/A
22 June	• Digital Programme update • Internal audit progress and implementation • Information assurance and security • Annual Report and accounts • External audit report • Strategic risk register • Bi-annual human resources report • Resilience and business continuity management	N/A
Other comments:	None	
Scientific and Clinical Advances Advisory Committee:		
7 June 2021	• Monitoring the effects of COVID on fertility, assisted conception and early pregnancy	• No changes to the HFEA's guidance on COVID were recommended.
	• Add-ons Application – Endometrial Receptivity Analysis (ERA)	• ERA was recommended for inclusion in the list of add-ons that the HFEA provides information on.
	• Artificial intelligence (AI) and machine learning – literature review	• The Executive will scope out the HFEA remit and workplan for AI in the UK fertility sector
	• Fertility Trends Report update	• Comments from the Committee were noted.

Meetings held	Items considered	Outcomes
Other comments:	The HFEA will conduct a literature review of the evidence for the use of ERA and SCAAC will give the add-on a RAG rating recommendation at the October meeting.	

3. Recommendation

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

Performance report

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	5
Meeting date:	7 July 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 until 31 May 2021.

1.2. Performance was last reviewed by SMT at its 21 June meeting.

2. Key trends

2.1. In May, performance was generally good. There was one red indicator.

Red indicators - May

2.2. The indicator classed as red is:

- **C3 - PGD average processing**

2.3. This compares to three red indicators in April.

Red indicators - April

2.4. The indicators classed as red are as follows:

- **R2 Register data errors**
- **F3 Prompt Payment**

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

3. Prior period adjustments and ongoing improvements to performance reporting

3.1. Following on from our recent Performance audit, we have taken steps to ensure that in future we formally revise data reported in earlier months when further data is known, for instance for some data this means re-running reports the following month, to check for data that was reported late, after the performance report data was captured. These are called prior period adjustments.

3.2. During our recent performance internal audit, the internal auditor also identified a number of reporting errors from teams. These were mainly minor, but in relation to one KPI, turnover, these had a substantive implication for two RAG ratings reported during 2020. These were as follows:

- HR1 – sickness absence - manual input errors in data for the Months May, June, July and September 2020 – this did not impact the RAG rating
- HR2 - Staff Turnover – error found in the formula - November and December 2020 indicators changed from Green to Amber
- R2 - Forms and errors in the current month - Manual input error in April 2020 - no RAG change
- Website session per month (tracker not KPI) – input error, May 2020 website users under-reported by 8,000 users.

3.3. Reporting prior period adjustments also means going back to earlier months for outliers that miss a particular deadline (the month that they would usually have been reported in), to ensure the data does not paint an artificially rosy picture. We plan to flag these to Authority whenever they occur and have an impact on a RAG rating that was reported earlier. There has been one such change to report this month:

- Prior period adjustments resulted in March PGD data moving from Amber as reported to SMT (average of 79 working days) to red (average of 85 working days) once the outliers were completed.

3.4. This month we discovered an issue in the calculation of the PGD performance data, as public holidays were omitted from the calculation in error. This actually means that the data reported is somewhat better than previously stated, but the implication is also that where target dates have changed, some data was reported in the incorrect months.

3.5. Since the discovery, all teams have been contacted to notify them of this issue to ensure that they check their own calculations. We have already identified that the same issue impacted FOI reporting (the date that responses were due) and the finance data, but in neither case did this affect RAG ratings. We are also investigating and documenting this as an internal incident to ensure we document the extent of the issue and identify clear learning and actions to avoid a recurrence.

3.6. To reduce the risk of misreporting due to calculation or data entry error ongoing we have a clear plan in place to improve KPI standard operating procedures across the organisation and dip-test data on a regular basis to identify any errors that occur and put this right in a timely way. This will be rolled out incrementally over the coming months.

Annex 1 HFEA Performance scorecard and management commentary – May 2021 data

Breakdown of total Red, Amber, Green and Neutral Indicators

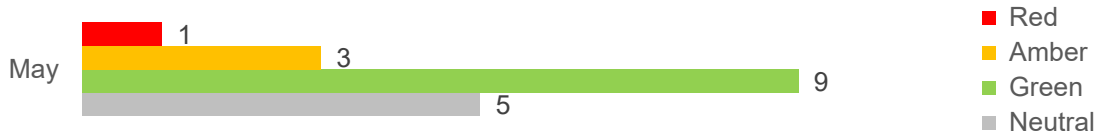


Figure 1 – Only 1 red indicator this month

RAG	Area	Trend and key data
Green – within target range	**People -** Employee turnover Target: between 5%-15%	10.20 % Turnover No leavers
Green – at target	**Regulatory efficiency -** Time for end-to-end inspection and licensing process Target: 100% in 70 working days or less	100% within target. Average of 46wds (items beginning with an inspection)
No target	**Engagement -** HFEA website sessions	67,132 sessions (148,362 in same month last year – high number then was due to publication of list of centres authorised to reopen under GD0014 v2)

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

Type	Actual in YTD £'000s	Budget YTD £'000s	Variance Actual vs Budget £'000s
Income	**1,133**	**1,031**	**102**
Expenditure	**(1,219)**	**(1,157)**	**(62)**
Total Surplus/(Deficit)	**(86)**	**(126)**	**40**

Commentary on financial performance to 31 May 2021

Year to date, we have a surplus against budget of £40k. This is largely due to our income for the first 2 months being in higher than budgeted (£102k). Our expenditure is over budget (£61k) as explained in the detailed commentary.
We will conduct our first detailed review at the end of June where we will forecast our spend and income for the remainder of the year.

Management commentary

In May performance is generally good. We had only one red indicator. Thanks to the hard work of the staff involved and new staff becoming fully operational, for the first time since reopening the service, May saw us respond to as many Opening the Register requests as were submitted to us. It is still early days, but application volumes also seem to be levelling off to pre-pandemic levels. We will soon have some turnover in this team, so there will be some ongoing disruption for several months, as further new starters are trained and come up to speed, though ultimately this will increase our processing capabilities.

Although turnover actually dropped in May, we are anticipating it increasing over the coming several months following a number of resignations. Consequently, this indicator is likely to move into amber as this is reflected in the monthly data. This is to be expected, following a long period where it remained at a very low level (in part because of the impact of Covid-19 on the job market). There are now signs that the job market is recovering and as a small organisation with limited promotion opportunities we should expect turnover to rise over time. We will be monitoring the impacts of this churn and related recruitment pressures and will ensure that risk is effectively managed where this arises.

Red indicators:

Compliance

- **C3 - PGD average processing.** Our target is for PGD application to be processed within 75 working days. In May, all seven of the PGD applications that were due missed the 75 working day target. These took between 80 and 95 working days to complete, with an average of 88 working days. This was due to scheduling to meetings. 6 of the PGD items were initially ready for the March SAC meeting but as the meeting was full, they had to be scheduled to the April SAC meeting. One further PGD was ready for the April meeting but that meeting was then full, so it was moved to May SAC. High numbers of Special Direction applications is one of the factors affecting meeting availability.

The April earlier red indicators were as follows:

Information

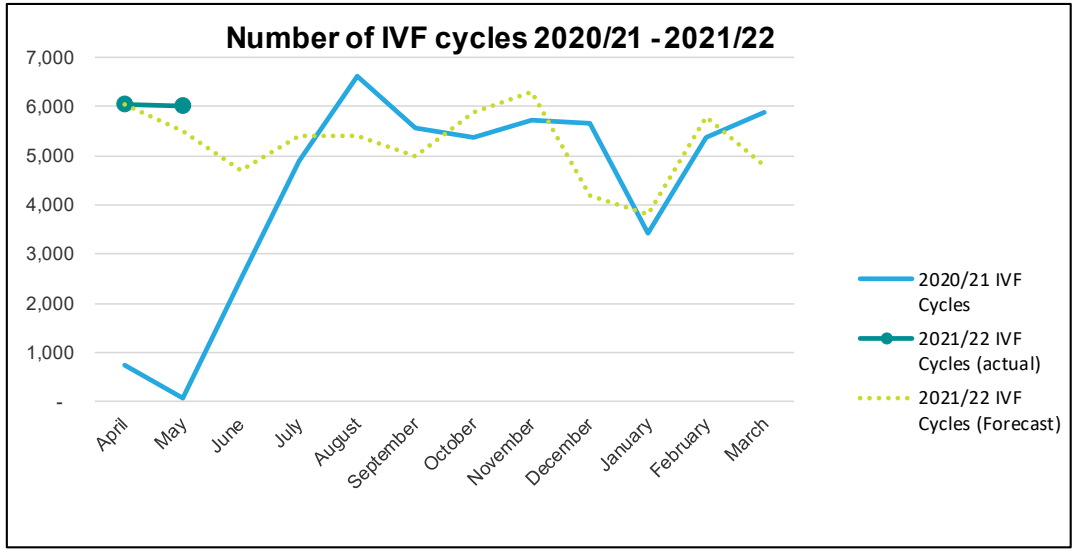
- **R2 Register data errors.** Our target is for a greater than 5% drop in outstanding errors**.** In April, our performance was a 5.5% increase in the total number of outstanding errors in the system taking into account the eight weeks centres are given to resolve (i.e., a snapshot of the number of errors that are 2 to 14 months old). This can be explained by pressure on the register team which was largely dedicated to familiarisation with PRISM and RITA and was diverted from some of their normal business as usual tasks to allow them to train on these tools. By May performance was a 1% decrease in errors which is rated amber.

Finance

- **F3 Prompt Payment.** In April, our performance was 39% of debts paid within 10 working days compared with our target of 85%. This was due to two invoices not being received and approved on time (total: £70k). Our performance was within target again in May.

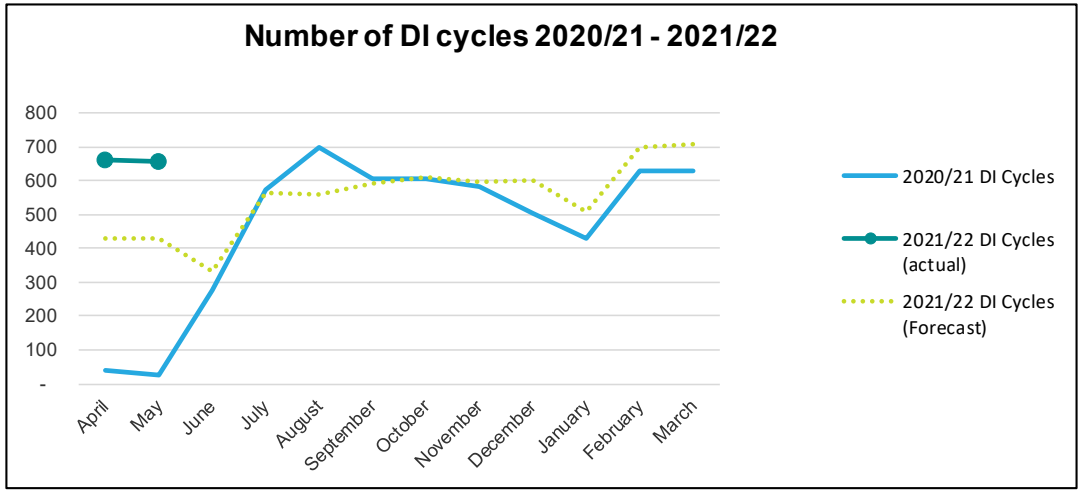
Annex 2 Financial management information

2021/22 Income



IVF Cycles	YTD		YE Position	
	Volume	£	Volume	£
2020/21 IVF Cycles	818	65,440	51,795	4,143,600
2021/22 IVF Cycles (actual)	12,061	964,880	63,361	5,068,880
Variance	11,243	899,440	11,566	925,280

At month 2 (May 2021) of the 2021/22 financial year, IVF cycles are higher than the normal annual treatment cycle trend.



DI Cycles	YTD		YE / Forecast	
	Volume	£	Volume	£
2020/21 DI Cycles	66	2,475	5,598	209,925
2021/22 DI Cycles	1,318	49,425	7,089	265,838
Variance	1,252	46,950	1,491	55,913

As with IVF cycles, DI volumes are higher in May than the the historic trend.

HFEA Income & Expenditure May-21

	Year to Date			
	Actual £'000	Budget £'000	Variance £'000	Variance YTD %
Income				
Grant-in-aid	-	-	-	-
Non-cash (Ring-fenced RDEL)	86	86	-	-
Grant-in-aid - PCSPS contribution	17	17	-	-
Licence Fees	1,010	904	(106)	-12%
Interest received	-	-	-	-
Seconded and other income	20	24	4	16
Total Income	1,133	1,031	(102)	**(10)**
Revenue Costs				
Salaries (excluding Authority)	778	804	26	3
Staff Travel & Subsistence	6	8	2	21
Other Staff Costs	9	9	0	1
Authority & Other Committees costs	36	35	(2)	(5)
Facilities Costs incl non-cash	298	156	(142)	(91)
IT Costs	55	105	50	47
Legal / Professional Fees	20	23	3	13
Other Costs	18	18	0	2
Other Project Costs	(1)	-	1	-
Total Revenue Costs	**1,219**	**1,157**	**(62)**	**(5)**
TOTAL Surplus / (Deficit)	**(86)**	**(126)**	**40**	
Adjusted for non-cash income/costs	**(125)**	**(126)**	**1**	

Management commentary

Income.
Licence fees are above budget by £106k (12%). This increase is a continuation from April and May's higher than usual volumes for IVF licence fees. Seconded and Other income shows a small deficit against budget. Confirmation of recharged costs are being sort and the forecast will correct this variance.

Expenditure by exception.
Year to date we are overspent by £62k.

Salary costs - are under budget (£26k). There are underspends in salary costs (£23k) due to vacancies and within our temporary staff costs an underspend of £3k.

Staff Travel and Subsistence - the underspend of £3k reflects the slow return to onsite inspections.

Authority & Other Committee costs - overspend of £2k represented by underspends (£5k) Authority Members' national insurance costs, offset by overspends in non-committee costs (£7k) being higher than expected.

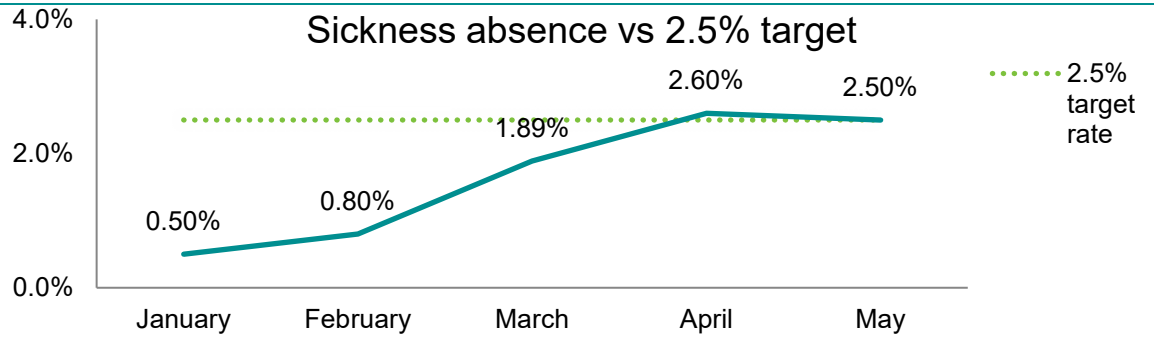
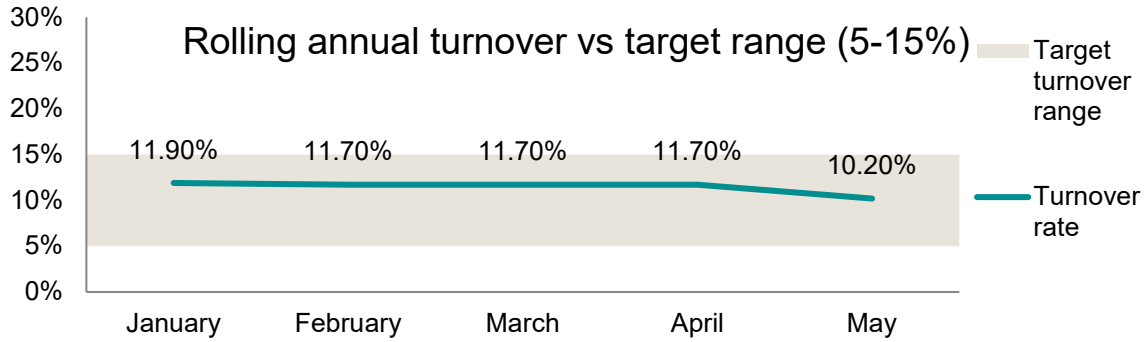
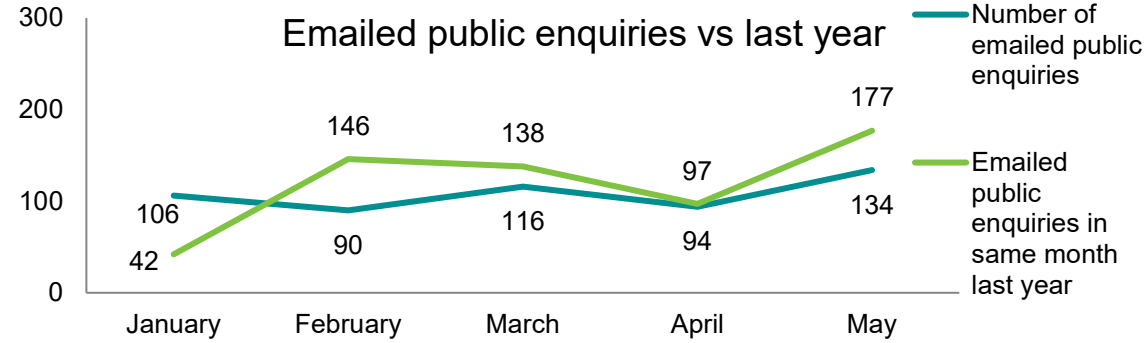
Facilities costs - overspent by £142k which relates to accommodation costs accrued for 2 Redman Place (£181k) for the quarter ended 31 March and the two months ended 30 May. We are waiting for DHSC to bill us for these costs even though the MOTO has now been signed. Offsetting this overspend is our non-cash costs (£39k)which relate to the amortisation of PRISM costs which will not commence until we go-live.

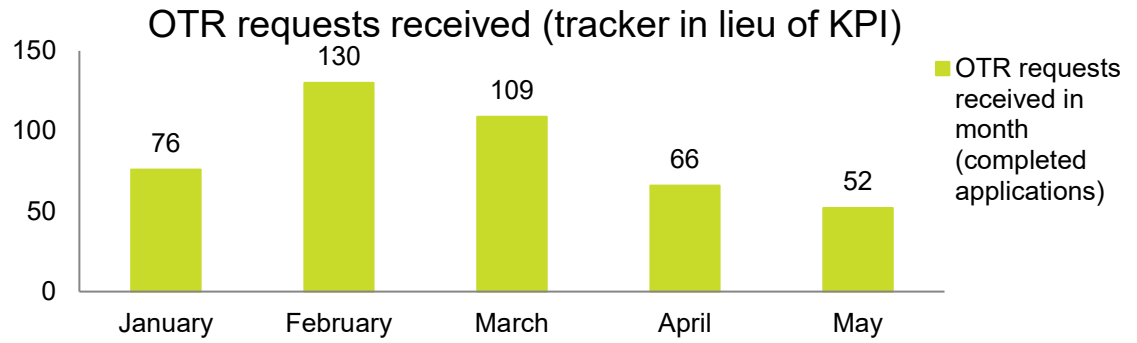
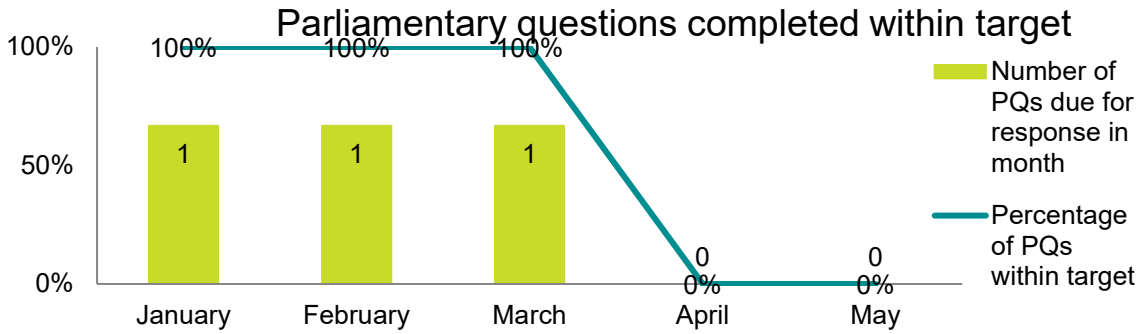
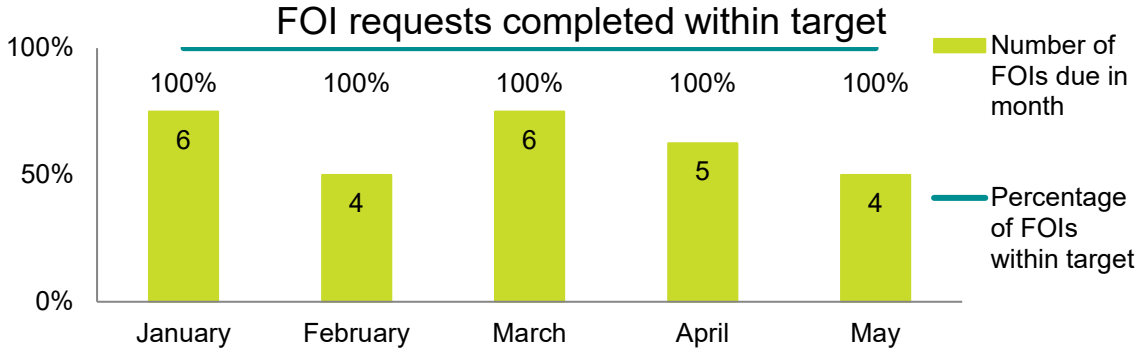
IT Costs - underspent by £50k. The main underspend are within our Support costs £41k and Subscriptions £12k, these are being reviewed to ensure we have captured all costs. Also underspends within our Low value fixed assets (£2k), Telecommunications £11k. Offsetting these (due to the budget profiled quarterly) is the overspend against Low value software of £16k. The low value software includes accruals for charges for equipment at 2 Redman Place yet to be billed.

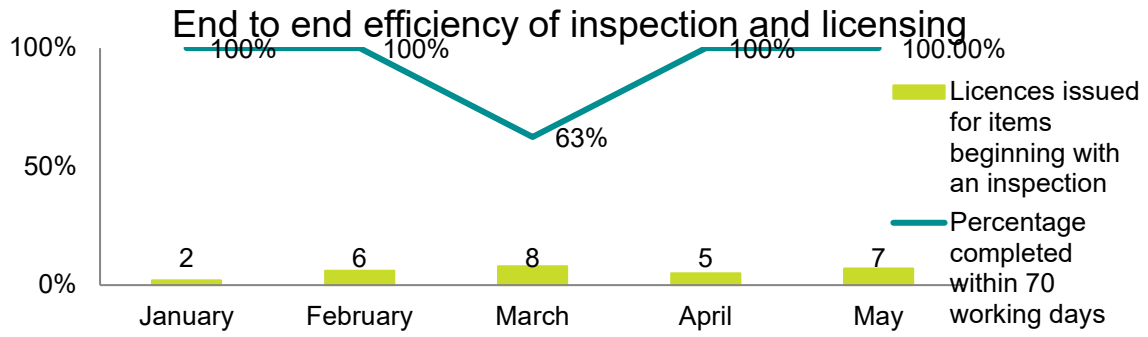
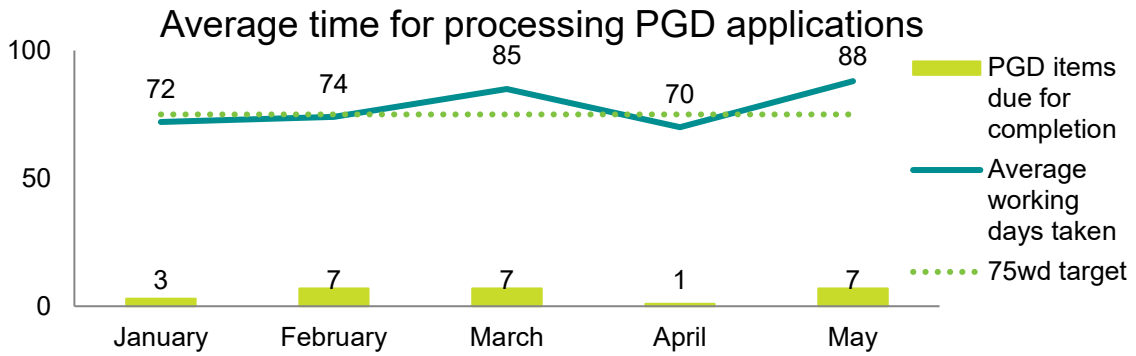
Legal/Professional Fees - under budget by £3k

Other Project cots - this line represents the costs incurred for EU Transition which will be funded by Grant in aid of (figure to be confirmed). Credit is due to an accrual for Morgan Cole that has been reversed.

Annex 3 – Key performance indicators – Authority summary

Key performance indicator name and description	Graph showing performance trend for last 5 months	Commentary (if any)	RAG rating
HR1 – Sickness **Target**: less than or equal to 2.5%. Target is based upon ONS 2018 data (2.7% for the public sector)		Sickness is steady. This includes a staff member on long term sick leave.	Green
HR2 - Turnover **Target**: between 5 and 15% turnover for the rolling year.		70- Headcount 68 - Establishment (posts) Turnover is low for now, however, we have received resignations so we will see a rise in the next few months.	Green
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.			Neutral
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 –. Most days taken:75 working days Least days taken: 21 working days	Green
C3 – Average PGD processing **Target:** average processing time of 75 working days. Average number of working days taken for those due in month. Note: Target changed from 66 to 75 in April 2020.		Most days taken: 95 working days Least days taken: 80 working days	Red

:

Code of Practice update, October 2021

Details about this paper

Area(s) of strategy this paper relates to:	The right information – to ensure that people can access the right information at the right time
Meeting:	Authority
Agenda item:	7
Meeting date:	07 July 2021
Author:	Emily Tiemann, Policy Manager Joanne Anton, Head of Regulatory Policy
Annexes	Annex 1: Guidance note 4 (Information to be provided prior to consent) Annex 2: Guidance note 5 (Consent to treatment, storage, donation, and disclosure of information) Annex 3: Guidance note 6 (Legal parenthood) Annex 4: Guidance note 11 (Donor recruitment, assessment and screening) Annex 5: Guidance note 14 (Surrogacy) Annex 6: Guidance note 15 (Procuring, processing and transporting gametes and embryos) Annex 7: Guidance note 16 (Import and exports) Annex 8: Guidance note 17 (Storage of gametes and embryos) Annex 9: Guidance note 18 (Witnessing and assuring patient and donor identification) Annex 10: Guidance note 19 (Traceability) Annex 11: Guidance note 20 (Donor assisted conception) Annex 12: Guidance note 25 (Premises, practices and facilities) Annex 13: Guidance note 26 (Equipment and materials) Annex 14: Guidance note 30 (Confidentiality and privacy)

Output from this paper

For information or decision?	For decision
Recommendation:	Authority members are asked to approve the proposed amendments to the Code of Practice, to be introduced later in 2021 subject to sign off by the Minister for Health and Social Care.
Resource implications:	Within Budget
Implementation date:	We are preparing for publication in October 2021, dependent on ministerial approval. We will keep Authority members and clinics informed in advance of the publication of this update.
Communication(s):	Code of Practice, Chair's Letter and Clinic Focus article
Organisational risk:	Medium

1. Overview

1.1. The Human Fertilisation and Embryology Act 1990 (as amended) (the Act) sets out the statutory framework for the use and storage of sperm, eggs, and embryos for human application, as well as all research involving the use of human and admixed embryos. Section 25 of the 1990 Act requires us to publish a Code of Practice which provides guidance to help licensed clinics comply with the Act and relevant legislation. This Code of Practice is regularly reviewed and updated and is primarily aimed at clinics. It also serves as a useful reference for patients, donors, donor-conceived people and researchers.

1.2. In March 2021 Authority members received a background paper outlining the areas for proposed change in the next Code of Practice update. This paper sets out the final changes that Authority are asked to approve today. The focus of this update is to incorporate legal changes that have come into force since the last Code publication in 2019, and to provide additional guidance that seeks to build upon and clarify areas of existing HFEA guidance. We have divided the changes into three sections: 1. Legislative changes 2. More substantive changes and 3. Smaller changes.

1.3. The legislative changes are:

- Amendments of the Act brought about by EU Exit, which primarily relate to the import and export of gametes and embryos and traceability requirements, among others, and which requires slightly different guidance depending on whether the clinic is based in Great Britain (England, Scotland and Wales) or Northern Ireland.
- Amendments of other legislation due to EU Exit including the Medical Devices Act 2002 (as amended), which has introduced new requirements for the marking of medical devices, and The Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019 which has introduced UK GDPR.
- Introduction of the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020 which amend the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009.

As these changes follow new statutory requirements the amended guidance is included for information only.

1.5. The more substantive changes are:

- Definition of a family for the existing 10-family limit policy
- Guidance on the use of electronic consenting platforms
- Guidance relating to legal parenthood and the use of gametes or embryos when relationships break down and patients subsequently return for further treatment
- Witnessing – requiring three identifiers
- Medicines management – complying with the relevant regulations, best practice, and professional body guidance

1.6. The smaller changes are:

- Reference to the CMA guidance on consumer law for the fertility sector
- Storing gametes and embryos that have been imported into the UK
- Storage when legal proceedings are threatened or commenced

- Exporting gametes or embryos for patients seeking commercial surrogacy abroad
- Disclosure of medical records of a deceased patient
- PGS and PGS terminology change to PGT-A and PGT-M
- Corrections and minor clarifications

1.4. Stakeholder engagement

As set out in the March background paper, to help inform the development of this draft guidance, in December 2020 we circulated a survey to clinics and other stakeholders to gather comments on areas of the guidance that we planned to update. We received 54 responses from a wide range of clinic staff including from 17 PRs. We also engaged with the Professional Stakeholders Group (PSG), the Association of Fertility Patient Organisations (AFPO) our Licensed Centres Panel (LCP), as well as other stakeholders on relevant issues. All of this has provided valuable feedback on the areas we will update, raising important considerations which have helped us with the development of the guidance.

1.5. Next steps

The following sections of this paper outline the rationale for amendments to the proposed new edition of the Code of Practice. Each recommendation summarises the proposed changes and makes reference to the annex(es) which contain the relevant guidance notes where changes for that topic are set out in full. Additions to the Code are shown in red font and deletions are highlighted in yellow. Some guidance notes remain unchanged or contain only minor amendments, so we have not annexed them, but the current version of the Code of Practice is searchable in full here. There may be final minor changes to the wording following a plain language check and some minor changes to colours and formatting following an accessibility check, however any changes will not affect the meaning behind the proposed guidance in the annexes.

1.6. Following Authority approval, we will put the Submission to Ministers in July with the aim of receiving clearance before the Summer recess. This would enable the Code to be laid in Parliament at the beginning of September for the planned October publication date.

2. Amendment of guidance due to legislation changes

2.1. Since the Code of Practice was last updated in 2019 there have been legislative changes that now need to be incorporated into the Code. We have already communicated these changes to licensed clinics through Chair's Letters, and the requirements are already in force.

2.2. EU Exit

The United Kingdom (UK) left the European Union (EU) on 31 January 2020, which resulted in a number of new regulatory requirements coming into force since the last Code update. The Human Fertilisation and Embryology Act 1990 (HF&E Act) continues to apply UK wide, however with some amendments resulting in certain provisions applying in relation to Northern Ireland (NI) only and, in some instances, to Great Britain (GB) only. The regulations that make these changes are The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019 and 2020 which were in turn required to give effect to EU Exit and the position that arises as a result of the Northern Ireland Protocol. The Code has been updated to reflect these changes and to make it clear what requirements apply to centres in GB only, NI only or to both GB and NI. Additionally some Standard Licence Conditions (SLCs) have been amended to

reflect changes in the legislation necessitated by EU Exit, for instance concerning traceability and the marking of medical devices. Where there are distinct SLCs or guidance for centres in NI only, the NI guidance has been highlighted within a light grey box. In every Guidance note which contains distinct SLCs or guidance for centres in NI, a box has been inserted at the very top under the title to highlight this.

2.3. To reflect the legal changes we have made amendments to guidance note 11 (Donor recruitment, assessment and screening) due to new versions of T53, guidance note 15 (Procuring, processing and transporting gametes and embryos) due to new versions of T51 and updated guidance on the Single European Code (now only applicable for centres in NI), guidance note 16 (Import and exports) due to amended legislation and different guidance depending on the location of the centre, guidance note 17 (Storage of gametes and embryos) due to new versions of T53, guidance note 19 (Traceability) due to new versions of T100 and T100, guidance note 26 (Equipment and materials) due to new versions of T30 and new guidance on the marking of medical devices, and guidance note 30 (Confidentiality and privacy) as EU GDPR is brought into UK law as UK GDPR.

2.4. **Recommendation**

The amendments to guidance notes 11, 15, 16, 17, 19, 26 and 30 can be found at Annexes 4, 6, 7, 8, 10, 13 and 14. As these follow the new statutory requirements the amended guidance notes are included for information only.

2.5. **Storage: COVID-19 Regulations**

To address difficulties arising due to the COVID-19 pandemic and fertility clinics being temporarily closed in April 2020, The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020, were introduced and came into force in July 2020. These Regulations make changes to section 14 of the 1990 Act as well as to the 2009 Regulations which provide for the extension of storage in certain circumstances. The 2020 Regulations enable patients who satisfy certain requirements to store their gametes or embryos for a further two-year period. To reflect the change to the legislation we have made changes to guidance note 17 (Storage of gametes and embryos) to the mandatory requirement boxes 17C and 17D, as well as adding 17.20-17.26. In line with the undertaking made by the Authority some time ago, we have also included more detailed guidance on the correct application of the 2009 Regulations as they apply to gametes and embryos first placed in storage both prior to 1 October 2009 when the regulations came into effect, as well as after that date. This is one of the most challenging area for clinics and is often a cause of non-compliance identified on inspection.

2.6. **Recommendation**

The amendments to guidance notes 17 can be found at Annex 8. As these follow the new statutory requirements the amended guidance changes are included for information.

3. More substantive changes to guidance

3.1. The following sections outline the more substantive changes to guidance which will be added to the Code in order to build upon and clarify areas of existing HFEA guidance. These areas have been identified through enquiries with the sector and discussions with HFEA staff and stakeholders.

3.2. **Definition of a family for the existing 10-family limit policy**

The Authority has long adopted a policy which states that donor gametes should not be used to create more than 10 families (or any lower limit specified by the donor). We have received queries from the sector about how we define a family under the limit, specifically in scenarios where a couple who conceives a child using donor sperm separate and one or both parties return to a clinic seeking further treatment using the same donor, alone or with a new partner. In the absence of a definition of family, it is not always clear to clinics whether in these circumstances each person having treatment would be creating a new family, or whether this would constitute an extension of the existing family.

3.3. We have added guidance to guidance note 11 (Donor recruitment, assessment and screening) and guidance note 20 (Donor assisted conception) to clarify this. Under the section on monitoring and complying with the 10-family limit (11.55-11.59), we have included a definition which says that a 'family' is defined as the patient to be treated and their partner (if they have one) and any existing legal child or children of either partner. We have also included some examples and made it clear that this limit applies in the UK only. In guidance note 20 we have added 20.9 to say that as part of discussions about the implications of using donated gametes or embryos, centres should explain the 10-family limit and how a family is defined according to the limit.

3.4. **Recommendation**

The amendments to guidance notes 11 and 20 can be found at Annex 4 and Annex 11 to this paper. The Authority is asked to approve the proposed changes.

3.5. **Guidance on the use of electronic consenting platforms**

New technology and the introduction of electronic consenting (e-consenting) platforms, as well as the effect of COVID-19 and the increase in virtual consultations, has increased the use of and demand for e-consent in UK fertility clinics. In September 2019 a Clinic Focus article on e-consenting was issued, as well as an updated version of General Directions 0007 on Consent (version 8). The guidance that was published in the Clinic Focus article has been put in to guidance note 5 (Consent to treatment, storage, donation, training and disclosure of information) and we have included further detail in a dedicated section entitled 'Guidance for centres considering introducing electronic methods of taking consent' (5.31-5.38). This includes guidance on what we expect from clinics to ensure the e-consenting platform they use is secure.

3.6. **Recommendation**

The amendments to guidance note 5 can be found at Annex 2 this paper. The Authority is asked to approve the proposed changes.

3.7. **Legal parenthood when relationships break down and patients return for further treatment**

Legal parenthood can be complex, particularly when relationships break down and patients return for further treatment, and generates many enquiries from clinics and patients. We have reviewed guidance note 6 (Legal parenthood) and added to 6.7-6.8 to make it clearer that marital status must be recorded when patients come for treatment. Additionally, we have amended 6.23-6.28 and 6.29-6.34 to include guidance on what centres should do to ensure correct recording of legal parenthood in the scenarios where a woman who is married to or in a

civil partnership with a man or a woman returns for subsequent treatment without her husband, wife or civil partner present. We have additionally added guidance (6.35-6.39 and 6.40-6.44) on scenarios where a woman has a male or a female partner who is not her civil partner, husband or wife.

3.8. **Recommendation**

The amendments to guidance note 6 can be found at Annex 3 this paper. The Authority is asked to approve the proposed changes.

3.9. **Witnessing – requiring three identifiers**

Currently our witnessing guidance requires that centres use a patient's or donor's full name and one or more additional identifier. Not using a third identifier may result in a risk of misidentification of a sample, and many clinics already routinely use three identifiers to reduce this risk. We have amended guidance note 18 (Witnessing and assuring patient and donor identification) 18.21-18.22 to require that the patient's or donor's full name and two other identifiers are used to identify samples. We have also added to 18.4 to include a witnessing step when donor gametes or embryos are allocated to a patient.

3.10. **Recommendation**

The amendments to guidance note 18 can be found at Annex 9 this paper. The Authority is asked to approve the proposed changes.

3.11. **Medicines management – complying with the relevant regulations, best practice, and professional body guidance**

Medicines management is an area in which we have seen a high number of non-compliances on inspection, we are therefore providing additional guidance in guidance note 25 (Premises, practices and facilities) on the duty of clinics to comply with the relevant regulations, best practice, and professional body guidance pertaining to medicines management and controlled drugs, to reduce the number of these non-compliances. We have amended 25.21-25.28 to include reference to regulations and best practice, and we have included additional guidance on the controlled drug register.

3.12. **Recommendation**

The amendments to guidance note 25 can be found at Annex 12 this paper. The Authority is asked to approve the proposed changes.

4. Smaller changes to guidance

4.1. The following section outlines the smaller proposed additions to our Code of Practice, mostly incorporation of guidance or information previously communicated through our Clinic Focus newsletter.

4.2. **Reference to CMA guidance on consumer law for the fertility sector**

The Competition and Markets Authority (CMA) and the Advertising Standards Authority (ASA) have published new guidance for fertility clinics in the UK, which explains what clinics should do to make sure their terms and practices are fair under consumer law and how to ensure compliance with advertising codes. We have referred to this guidance in guidance note 4 (Information to be provided prior to consent) in 4.1 and 4.10, and also added 4.12-4.13 to provide more guidance on obligations under Consumer Protection and contractual

arrangements, which has been taken from the CMA guidance on consumer law for the fertility sector. This can be seen in Annex 1.

4.3. **Additional information about add-ons**

Due to our continued work on add-ons, we have included additional references to what information should be provided about treatment add-ons in 4.8 and 4.11. This can be seen in Annex 1.

4.4. **Storing gametes and embryos that have been imported into the UK**

In February 2021 we released a clinic focus article to provide clarification on how to calculate storage periods for gametes and embryos that may have been exported then re-imported back into the UK. This has been added to Guidance Note 17 on storage (17.11-17.13), which can be seen in Annex 8.

4.5. **Storage when legal proceedings are threatened or commenced**

In 2003 a Chair's Letter CH(03)03 was sent to the sector about withdrawal of consent, and HFEA inspectors regularly refer to this letter when providing guidance in relation to ongoing storage when legal proceedings are threatened or commenced. This has been added to Guidance Note 17 on storage (17.27-17.30), which can be seen in Annex 8.

4.6. **Exporting gametes or embryos for patients seeking commercial surrogacy abroad**

In December 2020 we released a clinic focus article to provide clarification about whether, or in what circumstances, it is possible to export gametes or embryos for surrogacy, particularly when patients intend entering into commercial surrogacy arrangements abroad. This has been added to Guidance Note 14 on surrogacy (14.15), which can be seen in Annex 5.

4.7. **Disclosure of medical records of a deceased patient**

In August 2020 we released a clinic focus article to provide clarification on key points to consider if centres receive a disclosure request for the medical records of a deceased patient at their clinic. This has been added to Guidance Note 30 on Confidentiality and privacy (30.35-30.36), which can be seen in Annex 14.

4.8. **PGS and PGS terminology change to PGT-A and PGT-M**

The umbrella term 'preimplantation genetic testing' or PGT has been introduced across the sector to encompass all types of genetic testing on embryos. In recognition of this we are changing references to 'Preimplantation Genetic Screening (PGS)' to 'PGT for aneuploidies' (PGT-A) and 'Preimplantation Genetic Diagnosis (PGD)' to 'PGT for monogenic/single gene disorders' (PGT-M). This includes changing the name of guidance note 9.

4.9. **Recommendation**

The Authority is asked to approve the proposed changes.

5. Recommendation and next steps

5.1. The Authority is asked to consider and approve the recommendations made throughout this paper. All changes will be incorporated in the next update of the 9th edition of the Code of Practice. This will come into in force, subject to Ministerial approval, in October 2021. There may be final minor changes to the wording following a plain language check and some minor changes to colours and formatting following an accessibility check, however any changes will not affect the meaning behind the proposed guidance in the annexes.

Human Fertilisation & Embryology Authority

Fertility trends 2019

Nora Cooke O'Dowd
Head of Research and Intelligence
7 July 2021

www.hfea.gov.uk

Fertility treatment 2019: trends and figures – 30 years of HFEA

Report information

- UK IVF and DI statistics 2019: HTML & underlying data tables
- Quality and Methodology Report
- Publication date: 27 May 2021

Key points from the report

- Birth rates
- Treatment type
- Use of donor gametes
- Demographics
- Funding
- Multiple birth rates & embryo transfer policy

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Birth rates

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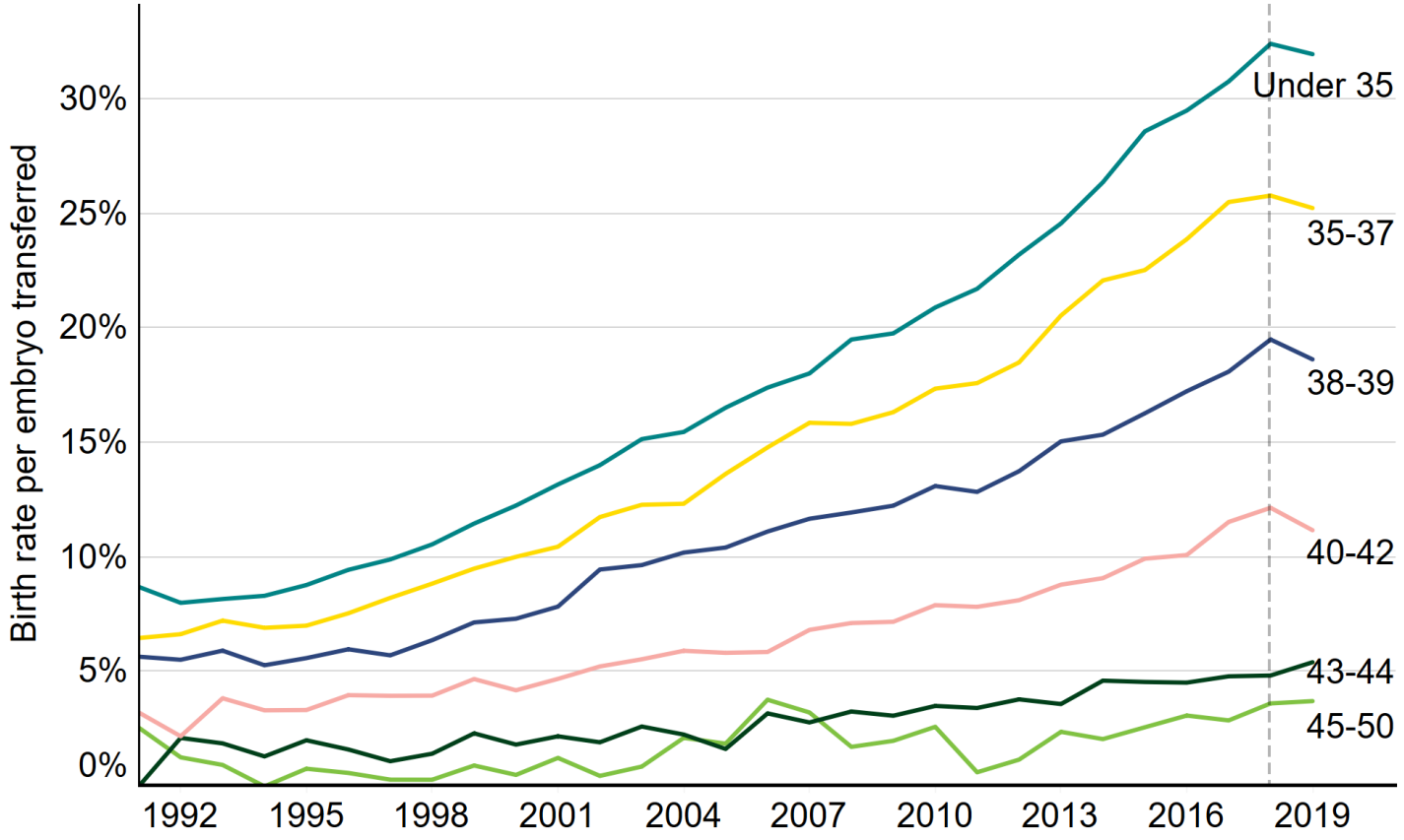
IVF birth rates in 2019 were three times higher than in 1991

Birth rates per embryo transferred by age band, 1991-2019*



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*Note: Birth rates for 2019 are provisional and yet to undergo validation. This data includes treatment cycles only, IVF, Patient egg. It excludes fresh and frozen PGD and PGS, surrogacy, and cycles where pregnancy was recorded but not outcome

Treatments

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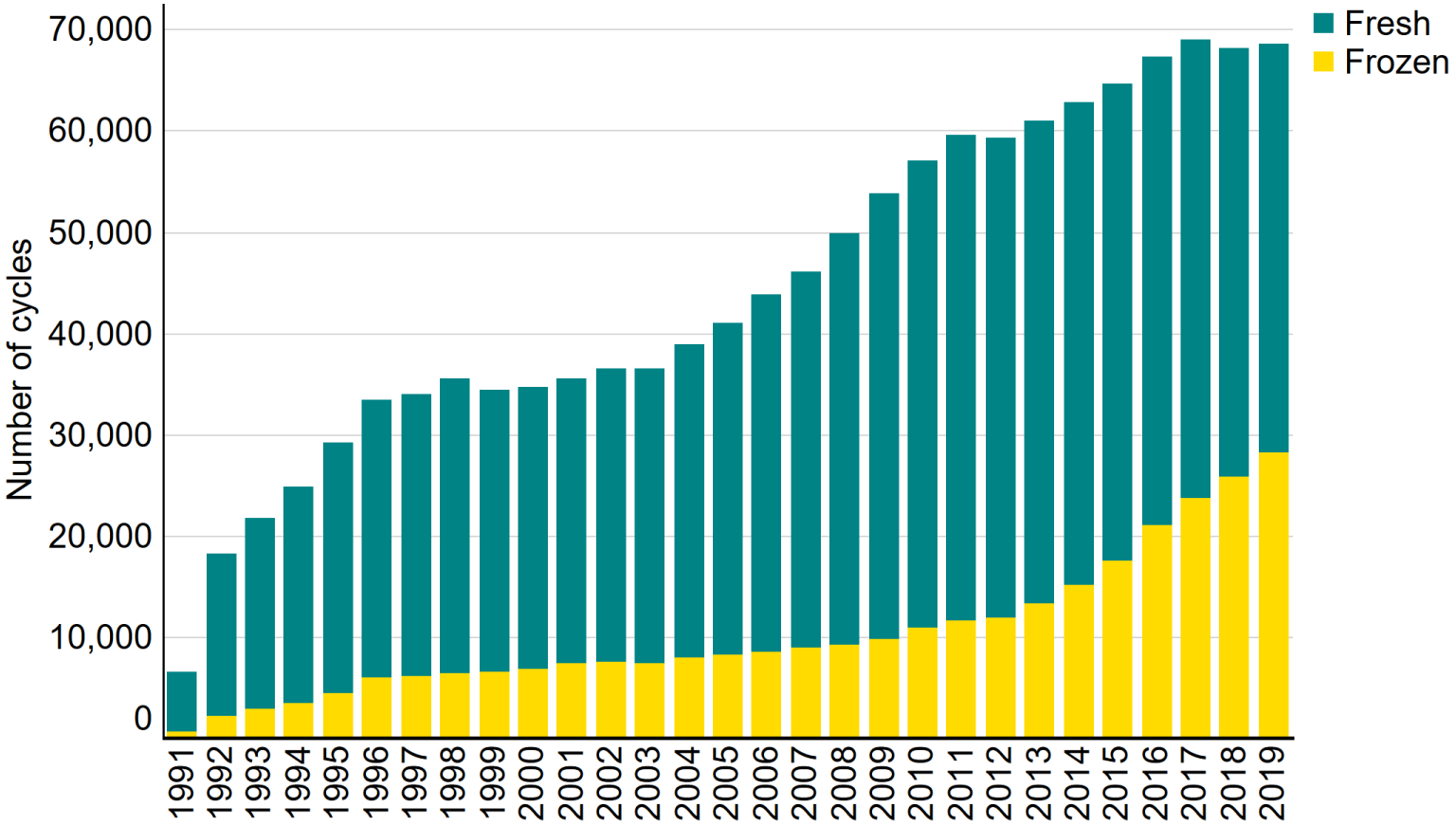
IVF cycles are levelling off, while frozen embryo transfer increases

Number of fresh and frozen IVF cycles over time, 1991-2019



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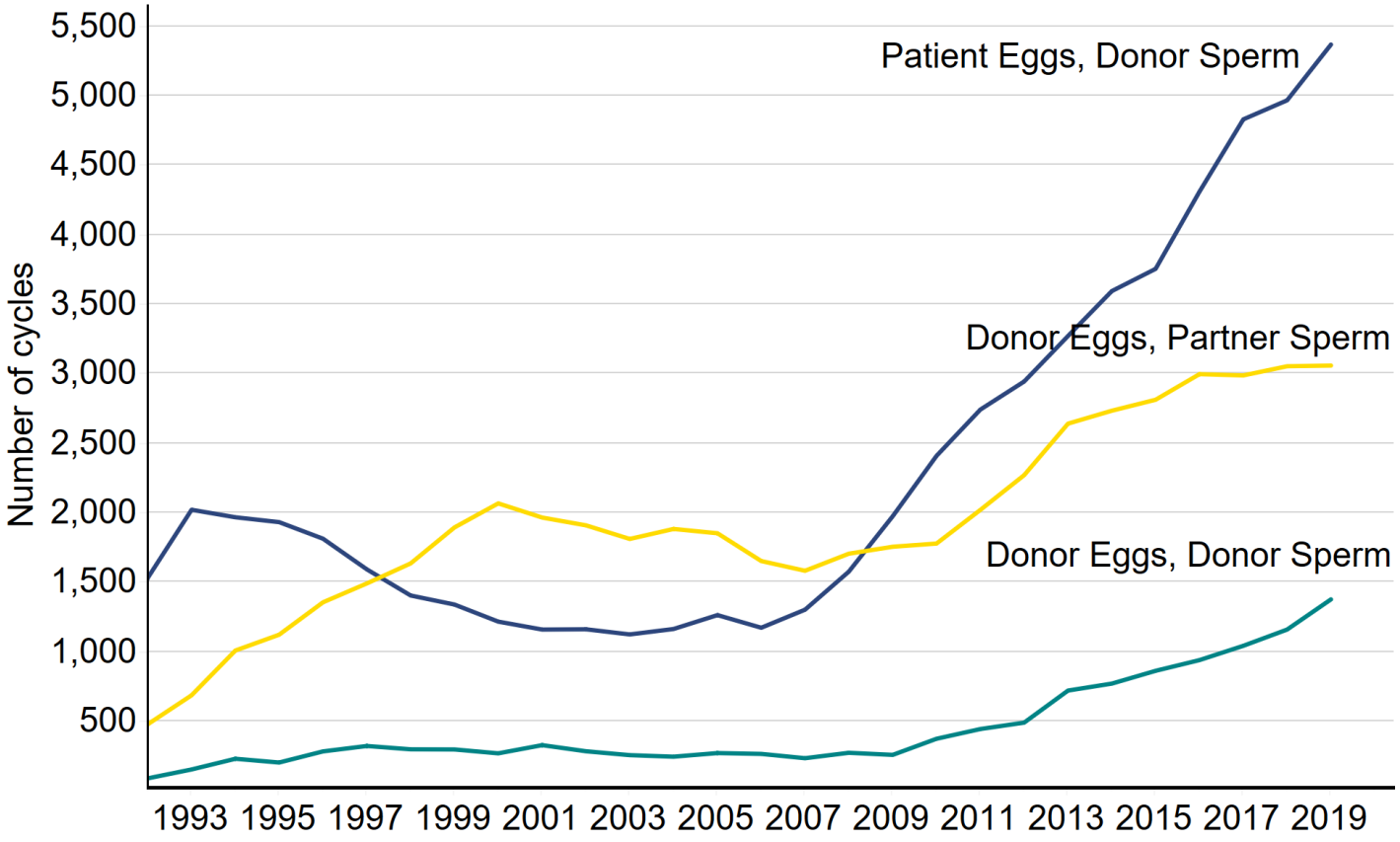
Note: This data includes IVF and treatment cycles. Partial year data for 1991.

Use of donor eggs and sperm have increased over the past 30 years

Number of IVF cycles using donor egg and sperm by egg and sperm source, 1991-2019



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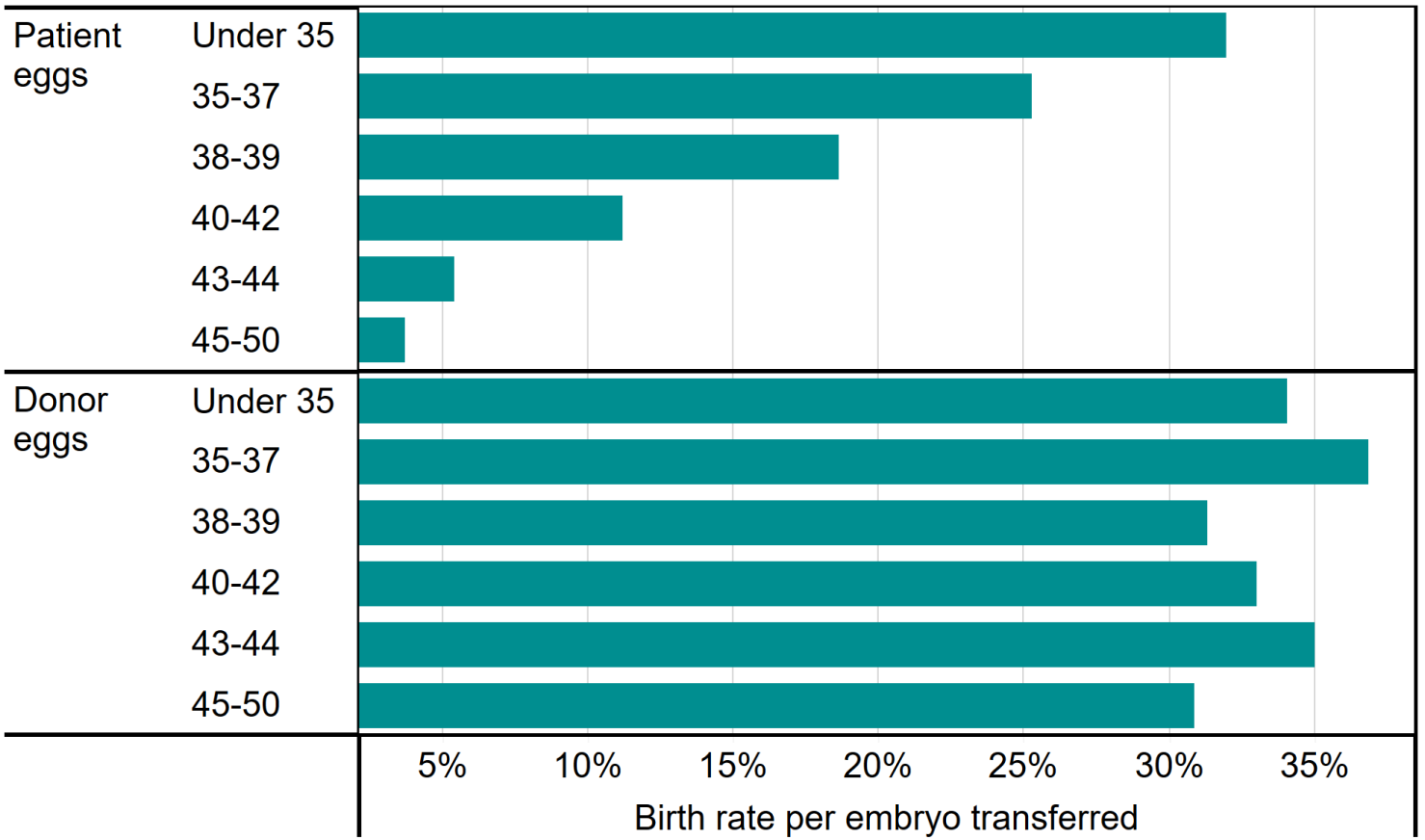
Note: This data includes treatment cycles and IVF only. It excludes cycles where sperm source was not recorded. Partial year data for 1991.

IVF birth rates are above 30% for all patients using donor eggs

Birth rates per embryo transferred by age band and egg source, 2019



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Note: This data includes treatment cycles only and IVF. It excludes fresh and frozen PGD and PGS, surrogacy, and cycles where pregnancy was recorded but not outcome. Birth rates for 2019 are provisional and yet to undergo validation.

Demographics

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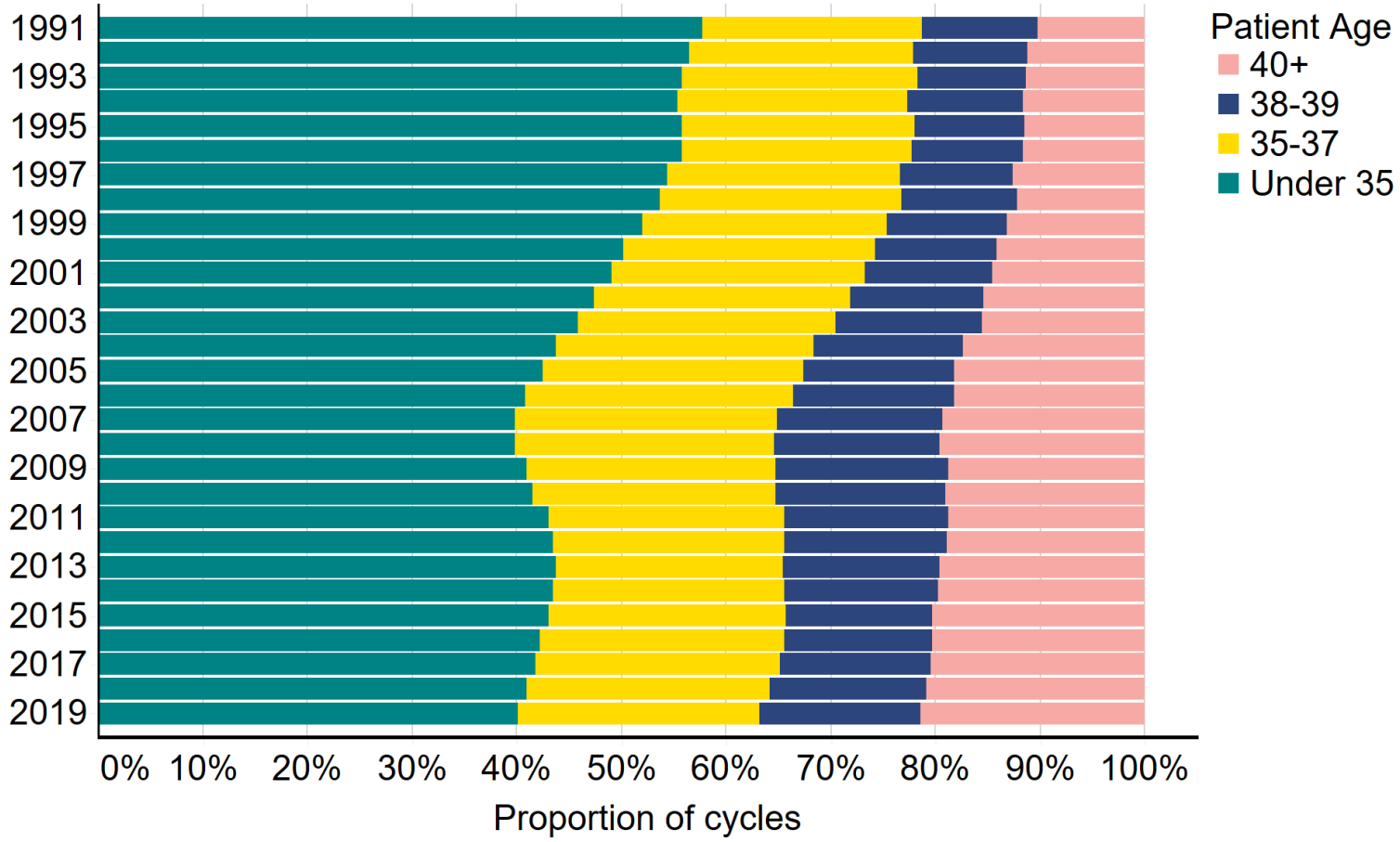
A growing proportion of IVF patients are aged 40 and above

Proportion of IVF cycles by patient age group, 1991-2019



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*Note: Birth rates for 2019 are provisional and yet to undergo validation. This data includes treatment cycles only, IVF, Patient egg. It excludes fresh and frozen PGD and PGS, surrogacy, and cycles where pregnancy was recorded but not outcome

DI is most commonly used by patients with a female partner

IVF and DI cycles by partner type 2009 and 2019

		Male partner		Female partner		No Partner	
		Cycles	%	Cycles	%	Cycles	%
IVF	2019	64,774	94%	2,435	4%	1,470	2%
	2009	53,396	98%	489	1%	565	1%
DI	2019	2,153	38%	2,514	44%	1,027	18%
	2009	2,211	57%	984	25%	702	18%

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Note: This data includes treatment cycles and excludes surrogacy. Reliable data not available prior to 2009

Funding

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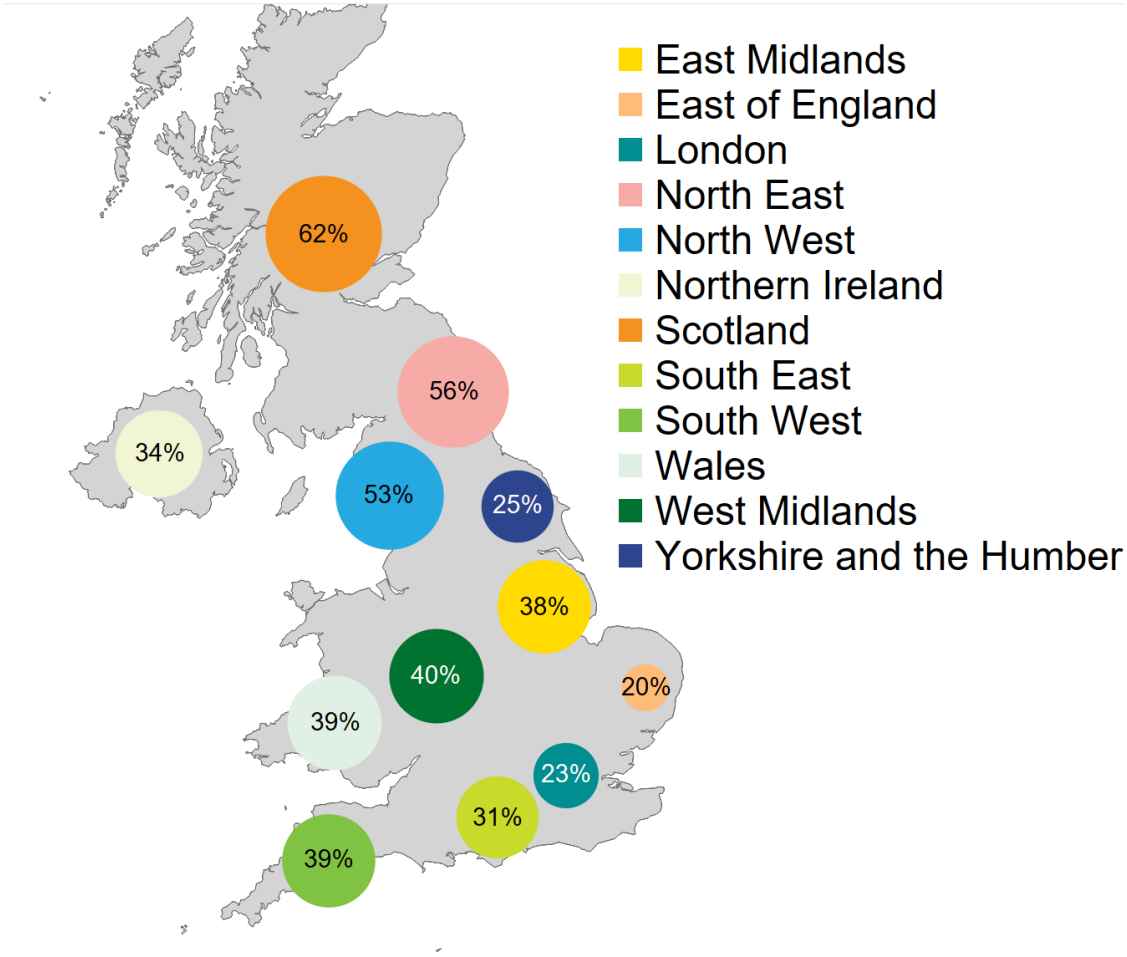
There is substantial variation in IVF funding across the UK

NHS funding of IVF cycles in UK nations & English regions, 2019



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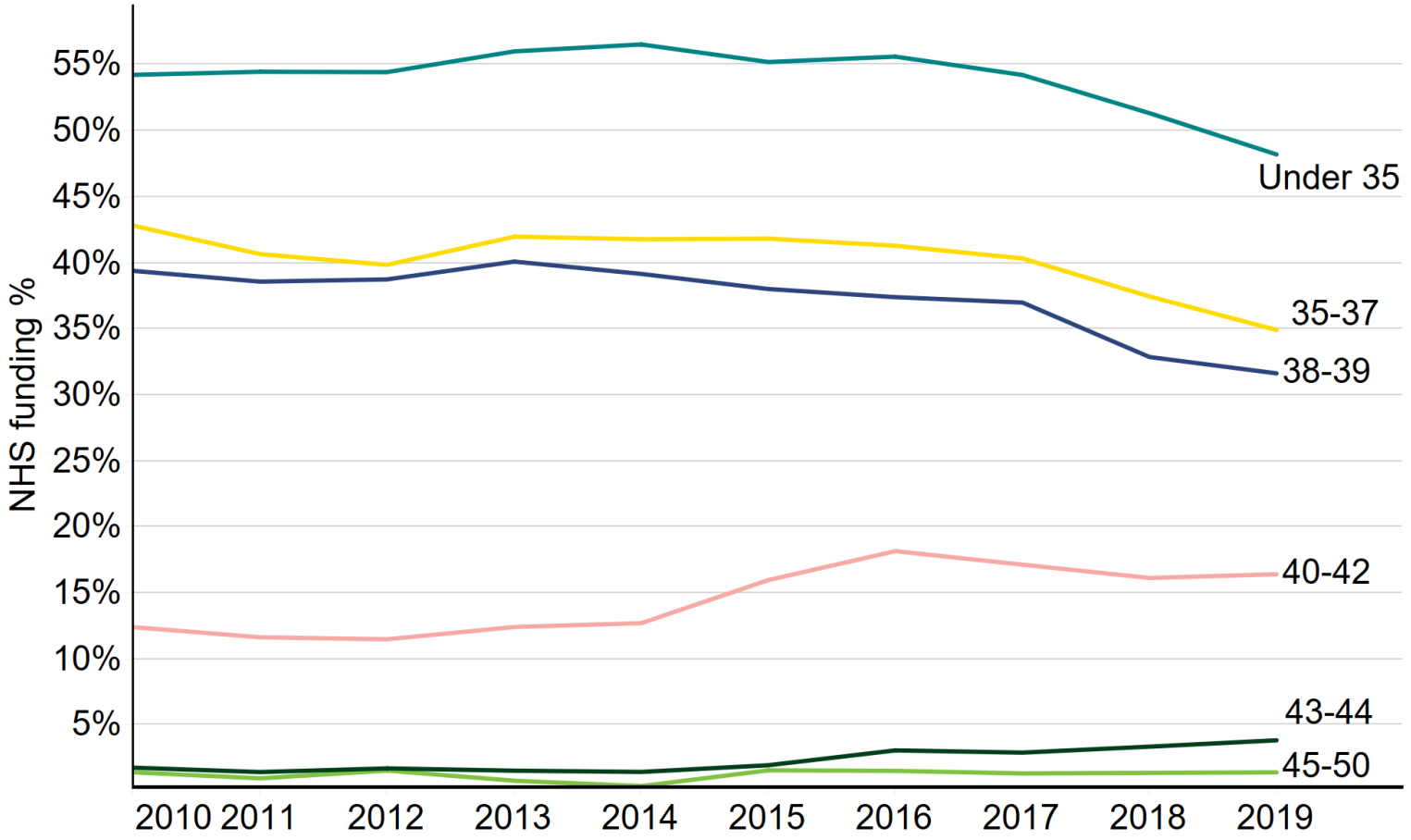
Note: This data includes treatment now and IVF only. The bubble sizes are in ratio to the number of IVF clinics in that region

NHS-funded cycles have declined among the younger age groups

Percentage of NHS-funded cycles by age, UK, 2009-2019



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Note: This data includes treatment cycles and IVF only. Where no age is indicated cycles have been excluded. Data not reliably available prior to 2009.

Multiple births

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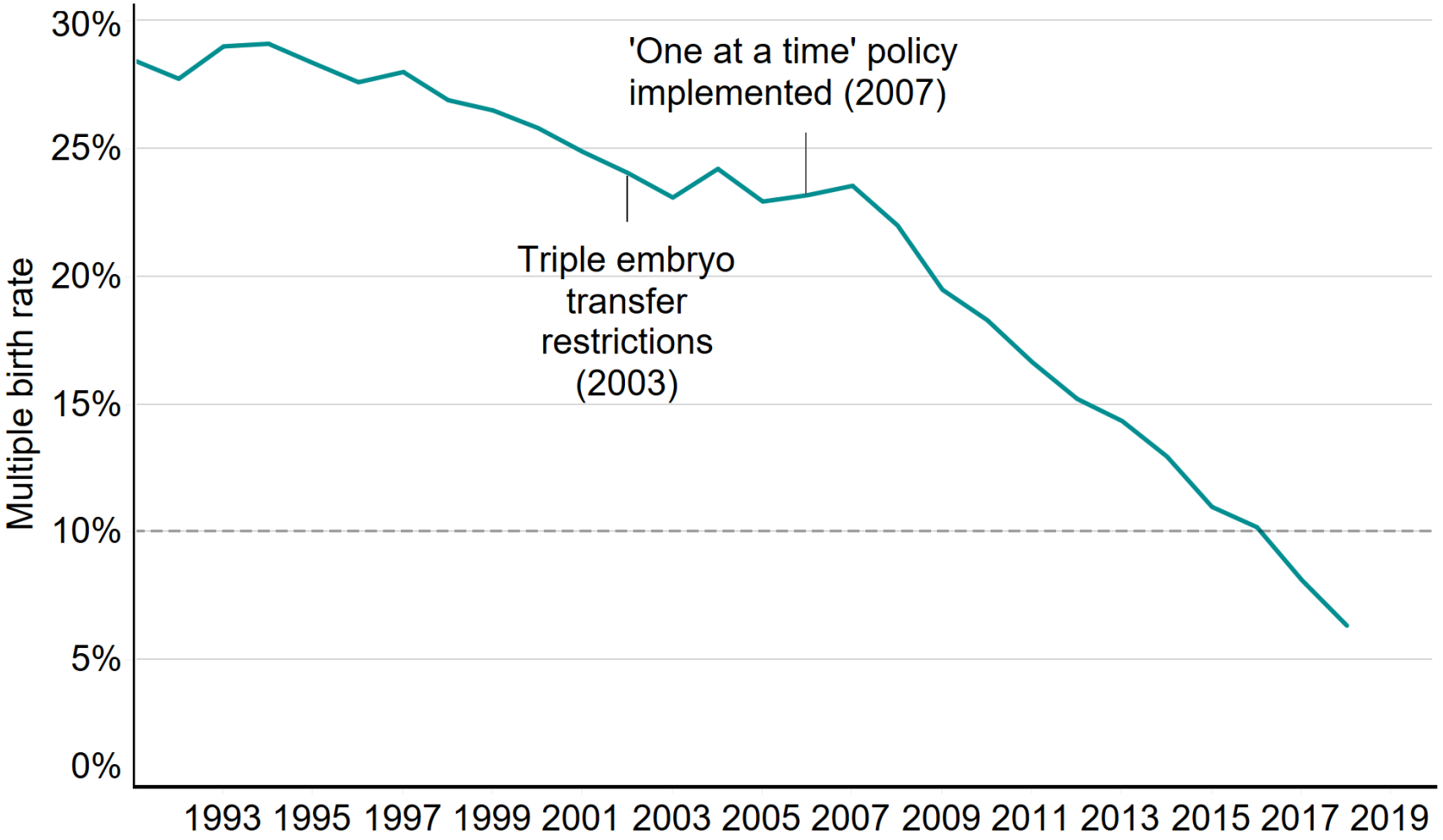
Multiple birth rate has decreased

Average live multiple birth rate, 1991-2019



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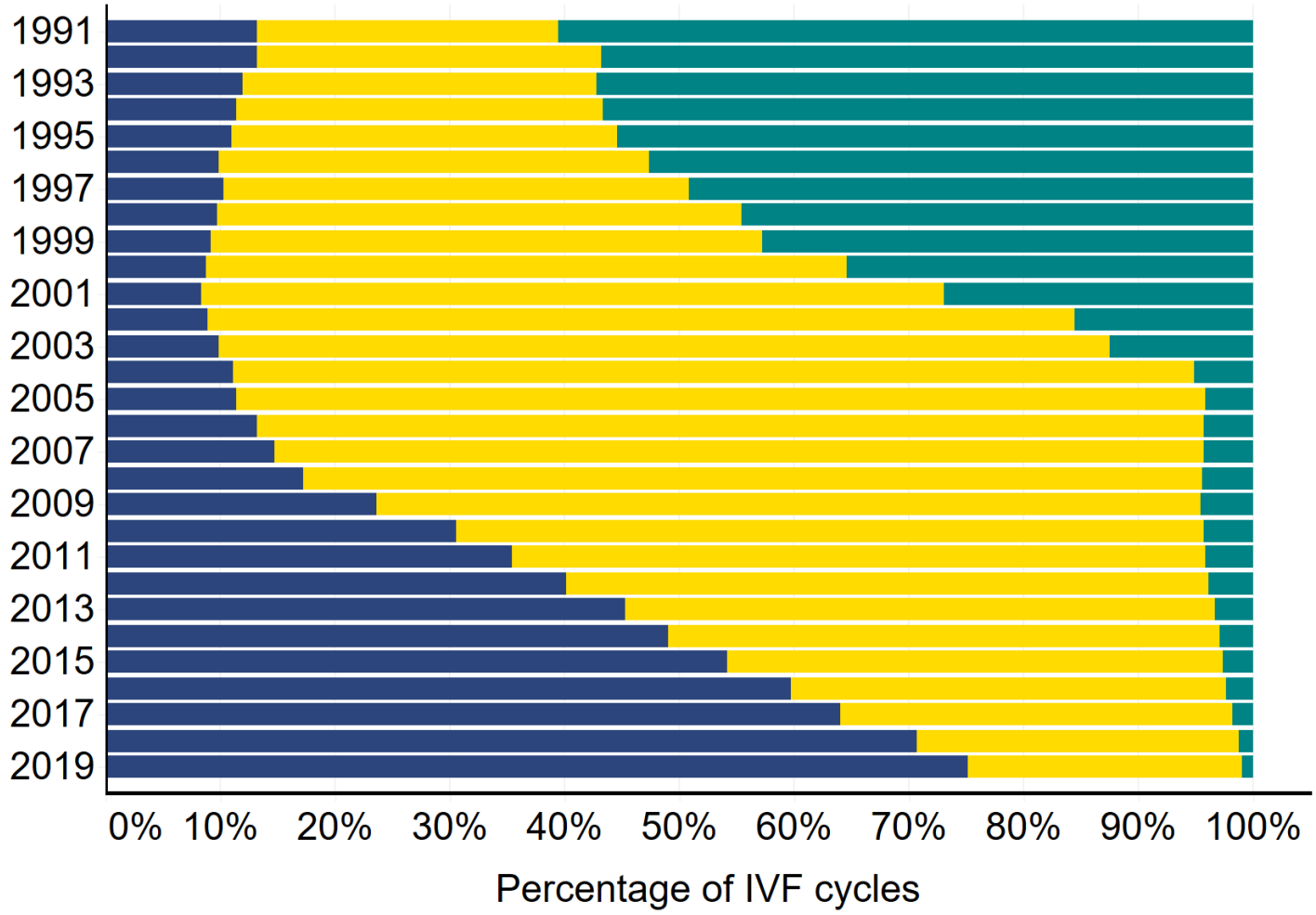
Note: This data includes treatment cycles and IVF only. It excludes cycles where pregnancy was recorded but not outcome.

Single embryo transfers increasing

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



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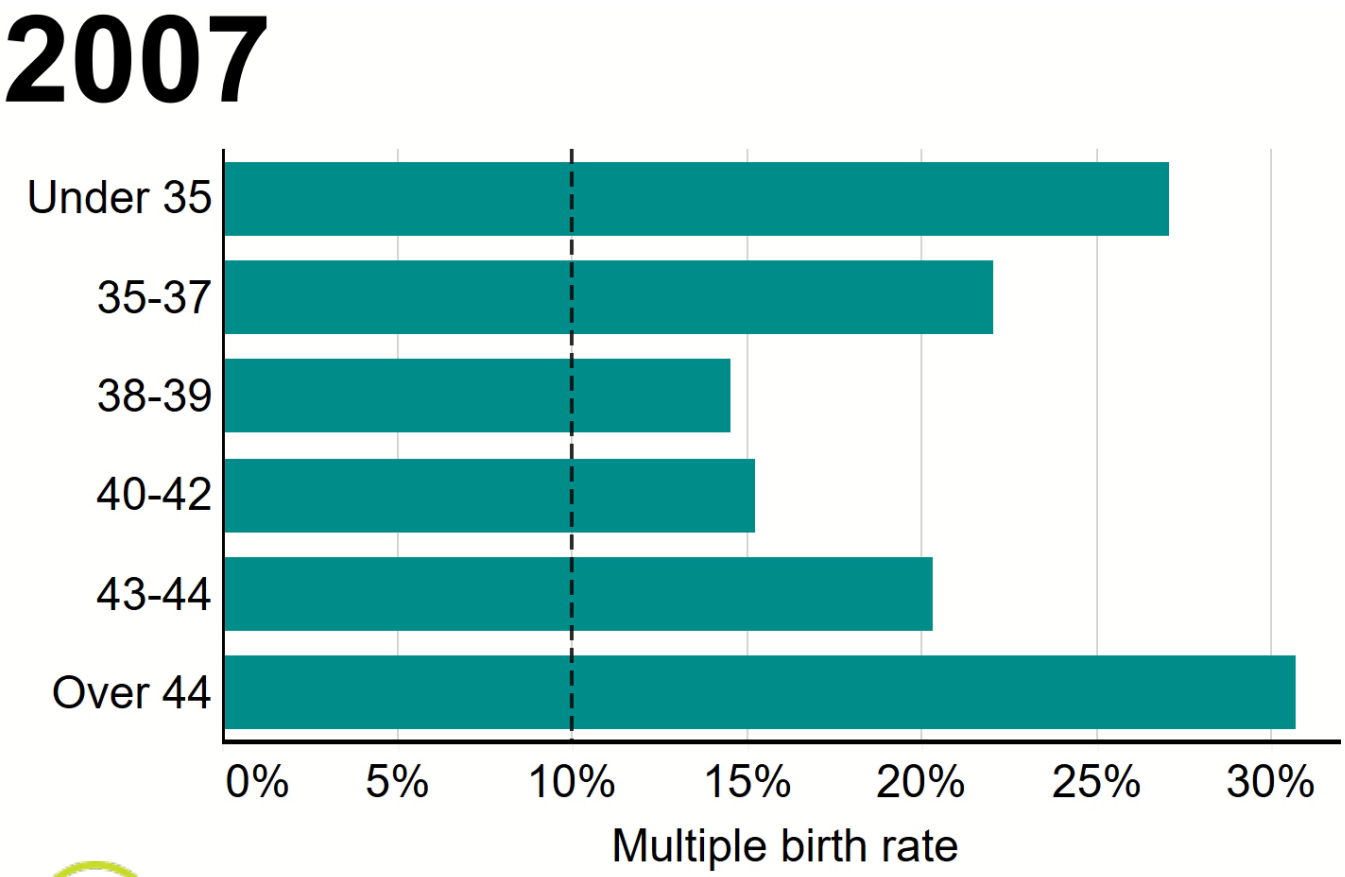
Note: This data includes treatment cycles and IVF only. It excludes cycles where pregnancy was recorded but not outcome.

Multiple births decreased most for youngest and oldest ages

Multiple birth rate by age groups, 2007-2019



Press play

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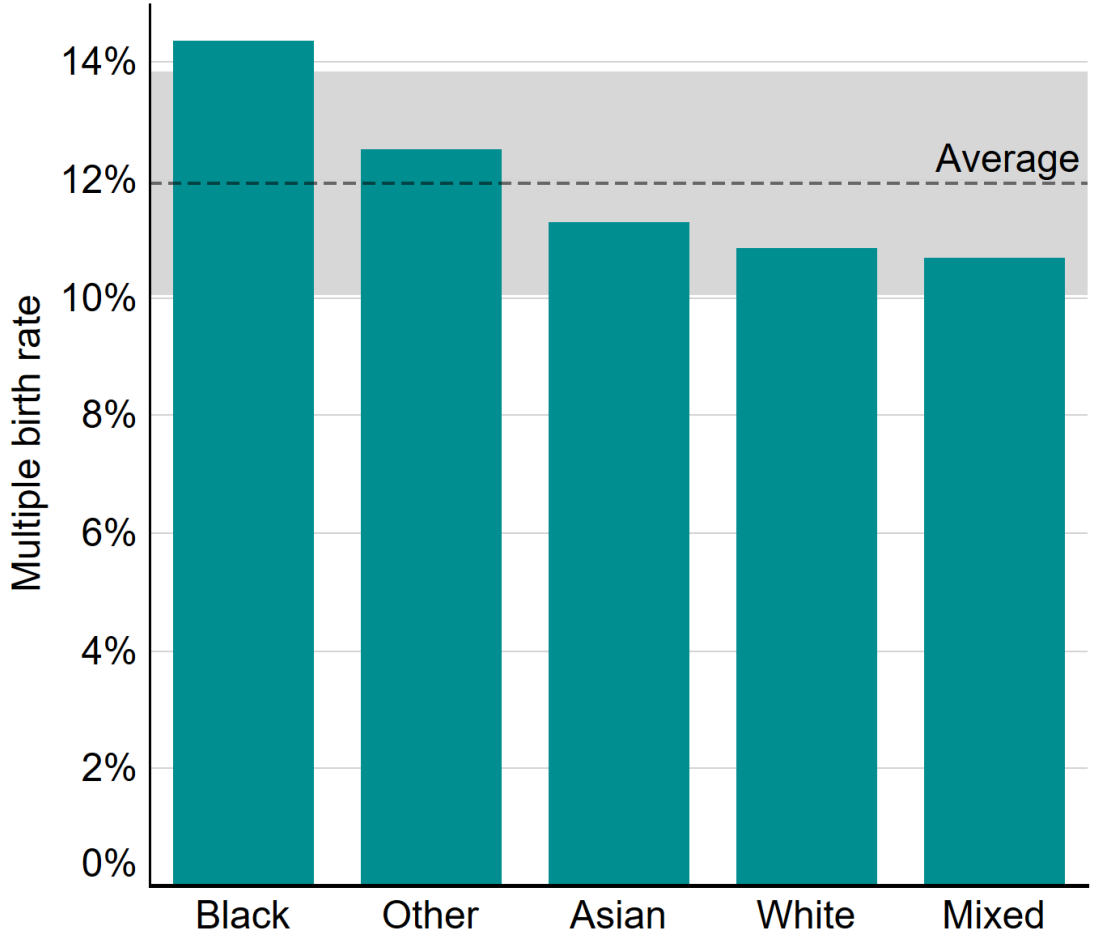
Note: This data includes treatment cycles and IVF only. It excludes cycles where pregnancy was recorded but not outcome.

Multiple birth rate higher for patients of Black ethnicities

Multiple birth rate by patient ethnicity, 2014-2018



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Note: Cycles where a pregnancy was recorded but not the outcome have been excluded. Average multiple birth rate (dashed line) only includes cycles with listed ethnicity. Grey shading represents 95% confidence interval.

80% of clinics had multiple birth rates below 10% in 2019

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**

Note: clinics with fewer than 150 cycles have been excluded to reduce extreme values. There were only 4 non-compliances related to multiple births in 2019/20 and clinics listed here as “above target” may be consistent with the national average.

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Next steps

There is a range of related upcoming work:

- Follow-up qualitative work from the ethnic diversity in fertility treatment publication speaking to patients/clinics
- Look at clinic variation on what factors are most important for high clinic performance
- Potential review at future Authority meeting on multiple birth policy considerations:
  - Does the Authority want to consider reviewing the multiple birth target?
  - What information would you need to discuss any changes to the multiple birth strategy?

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Any questions?

Please contact:

Intelligenceteam@hfea.gov.uk

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Update on work with the CMA and ASA

Clare Ettinghausen
Director of Strategy and Corporate Affairs
7th July 2021

www.hfea.gov.uk

Update

Will cover

- Background – what was the problem?
- What did the CMA and ASA do?
- Launch of the CMA guidance and enforcement notice
- Next steps for the CMA and ASA
- Next steps for the HFEA

What was the problem?

Background

- Concerns raised that Consumer Law and Advertising Codes were not well understood by the fertility sector
- CMA set out to provide guidance to enable compliance by clinics and others; ASA set out to provide guidance to be used by those advertising services
- HFEA closely involved in these conversations but limited in what we can do in either area by our current powers
- Working together with other regulators demonstrated how we can join forces effectively where our Act is in need of review

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What did the CMA and ASA do?

- After a great deal of background work, the CMA launched guidance for consultation during 2020. High level of engagement with HFEA, clinics, professional bodies, individual clinics and stakeholders, patient groups and individual patients
- ASA involved in background discussion and reviewed where they saw problems arising, e.g. claims made in clinic advertising
- Final CMA guidance and ASA enforcement notice launched June 2021, with a joint letter with the HFEA to all licensed clinics and publicised via media and social media
- Aim of both is to explain the law so that there is greater compliance

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Next steps for the CMA and ASA

Post June 2021

- Both regulators allow time for providers to review their information and make changes if needed
- After six months, they will carry out reviews to see if providers are compliant
- If they find cases of non-compliance then they may take enforcement action against their relative compliance regimes

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Next steps for the HFEA

Post June 2021

- CMA and ASA will provide training for our inspectors in relation to their legislation. NB. HFEA inspectors will *not* review compliance with CMA or ASA rules, but they do need to be aware of any issues and know what to do if they spot something, or a complaint is raised with them
- We will develop our Memorandums of Understanding and protocols with CMA and ASA covering sharing information, if relevant, and working together going forward
- We will develop proposals on transparency last discussed with Authority in May 2021, relating to how others publish information and will return to Authority later this year for further discussion.

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