Human Fertilisation & Embryology Authority

# Authority meeting

**Date:** 22 March 2023 – 1.30pm to 4.30pm

**Venue:** Thames 35&36 - HFEA Office, 2nd Floor 2 Redman Place, London E20 1JQ

| Agenda item | Time |
|---|---|
| 1. Welcome, apologies and declarations of interest | 1.30pm |
| 2. Minutes of the meeting held on 25 January 2023 and matters arising<br>For decision | 1.35pm |
| 3. Chair and Chief Executive's report<br>For information | 1.40pm |
| 4. Committee Chairs' reports<br>For information | 1.50pm |
| 5. Performance report<br>For information | 2.10pm |
| 6. Effective governance<br>For decision | 2.40pm |
| 7. Code of Practice update<br>For decision | 2.55pm |
| Break | 3.25pm |
| 8. Opening the Register - update<br>For information | 3.40pm |
| 9. Modernising Fertility Law - update<br>For information | 3.55pm |
| 10. Any Other Business | 4.25pm |
| 11. Close | 4.30pm |

# Minutes of Authority meeting held on 25 January 2023

| Details: | | | |
|---|---|---|---|
| Area(s) of strategy this paper relates to: | The best care – effective and ethical care for everyone<br>The right information – to ensure that people can access the right information at the right time<br>Shaping the future – to embrace and engage with changes in the law, science and society | | |
| Agenda item | 2 | | |
| Meeting date | 22 March 2023 | | |
| 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 25 January 2023 as a true record of the meeting. | | |
| Resource implications | | | |
| Implementation date | | | |
| Communication(s) | | | |
| Organisational risk | ☐ Low | ☒ Medium | ☐ High |

# Minutes of the Authority meeting on 25 January 2023

| | | |
|---|---|---|
| Members present | Julia Chain<br>Jason Kasraie<br>Frances Flinter<br>Zeynep Gurtin<br>Alison Marsden<br>Tim Child | Gudrun Moore<br>Alex Kafetz<br>Graham James<br>Jonathan Herring<br>Geeta Nargund |
| Apologies | Catharine Seddon<br>Alison McTavish | Frances Ashcroft |
| Observer | Amy Parsons (Department of Health and Social Care – DHSC) | |
| Staff in attendance | In person<br>Peter Thompson<br>Richard Sydee<br>Clare Ettinghausen<br>Rachel Cutting<br>Debbie Okutubo<br>Shabbir Qureshi<br>Amanda Evans | Online<br>Paula Robinson |

**Members**

There were 11 members at the meeting – seven lay and four professional members.

## 1. Welcome and declarations of interest

**1.1.** The Chair opened the meeting by welcoming Authority members and the DHSC colleague present. The Chair also welcomed staff and observers who were present and those online and stated that the meeting was audio recorded in line with previous meetings and for reasons of transparency the recording would be made available on our website to allow members of the public hear it.

**1.2.** Declarations of interest were made by:

- Jason Kasraie (PR at a licensed clinic)
- Tim Child (PR at a licensed clinic) and
- Geeta Nargund (Clinician at a licensed clinic).

## 2. Minutes of the last meeting and matters arising

**2.1.** Members agreed that the minutes of the meeting held on 16 November 2022 were a true record and could be signed by the Chair subject to the following change:

8.6 to read:

"…The Head of Information responded that the Donor Conception Network (DCN) currently provide information and peer support…"

**2.2.** Members agreed that action 8.20 on the matters arising report could be removed as the Executive had signed the contract with the Hewitt Centre and that there will not be any disruption to the existing service during the transition period.

**2.3.** The status of all other matters arising were noted.

## 3. Chair and Chief Executive's report

**3.1.** The Chair gave an overview of her engagement with key stakeholders, her attendance at sector related conferences and the decision-making committees of the Authority.

**3.2.** The Chair gave a summary of her attendance at the Fertility 2023 conference held in Belfast. She further commented that the legislative reform consultation will begin in February and that part of the plan was to visit clinics to ensure a wide range of views are gathered.

**3.3.** The Chief Executive (CE) provided an update on the key external activities that he had been involved in since the last Authority meeting.

**3.4.** Members were advised that the new Secretary of State for Health was keen that Arms-Length Bodies (ALBs) work together and share intelligence where relevant.

**3.5.** The Chief Executive continued that he had a meeting with the National Aids Trust to discuss their concern at the current restrictions on people living with HIV becoming donors. This issue has also been raised by some clinics who the Chair has visited. The DHSC is awaiting recommendations from the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) before considering any next steps with this issue.

### Decision

**3.6.** Members noted the Chair and Chief Executive's report.

## 4. Committee Chairs' reports

**4.1.** The Chair invited committee Chairs to add any other comments to the presented report.

**4.2.** The Licence Committee Chair (Alison Marsden) noted that a number of recent cases were very complex. Notably, they were having to meet out of their normal meeting cycle to review a particular complex case.

**4.3.** The Statutory Approvals Committee (SAC) Chair, (Jonathan Herring) stated that there had been three committee meetings since the last Authority meeting. At the December meeting, SAC conducted their annual committee effectiveness review.

**4.4.** The Audit and Governance Committee (AGC) deputy Chair (Alex Kafetz) gave a summary of the meeting in the absence of the Chair, Catharine Seddon. He commented that the committee agreed the approach to our risk appetite, tightened up the wording on the risk strategy and carried out the effectiveness review. Members were advised that at the end of the meeting there was a training on understanding financial statements which was facilitated by KPMG, our external audit partner firm.

**4.5.** The Chair thanked all Authority members for their hard work and time commitment on the various committees.

### Decision

**4.6.** Members noted the committee Chairs' reports.

## 5. Performance report

**5.1.** The Chief Executive commented on staff sickness absence which had increased significantly mainly due to two staff members on long term sick leave.

**5.2.** On PRISM, the Chief Executive commented that the system was working well. Three clinics had experienced delay in uploading information due to them switching to a third-party provider.

**5.3.** It was noted that back-dated validation errors had recently been released to clinics as part of the Choose a Fertility Clinic (CaFC) refresh plans. The Chief Executive thanked all clinics that were correcting the errors and further commented that this put us in good stead to predict when CaFC would be updated.

**5.4.** It was noted that we were aiming to have CaFC timelines confirmed between April and June 2023. However, the current prediction was that the best-case scenario for CaFC being ready to be updated was September 2023 whilst the worst case was June 2024 depending on validation errors being fixed and the verification period required.

### Strategy and Corporate Affairs

**5.5.** The Director of Strategy and Corporate Affairs presented this item.

**5.6.** It was noted that there was huge media coverage of the donation report published at the end of 2022 with significant interest in the number of children born from donor conception since 1991, the level of overseas donors at present and the upcoming changes to anonymity.

**5.7.** Members were advised that the consultation on changes to the Human Fertilisation and Embryology Act would open at the end of February for six weeks.

**5.8.** The next Scientific and Clinical Advances Advisory Committee (SCAAC) meeting will be held on 6 February and would be the first time that add-ons would be rated according to the new ratings system. Publicity on the new system and ratings would take place later in the Spring.

**5.9.** There had been some recent parliamentary interest in areas around fertility including two current private members bill in the House of Commons.

### Compliance and Information

**5.10.** The Director of Compliance and Information commented on the OTR service. It was noted that it continued to be a busy service. There were 57 applications in December and 43 applications in January 2023. The vacant post has been recruited to, and the team was now at its full staffing complement. The new improved team structure will assist in reducing the time to sign off applications.

**5.11.** In terms of licensing performance, it was noted that there were clinics who demonstrate good compliance but some clinics have more complex inspections due to several areas of non-compliance being identified. This may lead to post inspection activity such as management review meetings, requisitions for further information and accountability meetings. These activities can lead to an increase in the time it takes for reports for a licensing committee to be finalised. This will therefore mean our KPIs will not always be met.

**5.12.** The inspection schedule is very busy over the coming months with inspections currently booked to August 2023.

### Finance and Resources

**5.13.** The Director of Finance and Resources commented on the financial indicators in the performance report. As at November the forecast was showing a surplus against budget of £599k which was largely due to our income and the underspends within our expenditure. There are less than 10 clinics that have not caught up with their submissions, but the remaining 92 have been reconciled and were billed on actual submissions.

**5.14.** Members asked that if we were showing a surplus of £599k and it was returned to the DHSC, that was a large part of our grant in aid. The Director of Finance and Resources responded that we would not be sending it back to the DHSC and that we were in discussion on its usage as the Treasury rules of not spending our surplus still applied.

### Decision

**5.15.** Members noted the performance report.

## 6. Draft Business Plan 2023/24

**6.1.** The Chair advised members that we were required to set a business plan each year and that it would need to be approved by the DHSC. Members were reminded that there was an initial discussion at the November Authority meeting where priorities were noted and the Head of Planning and Governance subsequently circulated a report to members on priorities and trade-offs.

**6.2.** The Head of Planning and Governance thanked members for their responses and commented that in addition to our statutory work, in the first half of the coming business year, the major priorities would be:

- development work on the Opening the Register (OTR) service
- servicing our public body review, and
- completing our current work on the Act reform.

**6.3.** We would then assess the resource available to progress actions relating to regulatory transparency and the Government's Women's Health Strategy.

**6.4.** Members were advised that the full business plan might be brought back to the March meeting, or circulated for comment between Authority meetings, depending on the timing of the DHSC review and approval process.

**6.5.** Members asked how vacancies and staff sickness might impact the delivery of the work in the business plan. The Head of Planning and Governance responded that it had been taken into consideration, to the extent possible, when the Corporate Management Group (CMG) met to discuss priorities. The Chief Executive also commented that the business plan assumed that we had sufficient human resources to do the work and that if staff turnover and/or sickness affected delivery, we would do the maximum possible with the available resources.

**6.6.** Members were given the assurance that delivery would always be based on what could be achieved with the resources at any given time.

**6.7.** The Chair commented that we do not yet know the timetable for the public body review, but that if that was delayed, whether staff should consider if deprioritised work could be moved up the priority list. The Chief Executive responded that the public body review would impact mainly on the senior team but that available resources would still be taken into consideration.

Decision

**6.8.** Members approved the draft business plan activities for 2023/24 and noted that the further development of the business plan would now take place. Members would be kept informed of progress.

## 7. The Register research panel (RRP) and data research

**7.1.** The Head of Research and Intelligence presented this item. Members were reminded that the HFE regulations allowed disclosure of information for research purposes. As part of our work in reviewing the Act, staff met with some researchers in June 2022 who had used HFEA register data in their research to discuss where legislative changes would be of benefit to improve data research.

**7.2.** In their responses, four areas were highlighted:

- Cost recovery
- Research following egg, sperm or embryo donation
- Consent to non-contact research, and
- Child consent.

**7.3.** Members were advised that since the introduction of the 2010 regulations, the RRP had approved 20 projects: nine projects were currently active and 11 had been completed.

**7.4.** Members commented that limited number of researchers were using this data. The Head of Research and Intelligence confirmed this but commented that the plan was on raising awareness and we had the processes in place to handle requests.

**7.5.** In response to a question, members were advised that researchers are required to provide reasoning for why each data field is required in their research. Research projects require research ethics committee approval and researchers typically only use identifiers to link HFEA register data to other health databases. Identifiers are stripped from the linked data prior to being provided to the research establishment.

**7.6.** Members commented that the panel seemed to be entirely reactive, but the proposal looked like it was designed to promote research. The Chief Executive responded that we were not suggesting that the panel should limit research but we have an unused asset and we would like it to be better utilised.

**7.7.** Members discussed the proposal to approach DHSC with suggested changes to the 2010 regulations and the following points were discussed:

**7.8.** Members were concerned that raising the price from the current capped £5,000 could discourage research applications. The Director of Strategy and Corporate Affairs responded that we could not unilaterally do this as costs are set in regulation and we would be seeking a cost recovery model

rather than a single cost. She further commented that informal discussions and feedback received was that other organisations charged far greater amounts for access to their data.

**7.9.** It was noted that regulations restricted research to UK based or UK related organisations that could utilise the research.

**7.10.** Members commented that any change to an opt out system of consent to research was only useful if people knew to opt out and asked how users would be made aware. The Head of Research and Intelligence responded that we would have to respect the consent given previously and we would need to find ways of making the public aware of how to opt out of their data being used in research.

**7.11.** The Director of Compliance and Information responded that at the Fertility 2023 conference, feedback was that when consent shifted to electronic consent it decreased.

**7.12.** Professional members commented that clinic staff were very good at discussing the issues involved and getting consent from patients to data research.

**7.13.** Members asked if there could be a UK hub to encourage international collaboration as it was important to encourage international use of the data.

**7.14.** In response to a question, the Head of Research and Intelligence commented that according to legal advice, section 251 was not applicable to our regulations.

**7.15.** Also, that enabling data sets following linkage to be available to other researchers following the completion of the original project was one of the directions of travel we were pursuing. Members were advised that should they be convinced of the case for reform, the DHSC will be approached and members will be kept updated.

**7.16.** The Director of Strategy and Corporate Affairs commented that we have always had limited capacity to handle a high volume of requests and that 2023 would be a test year to see how things developed. It was also noted that through higher coverage of our data reports and use of data in the media and social media, anonymised register information is featured publicly on a daily basis.

**7.17.** The Chair commented that it was good to see that we were getting good use of our data.

Decision

**7.18.** Members supported an approach to the DHSC to make the case for changes to the 2021 regulations.

## 8. Presentation on Opening the Register (OTR)

**8.1.** The Directors of Compliance and Information and Strategy and Corporate Affairs presented this item.

**8.2.** Members were reminded that the change in the law in 2005 meant that donor conceived children could access identifying information about their donor once they turned 18 in 2023.

**8.3.** The Director of Compliance outlined key challenges for donor conceived individuals, donors, clinics and the HFEA.

**8.4.** The Director of Strategy and Corporate Affairs outlined three workstreams planned for this year, as well as the key risks and what we could do to mitigate them.

**8.5.** Members noted the risks identified including the reputational risks and that the use of postal address to communicate was very limiting.

**8.6.** A member asked if patients could be contacted using NHS numbers and see if the HFEA could find out if donors were still alive. The Director of Strategy and Corporate Affairs responded that this was something that we were currently seeking advice on and we would need to consider what information, and basis for contact, the donor had been given initially.

**8.7.** Members were given the assurance that we would bring updates back to them and engage with external stakeholders and clinics.

**8.8.** Members commented that we need to find positives in these stories and that a number of donors were open to contact following the change in legislation.

**8.9.** Members suggested that a cautious approach in relation to cyber security should be taken and should also be added to the risk register.

**8.10.** The Chair commented that there was a great deal of interest in this area and as the information provider, we would need to proceed with care.

**8.11.** Members would be provided with short talking points on the key facts in this area.

Action

**8.12.** Include cyber security in the risk register and provide members with talking points and regular updates to future Authority meetings.

Decision

**8.13.** Members noted the ongoing activities relating to Opening the Register.

## 9. Any other business

**9.1.** There was no other business.

**9.2.** The next meeting will be on 22 March 2023.

## Chair's signature

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

Signature

Chair: Julia Chain

Date: 25 January 2023

# Authority meeting

# Matters Arising

## Details about this paper

| | | | |
|---|---|---|---|
| Area(s) of strategy this paper relates to: | The best care – effective and ethical care for everyone<br>The right information – to ensure that people can access the right information at the right time<br>Shaping the future – to embrace and engage with changes in the law, science, and society | | |
| Meeting | Authority meeting | | |
| Agenda item | 2 | | |
| Meeting date | 22 March 2023 | | |
| Author | Debbie Okutubo, Governance Manager | | |
| **Output:** | | | |
| For information or decision? | For discussion | | |
| Recommendation | To note and comment on the updates shown for each item and agree that items can be removed once the action has been completed. | | |
| Resource implications | To be updated and reviewed at each Authority meeting | | |
| Implementation date | 2022/23 business year | | |
| Communication(s) | | | |
| Organisational risk | **X** Low | ☐ Medium | ☐ High |

| ACTION | RESPONSIBILITY | DUE DATE | PROGRESS TO DATE |
|---|---|---|---|
| **Matters arising from the Authority meeting – actions from 25 January 2022** | | | |
| **8.12.** Include cyber security in the risk register<br>Provide members with talking points and regular updates to future Authority meetings. | The Risk and Business Planning Manager<br><br>Head of Information Technology | March 2023 | This has been added to the Strategic Risk Register and will be discussed at the March AGC meeting along with the other risks.<br><br>Feedback from AGC will be brought forward to Authority as required. |
| **Matters arising from the Authority meeting – actions from 16 November 2022** | | | |
| **4.7** The Executive to consider developing a framework to identify artificial intelligence (AI) models falling within HFEA remit. | Chief Executive | For SCAAC during 2023 | Discussions will be held at future SCAAC meetings where relevant.<br>**Propose to close as it is planned with SCAAC** |
| **6.7** The risk appetite statement would be reviewed in a year's time to see how it was embedding and to consider whether option three (the most detailed option) might then be preferable. | The Risk and Business Planning Manager | November 2023 | This was presented to the December 2022 AGC meeting and will remain under review.<br>**Propose to close** as the risk strategy review has been done and we have a working risk appetite statement. We may bring it back again to AGC and the Authority for a future update after monitoring for a year. |
| **Matters arising from the Authority meeting – actions from 19 July 2022** | | | |
| **7.15** A targeted consultation to occur by summer and the outcomes reported to the board. | Director of Strategy and Corporate Affairs | January 2023 | Law reform consultation launched 26 February 2023.<br>**Propose to close** as covered under directorate updates and other Authority papers. |
| **Matters arising from the Authority meeting – actions from 18 May 2022** | | | |
| **3.6** Some members that are yet to complete their cyber security training. | Governance Manager | May 2023 | In accordance with our annual process, the 2023 Authority member training in information security has commenced, using the Civil Service Learning training portal. In addition, this year, members are |

| ACTION | RESPONSIBILITY | DUE DATE | PROGRESS TO DATE |
|---|---|---|---|
| | | | also required to complete a module on Equality, Diversity and Inclusion.<br><br>As at 15 March, six members have completed their Equality, Diversity and Inclusion learning; and five have completed their Information Security training. |
| **Matters arising from the Authority meeting – actions from 24 November 2021** | | | |
| **11.10** Options on how compliance information including inspection reports and licensing decisions could be made more visible and easier to find on the website. | Director of Strategy and Corporate Affairs | November 2023 | No further progress. Legislative changes relating to storage and other key areas have taken priority at this point.<br><br>Work on transparency and regulation will be addressed as part of the 2023-24 business plan. **Propose to close as worked planned for 2023-24.** |
| **Matters arising from the Authority meeting – actions from 23 September 2021** | | | |
| **5.18** Backlog on OTR | Director of Compliance and Information | March 2023 | The vacant post has been recruited to so the team is at its full compliment. Improved team structure will help reduce the time to sign off. However, application numbers have increased over recent months and we will need to monitor demand and capacity carefully. |
| **Matters arising from the Authority – actions from 7 July 2021** | | | |
| **5.7** PGT-M being out of target of the 75 working days | Director of Compliance and Information | January 2023 | The Scientific Officer is nearly towards the end of probation. PGT-M's are progressing well (as are ITE certificates).<br>The rate of PGT-M applications varies, which means workload can suddenly increase, this is unavoidable as it will be driven by patient needs. KPIs were met for September 2022 to January 2023. |
| | | | |

# 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: | 22 March 2023 |
| 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

- The paper sets out the range of meetings and activities undertaken since the last Authority meeting in January 2023.
- Although the paper is primarily intended to be a public record, members are of course welcome to ask questions.

# 2. Activities

## 2.1 Chair activities

- The Chair has continued to engage with the decision-making functions of the Authority and with key external stakeholders:

    - 16 February – spoke at the New North London Synagogue
    - 28 February – spoke on BBC Radio 4's Woman's Hour regarding the launch of our consultation on modernising the HFE Act
    - 9 March – spoke at the Public Chairs Forum on the role of Public Bodies in policy making.

## 2.2 Chief Executive

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

    - 1 February – met Mr Jacob Daniels, Office of the State Comptroller of Israel regarding data and Fertility Procedures. On the same day I attended the Public Chairs Forum and ACE Annual Conference 2023
    - 3 February – attended a meeting with all ALB Chief Executives with Shona Dunn Second Permanent Secretary, Department of Health
    - 7 February – met Eri Maeda and colleagues of Department of Environmental Health Science & Public Health Akita, Japan to discuss our Regulatory practices in the UK
    - 8 February – attended Fertility Network UK reception at the Senedd, Cardiff. The same day met Welsh Minister for Health and Social Services, Eluned Morgan and visited the London Womens Clinic, Wales Centre
    - 9 February – met Mary Jo-Biggs and colleagues to discuss the regulation of ART in Ireland. Later that same day met Sally Taber ISCAS Director to discuss provision of ADR in the fertility sector.
    - 23 February – spoke at a workshop on legal issues in ART at LSE organised by Professor Emily Jackson
    - 3 March – spoke at Sir John Talbots School, Whitchurch, as part of Speakers for Schools programme
    - 7/8 March – attended the Third International Summit on Genome Editing at the Crick Institute
    - 9 March – informal clinic visit to Cambridge IVF and to the Babraham Research Institute
    - 14 March – attended our Audit & Governance Committee. The same day I made an informal clinic visit to Barts Health Centre for Reproductive Medicine
    - 15 March – Quarterly Accountability Meeting with DHSC sponsors
    - 16 March – informal clinic visit to Guy's Hospital
    - 21 March – informal clinic visit to IVF London.

# Committee Chairs' reports

## Details about this paper

| | |
|---|---|
| Area(s) of strategy this paper relates to: | The best care/The right information |
| Meeting: | Authority |
| Item number: | 4 |
| Meeting date: | 22 March 2023 |
| Author: | Paula Robinson, Head of Planning and Governance |
| Annexes | - |

## Output from this paper

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

# 1. Committee reports

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

# 2. Recent committee items considered

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

| Meetings held | Items considered | Outcomes |
|---|---|---|
| **Licence Committee:** | | |
| 12 January 2023 | 1 initial (research)<br>4 renewals<br>1 additional targeted inspection | 2 granted<br>4 adjourned |
| 26 January 2023 | 1 renewal | Refused, suspended and revoked |
| 1 February 2023 | 1 additional targeted inspection | Suspended and revoked. |
| 9 March 2023 | 1 renewal (research)<br>2 executive updates | Minutes not yet approved. |
| Other comments: | None. | |
| **Executive Licensing Panel:** | | |
| 24 January 2023 | 3 Renewals<br>1 Variation of activities<br>1 Change of centre name<br>1 Change of Person Responsible | All granted |
| 7 February 2023 | 1 Interim<br>2 Changes of Person Responsible | All granted |
| 21 February 2023 | 3 renewals | All granted |
| 8 March 2023 | 1 Renewal (research)<br>1 Interim | Minutes not yet approved. |
| Other comments: | None. | |
| **Licensing Officer decisions:** | | |
| December 2022 - February 2023 | ITE Import Certificates – 28<br>1 Change of Licence Holder<br>1 Change of Centre Name | All granted |
| Other comments: | Ten of the import certificates listed above were replacement documents that were needed owing to a change of centre address in Denmark. | |

| Meetings held | Items considered | Outcomes |
|---|---|---|
| **Statutory Approvals Committee:** | | |
| 23 January 2023 | 2 PGT-M<br>2 Special Directions | 3 granted<br>1 adjourned |
| 28 February 2023 | 4 PGT-M<br>2 Special Directions | Minutes not yet approved. |
| Other comments: | None. | |
| **Audit and Governance Committee:** | | |
| 14 March 2023 | • Proposed 2023/24 Internal audit plan and 2022/23 progress update<br>• Progress with current audit recommendations<br>• External audit work update<br>• Accounting judgements and financial models<br>• Strategic risk<br>• Digital projects / PRISM update<br>• Resilience, cyber security and business continuity<br>• Functional standards<br>• Counter-fraud strategy and fraud risk assessment<br>• Forward workplan | - |
| Other comments: | None. | |
| **Scientific and Clinical Advances Advisory Committee:** | | |
| 6 February 2023 | • Public health developments<br>• Prioritisation of issues identified through horizon scanning<br>• Review of ratings for treatment add-ons<br>• Synthetic embryo-like entities | • Continue to keep an eye on<br>• SCAAC workplan 2023/24 agreed<br>• See 'Other comments'<br>• Continue to keep an eye on |
| Other comments: | The SCAAC did not allocate ratings (according to the new 5-point rating system) to add-ons at this meeting. The Executive and the SCAAC have some work to do to refine the literature search strategy to ensure completeness of our add-ons work. The SCAAC plans to allocate new ratings to add-ons at their next meeting in June. | |

## 3. Recommendation

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

Human Fertilisation & Embryology Authority

# Monthly performance report

## For performance up to January 2023

**Shabbir Qureshi**
Risk and business planning manager
22/03/2023

www.hfea.gov.uk

# About this paper

| Details about this paper | |
|---|---|
| Area(s) of strategy this paper relates to: | Whole strategy |
| Meeting: | SMT & Authority |
| Agenda item: | - |
| Meeting date: | 22/03/2023 (Authority) |
| Author: | Shabbir Qureshi, Risk and Business Planning Manager |
| Contents | Latest review and key trends<br>Management summary<br>Summary financial position<br>Key performance indicators |

| Output from this paper | |
|---|---|
| For information or decision? | For information |
| Recommendation: | To discuss |
| 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.<br>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.<br>The Department of Health and Social Care reviews our performance at each DHSC quarterly accountability meeting (based on the SMT paper). |
| Organisational risk: | Medium |

Human Fertilisation & Embryology Authority

# Latest review and key trends

## Latest review

- The attached report is for performance up to and including January 2023.
- Performance was reviewed by SMT at its 14/03/2023 meeting.
- In January performance was generally good. There were five green, four amber, four red, and four neutral indicators

## Key trends

- The below table shows the red RAG statuses for the last three months

| November (7) | December (4) | January (4) |
|---|---|---|
| HR1 – Staff sickness | C2 – Inspection reports sent to PR within 20 working days | C2 – Inspection reports sent to PR within 20 working days |
| C2 – Inspection reports sent to PR within 20 working days | C4 – End to end licensing reports within 70 working days | C4 – End to end licensing reports within 70 working days |
| C3 – Inspection reports sent to committee within 55 working days | F1 – Debt collection | F1 – Debt collection |
| C4 – End to end licensing reports within 70 working days | F2 – Debtor days | F2 – Debtor days |
| F1 – Debt collection | | |
| F2 – Debtor days | | |
| F3 – Prompt payment | | |

Human Fertilisation & Embryology Authority

# Management summary

## IT and register performance reporting

- PRISM: Clinic activity is 352K units submitted from 103 clinics. The overall error rate is 4.3%.
- All clinics have confirmed they are caught up on submission backlogs except 3 – we are following up with inspectors.
- On 7 December, we released the first tranche of backdated validation errors (5755 registration errors) for clinics to fix as part of our OTR and CaFC plan. Of these, 4080 (71%) have been fixed with a lot of engagement from the Register Team.
- We are now moving to the second tranche of backdated errors relating to cycles in PRISM. We have identified and checked 6684 errors and these will be release to clinics in March. Again, we will monitor how clinics address these.
- The final tranche of backdated validations start in March and will feature EDI errors from the CaFC start date (1/1/20) that need to be fixed in PRISM.
- Once that final tranche is released, we will be able to start assessing how much further verification after validation is needed for CaFC and we will be able to give a more accurate publication date over our best and worst dates that we have given to AGC.
- We are making good progress towards our end of July 23 target to complete the reports required for the OTR team.

## Management commentary

- Performance has been variable across KPI indicators with four red, four amber, four neutral and five green indicators.
- HR indicators have continued the trend of moving towards our targets; we had one leaver (a retirement) and one joiner in January with our average headcount remaining at 73 for the last six months.
- Estimated incomes are still impacting the two red finance KPIs. This should improve as we approach year end.
- The OTR backlog has now increased to the highest level since this metric has been tracked (November 2021) due to an increase in applications. The team is now at capacity, however improvements in reducing the backlog will not be felt until the new team members have completed their training. The team is also working with the developers testing and providing feedback for the new OTR systems and reports.
- The licensing KPIs will be missed next month due to the extensive legal work needed following inspections of two clinics.

# Summary financial position

| Type | Actual in YTD £'000s | Budget YTD £'000s | Variance Actual vs Budget £'000s | Forecast for 2021/2022 £'000s | Budget for 2021/22 £'000s | Variance Budget vs Forecast £'000s |
|---|---|---|---|---|---|---|
| Income | 6,055 | 6,467 | 412 | 7,302 | 7,451 | 149 |
| Expenditure | 5,712 | 6,147 | 435 | 6,984 | 7,468 | 484 |
| **Total Surplus/(Deficit)** | **343** | **320** | **23** | **318** | **(17)** | **335** |

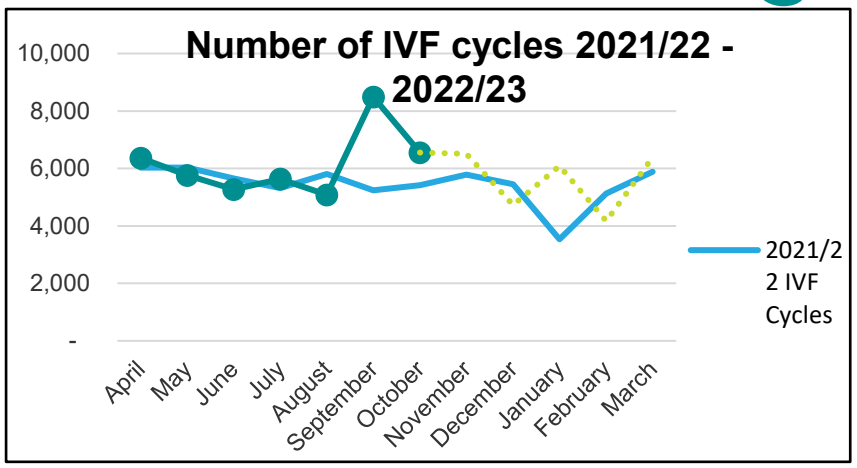
## Commentary on financial performance to January 2023

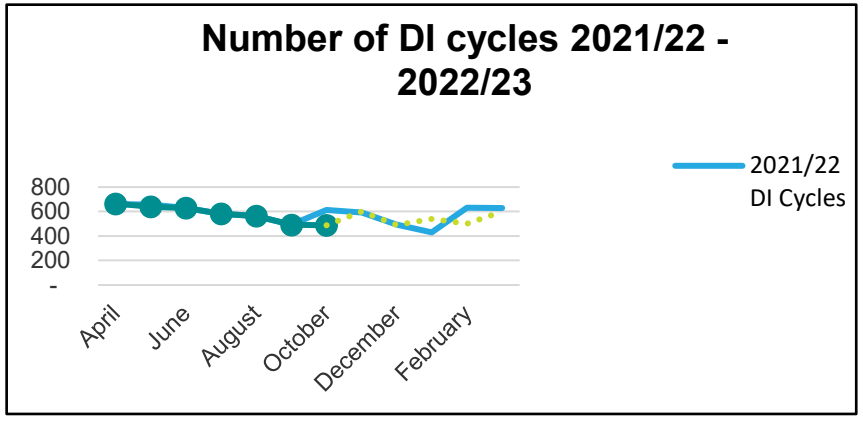
Year to date we have a surplus against budget of £23k. Our income is under budget by £412k which is due to adjustments made to reconcile our income with clinics. Underspends within our expenditure are detailed in the commentary later in the pack.

Full year forecast shows a surplus against budget of £335k impacted by underspends in our expenditure and we have amended our forecast income to reflect the impact of the reconciliation of clinic activity against estimates raised during the earlier part of the financial year. As of February, there remains 3 clinics who have yet to begin data submissions.

Human Fertilisation & Embryology Authority

# Financial management information




| IVF Cycles | YTD | | YE Position | |
|---|---|---|---|---|
| | Volume | £ | Volume | £ |
| 2021/22 IVF Cycles | 54,255 | 4,340,373 | 65,266 | 5,221,253 |
| 2022/23 IVF Cycles (actual) | 60,783 | 5,166,555 | 71,333 | 6,063,305 |
| Variance | 6,528 | 826,182 | 6,067 | 842,052 |

| DI Cycles | YTD | | YE / Forecast | |
|---|---|---|---|---|
| | Volume | £ | Volume | £ |
| 2021/22 DI Cycles | 5,711 | 214,163 | 6,968 | 261,300 |
| 2021/22 DI Cycles | 5,676 | 212,850 | 6,776 | 254,100 |
| Variance | (35) | (1,313) | (192) | (7,200) |

The year end position for 2022/23 is higher than that reported in the accounts due to adjustments from reconciling clinic activities that cannot be factored in. The year-to-date position is a better reflection of where we believe we are. As per the management accounts, we are forecasting a year end position of c£5.8m which includes DI cycles.

Human Fertilisation & Embryology Authority

# HFEA income and expenditure

**HFEA Income & Expenditure** **Jan-23**

| | Year to Date | | | | Full Year | | |
|---|---|---|---|---|---|---|---|
| | Actual £'000 | Budget £'000 | Variance £'000 | Variance YTD % | Forecast £'000 | Budget £'000 | Variance £'000 |
| **Income** | | | | | | | |
| Grant-in-aid | 748 | 1,098 | 351 | 0 | 892 | 1,098 | 206 |
| Non-cash (Ring-fenced RDEL) | 221 | 221 | - | - | 352 | 265 | (87) |
| Grant-in-aid - PCSPS contribution | 50 | 75 | 25 | 0 | 100 | 100 | - |
| Licence Fees | 4,922 | 4,951 | 29 | 0 | 5,857 | 5,842 | (15) |
| Interest received | 36 | 1 | (35) | (32) | 9 | 1 | (9) |
| Seconded and other income | 78 | 121 | 43 | 35 | 92 | 145 | 53 |
| **Total Income** | 6,055 | 6,467 | 412 | **6** | **7,302** | **7,451** | **149** |
| **Revenue Costs** | | | | | | | |
| Salaries (excluding Authority) | 4,110 | 4,145 | 35 | 1 | 4,866 | 5,068 | 203 |
| Staff Travel & Subsistence | 65 | 95 | 30 | 32 | 81 | 127 | 46 |
| Other Staff Costs | 84 | 82 | (2) | (3) | 101 | 106 | 6 |
| Authority & Other Committees costs | 175 | 190 | 15 | 8 | 244 | 231 | (13) |
| Facilities Costs incl non-cash | 367 | 589 | 222 | 38 | 491 | 711 | 221 |
| IT Costs | 350 | 546 | 196 | 36 | 537 | 657 | 119 |
| Legal / Professional Fees | 419 | 315 | (104) | (33) | 472 | 328 | (144) |
| Other Costs | 142 | 185 | 43 | 23 | 192 | 240 | 48 |
| Other Project Costs | 0 | - | (0) | - | 0 | - | (0) |
| **Total Revenue Costs** | **5,712** | **6,147** | **435** | **7** | **6,984** | **7,468** | **484** |
| **TOTAL Surplus / (Deficit)** | **343** | **320** | **23** | | **318** | **(17)** | **335** |
| **Adjusted for non-cash income/costs** | **201** | **254** | **(53)** | | **231** | **(18)** | **248** |

**Management commentary**

**Income.**
Year to date our total income is exceeds budget by 412k or 6%. As we near the end of the financial year, of the 101 or so clinics, only around 9 are yet to have submitted all cycles relating to 2021/22 and up to December 2022. Included in our income is our GIA which is under budget due to changes in accounting standards which resulted in reclassification from cash to capital.

**Expenditure by exception (over £10k variance)**
At the end of M10 (January 2023) we are underspending against budget by £435k.

**Salaries** - overall are under budget, however the contingent labour costs which mainly relate to PRISM, exceed budget by £179k, balance represented by underspends within PAYE and pension costs.

**Staff Travel & Subsistence** - are under budget by £30k year to date. The spend to date is significantly lower than in previous years which may be due to Inspectors being deployed more effectively (area-based).
**Authority & Other Committees Costs** - are below budget by £15k. This underspend mainly relates to T&S costs which are effected by our mix of Members and type of meetings held.

**Facilities costs** - underspent by £222K, We are underspending on accommodation costs by £185k which is due to rates and service charge costs accrued for being less than the actual charge and all relate to 2 Redman place. Due to the changes in accounting treatment of our rent (now treated as a lease), there has been an adjustment between the Income and Expenditure Account and the Balance sheet, causing a reduction in year-to-date costs (£118k)

**IT Costs** - are underspent by £196k year-to-date. The areas with significant underspends which are within our Consultancy and Support costs (£122k), IT Subscriptions (£24k) and the balance is represented by over and underspends within Consumables, Low value Fixed Assets, Telecoms and Photocopying costs.

**Legal/Professional fee** - are over budget by £104k. This is represented by an overspend within the legal budget of £117k and underspend of £13k within Audit Fees (Internal and External). The legal spend includes the secondment cost of a legal advisor which is not fully funded from the staff cost for a Head of Legal.

**Other costs** - are underspent by £43k. The most significant variance is within Stakeholder Events (£29k), plus smaller underspends sub £5k across areas within both the Compliance and Information and Strategy and Corporate Affairs directorate.

**Forecast** - we are currently forecasting an underspend of £318k and an underspend against budget of £335k. This position is not expected to change drastically with only 2 months left of the financial year.

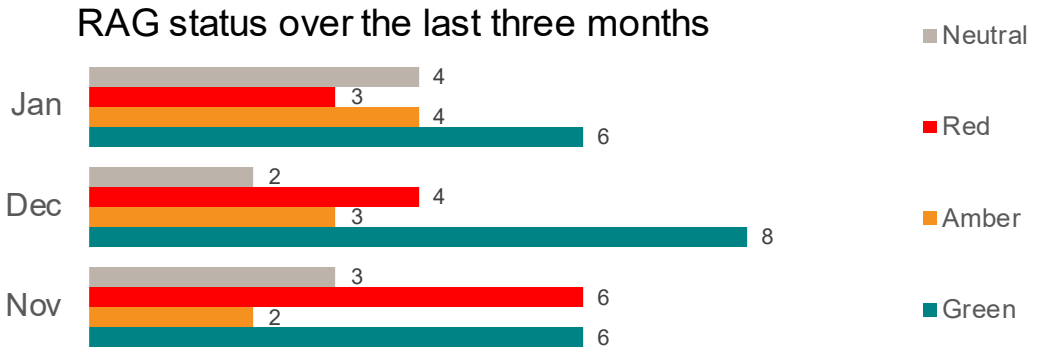
Human Fertilisation & Embryology Authority

# Key performance indicators

Human Fertilisation & Embryology Authority

**RAG status over last 3 months**

(17 KPIs in total for each month)



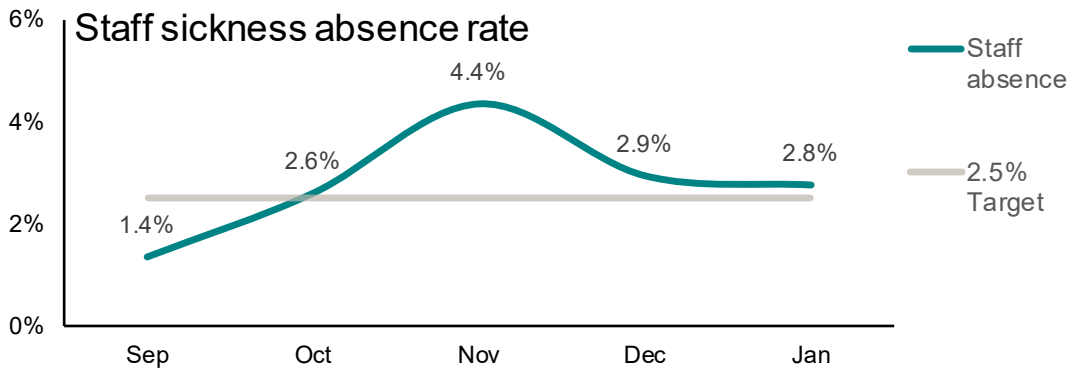

For January, the 4 red indicators are in these teams:

- Comms : 0
- **Compliance : 2**
- **Finance : 2**
- HR : 0
- Information : 0
- Intelligence : 0
- PlanGo : 0

**Status:** Amber

**HR1 – Sickness**

**Target:**
Less than or equal to 2.5%

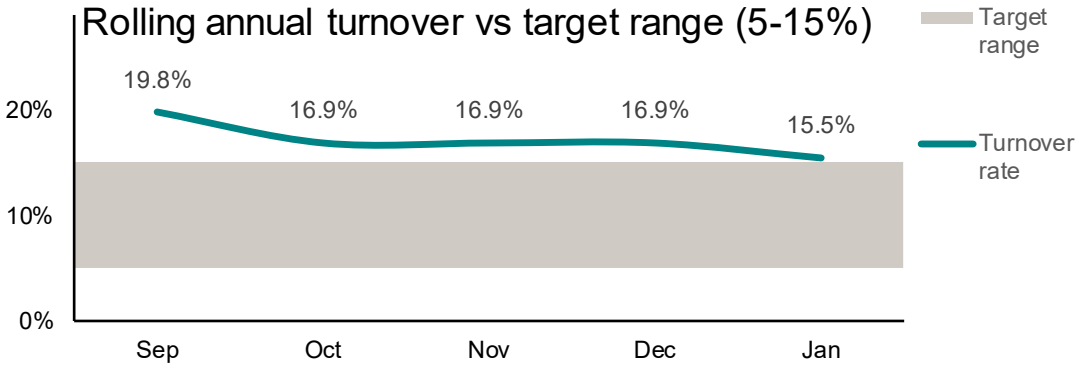



Sickness remains stable. We do have one member of staff on long term sick.

**Status:** Amber

**HR1 – Sickness**

**Target:**
Less than or equal to 2.5%




We had one leaver in January; this was a retirement.

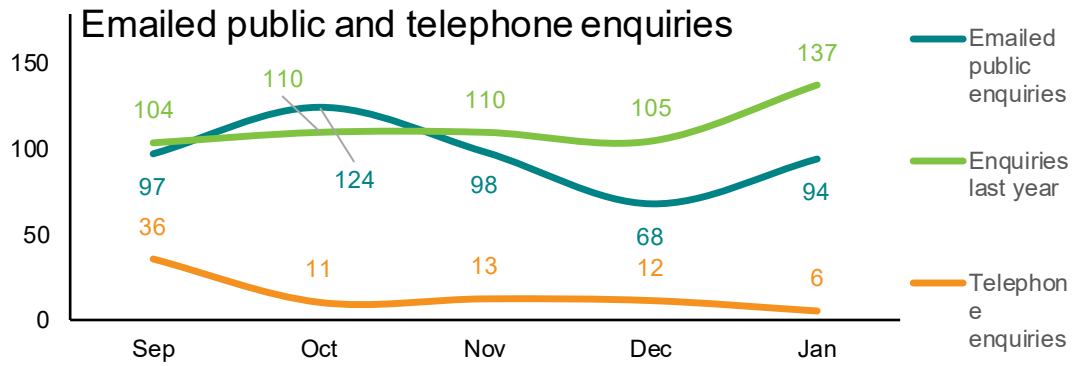
**Supplementary HR data**

Headcount : 74
Posts : 76
Starters : 1
Leavers : 1

Status: N/A

**Emailed public and telephone enquiries**

**Target:**
None defined

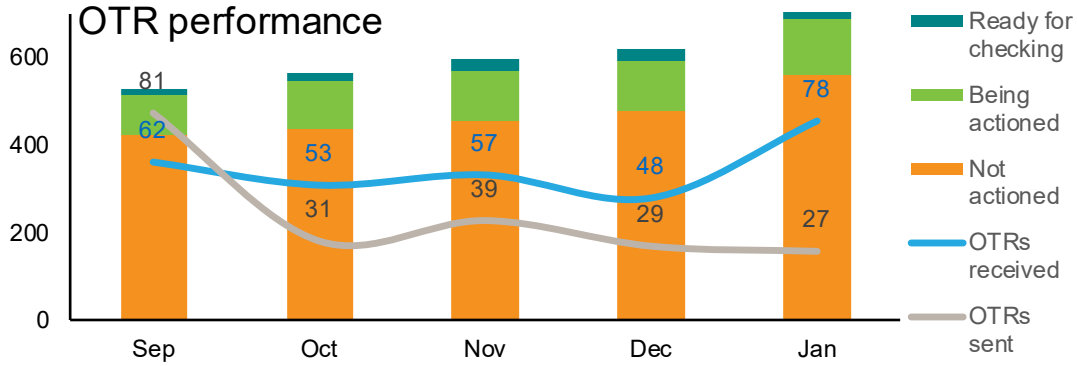



Range of public enquiries covering a wide range of issues

Status: N/A

**I1 – OTR performance**

**Target:**
To be developed

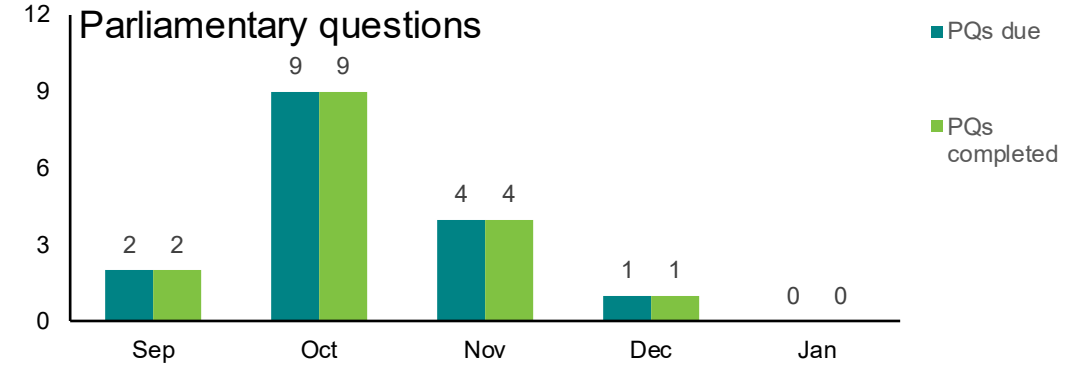



Continued reduced capacity in the team so still fewer OTRs being sent out. Annual leave and training a new starter has contributed to this.

Status: Neutral

**RI1 – PQs responses**

**Target:**
100% within deadlines set

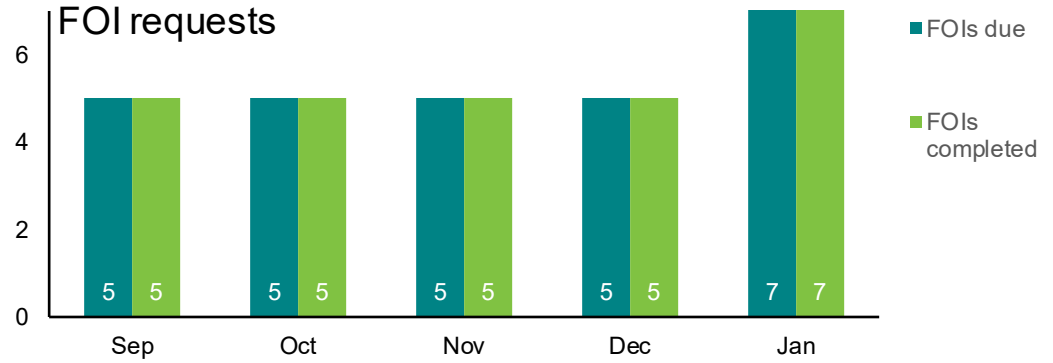



No PQ's due in January

Status: Green

**RI2 - FOI responses**

**Target:**
100% within statutory deadlines

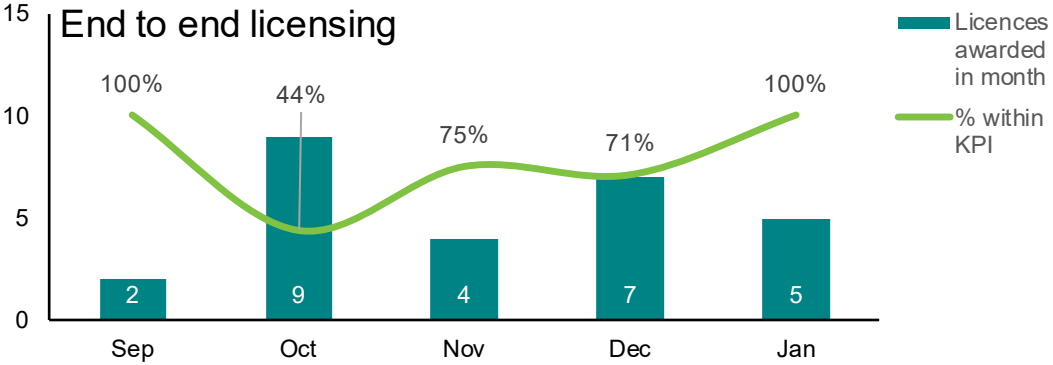



There were 7 FOIs due in January and all were answered within the deadline.

Status: Red

**C4 – End to end licensing process**

**Target:**
100% completed within 70 working days

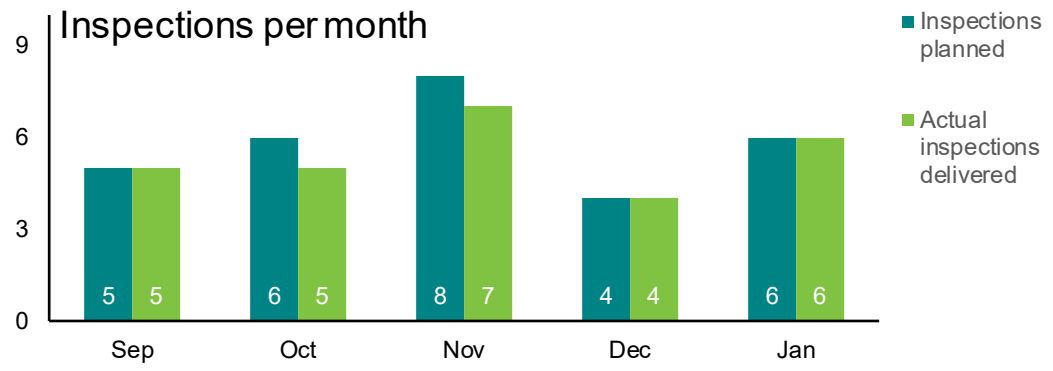



Clinic 1 - (73 days): unforeseen circumstances post-inspection (sickness), other inspections' commitments within the inspection team delaying post-inspection meeting; complex report requiring further review post 2nd QA; delay in QA due to Christmas period.

Status: N/A

**C1 – Inspections delivery**

**Target:**
tbc

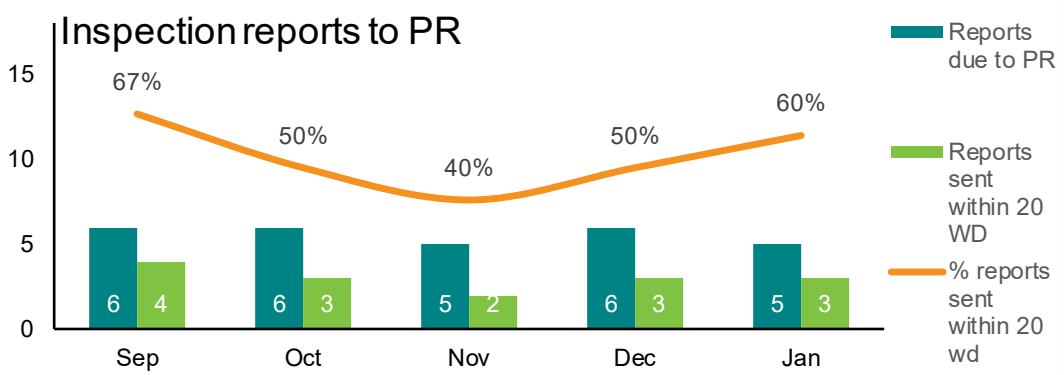



Clinic 1 - moved from January to February 2023, due to PR availability
Clinic 2 - complex inspection in December 2022; There were outstanding items to be provided provide post-inspection (delivery in January 2023)

Status: Red

**C2 – Inspection reports sent to PR**

**Target:**
100% sent within 20 working days

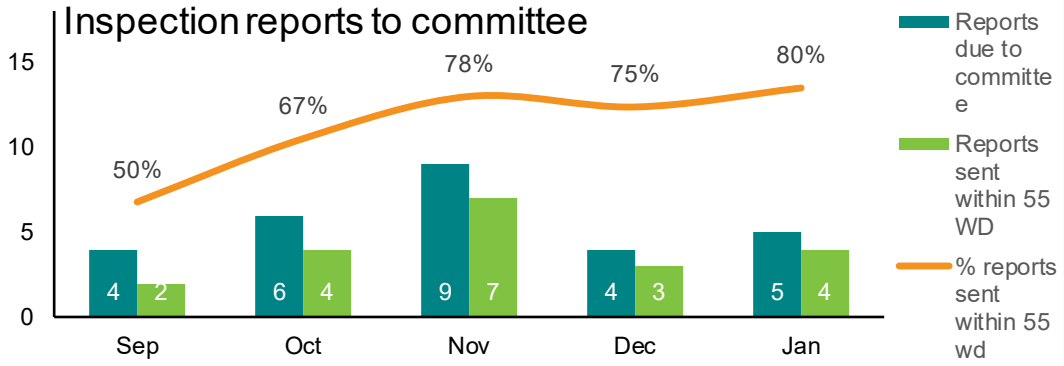



Clinic 1 - (24 Days): Documents clarification post-inspection.
Clinic 2 - (30 Days): Report needed additional drafting to include non-compliance identified at QA stage.

Status: Amber

**C3 – Inspection reports sent to relevant licensing committee**

**Target:**
100% sent within 55 working days

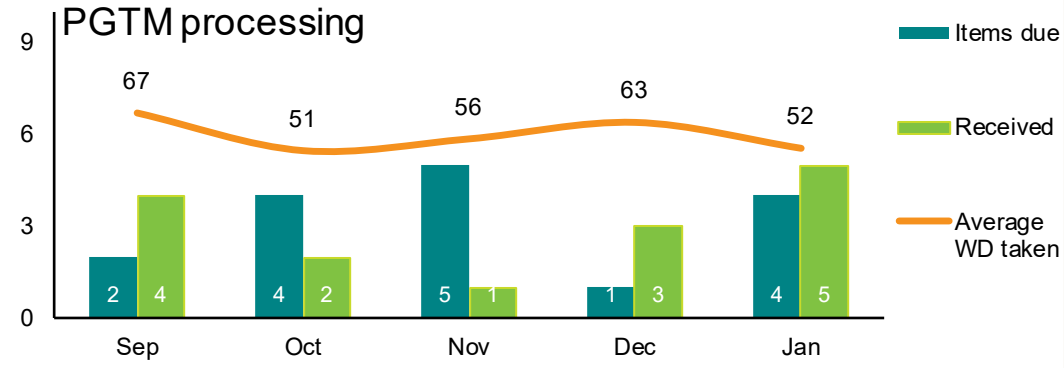



Clinic 1 - (59 Days): unforeseen circumstances post-inspection (sickness), other inspections' commitments within the inspection team delaying post-inspection meeting; complex report requiring further review post 2nd QA; delay in QA due to Christmas period.

Status: Green

**C6 – PGTM processing efficiency**

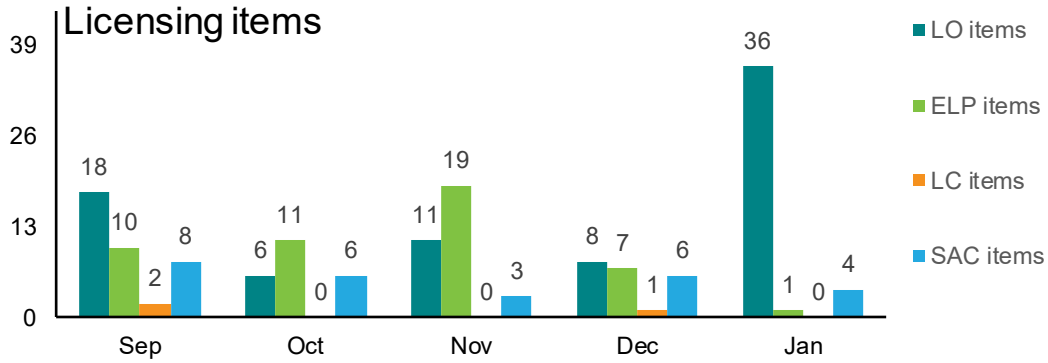
**Target:**
100% within 75 working days




No issues to report

| | |
|---|---|
| L1 - LO : | Green |
| L2 - ELP : | Green |
| L3 - LC : | Neutral |
| L4 SAC : | Green |

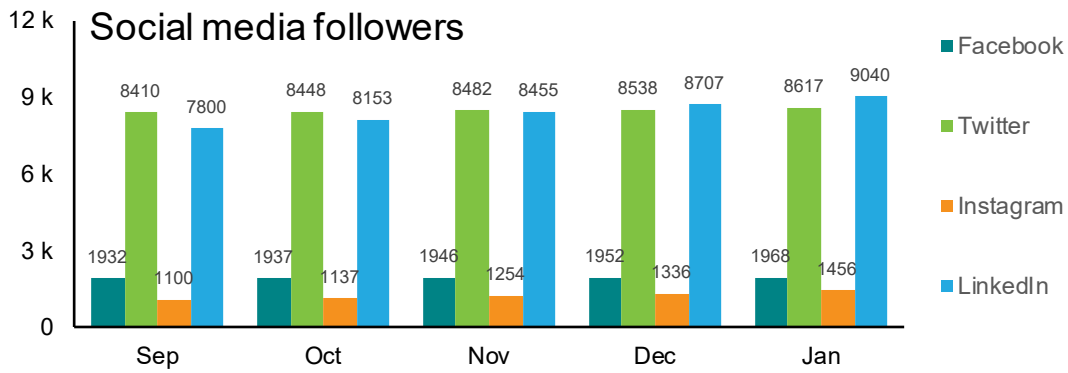
**Licensing efficiency**
Targets (WD):
LO - 5, ELP - 10
LC - 15, SAC - 20




Minutes from the meetings held on 12 January, 26 January and 1 February were not due to be completed until February, so we will report on them then. However it is worth noting in advance that these will all miss their KPIs owing to extensive work and legal advice being needed on two of the items.

Status: N/A

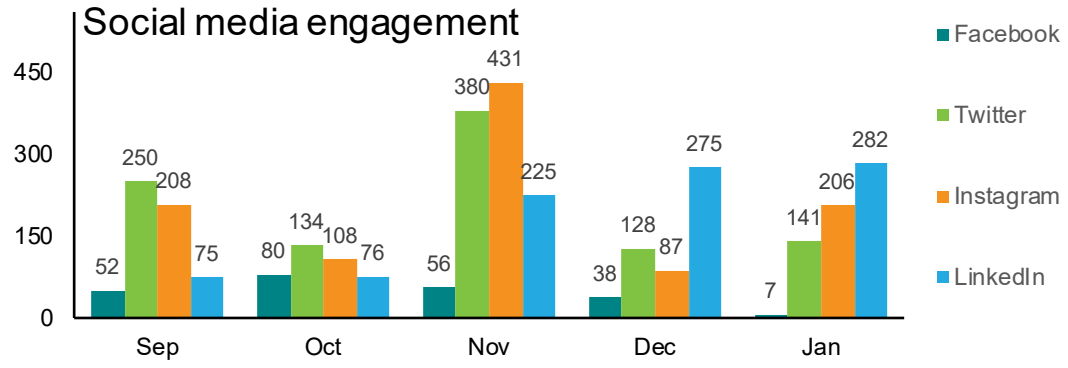
**Total number of followers across social media**




In January our content included posts about unregulated sperm donation, our new fertility glossary and data posts.

Status: N/A

**Engagement across social media (measurement systems vary)**

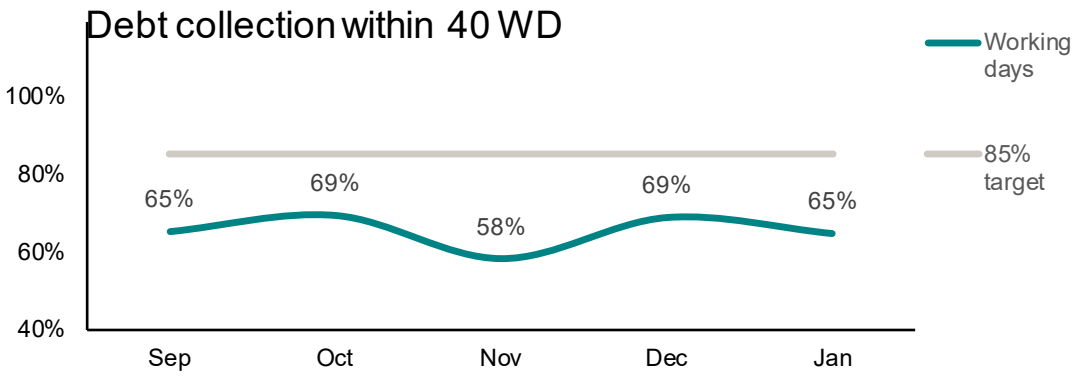



The post that performed the best was the post about our new A-Z glossary - https://www.hfea.gov.uk/about-us/a-z-fertility-glossary/.

Status: Red

**F1 – Debt collection**

**Target:**
85% or more debts collected in the month within 40 working days from billing

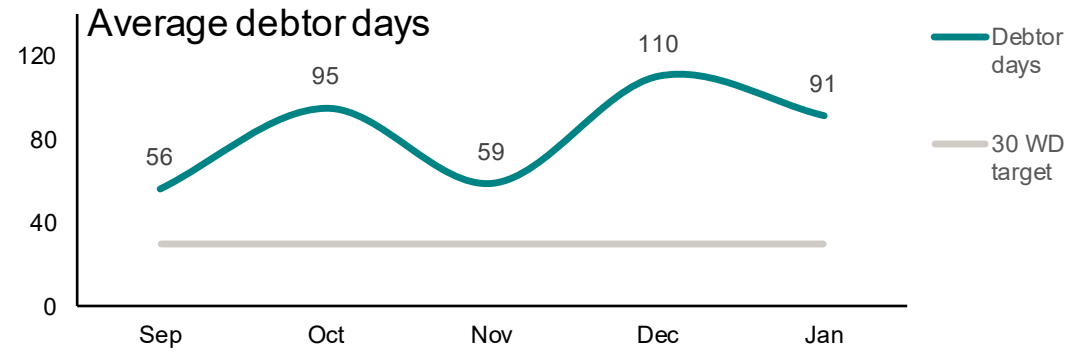



F1 - Improved over last month, still low due to estimation and the need to update customer details. Effort being made to resolve estimations queries and to ensure a drastic reduction in balance over Q4. Debt chasing & securing promises of settlement to be carried out in February with a target of reducing significantly, the debt level.

Status: Red

**F2 – Debtor days**

**Target:**
30 working days or less

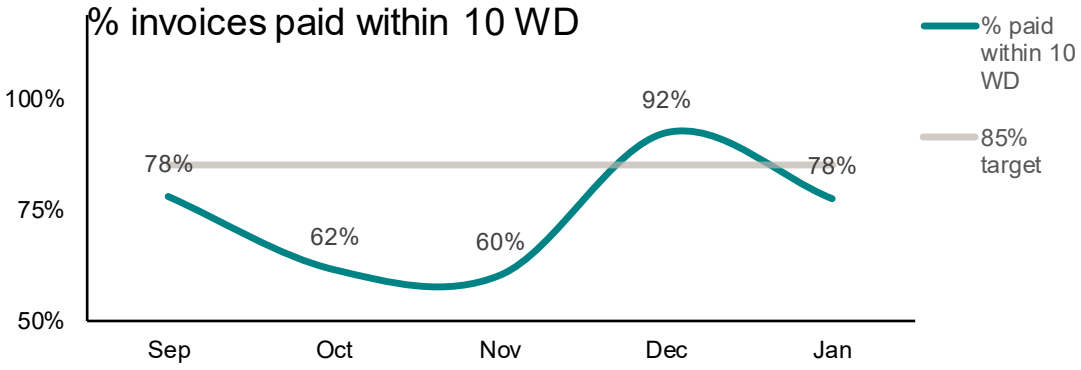



F2 - The delays brought on by necessary estimation of billing has impacted debtor days. With low number of clinics with estimated charges, and concerted efforts at resolving queries, this should improve in Q4. Number of clinics with estimates is to reduce to 7.

Status: Amber

**F3 – Prompt payment**

**Target:**
85% or more invoices paid within 10 days




F3 - Actually 87%. A 5k payment delayed for authorisation due to its value and being split across directorates affected this metric.

# Effective governance

## Details about this paper

| | |
|---|---|
| Area(s) of strategy this paper relates to: | The best care – effective and ethical care for everyone<br>The right information – to ensure that people can access the right information at the right time<br>Shaping the future – to embrace and engage with changes in the law, science and society |
| Meeting: | Authority |
| Agenda item: | 6 |
| Meeting date: | 22 March 2023 |
| Author: | Debbie Okutubo, Governance Manager |
| Annex: | Annex 1 – Standing Orders: Annex A Section 2 |

## Output from this paper

| | |
|---|---|
| For information or decision: | For decision |
| Recommendation: | • Agree the proposed change to Standing Orders, effective from 1 April 2023 (vote required).<br>• Note the annual reviews of committee effectiveness and the action points for each committee. |
| Resource implications: | In budget |
| Implementation date: | 1 April 2023 |
| Communication(s): | The Standing Orders are published on our website and on the staff Hub. They are also included in the standard licensing pack, which will be updated. |
| Organisational risk: | Low |

## 1. Introduction

**1.1.** As a public body, the HFEA is committed to adopting best practice in corporate governance. The HFEA has a number of committees established under Standing Orders which are made in accordance with the powers of the HFE Act.

**1.2.** High-quality decision-making processes are essential to maintain the integrity of the HFEA as a regulator and trust in the conduct of operational activities as it applies to everyone affected by fertility treatment including licensed centres, patients and the wider public.

**1.3.** This paper is intended to provide assurance over the structures established by the Authority, effectiveness of committees, decisions taken, and that activities of the HFEA are aligned with its statutory duties, responsibilities and objectives.

**1.4.** It also provides members with updates and recommendations related to the governance of the Authority, which is committed to an annual review of our governance arrangements consisting of a review of each committee's effectiveness and of standing orders.

## 2. Annual review of committee effectiveness

**2.1.** On an annual basis all committees are required to review their own effectiveness using a standard framework. Between September 2022 and January 2023 this exercise was conducted by the Licence Committee, Executive Licensing Panel, Statutory Approvals Committee, the Scientific and Clinical Advances Advisory Committee and the Register Research Panel.

**2.2.** The Audit and Governance Committee used the specific effectiveness tool for Audit Committees produced by the National Audit Office and carried out a 360° review whereby feedback was received from committee members, the Senior Management Team, and the External and Internal Auditors.

**2.3.** All Authority members sit on at least one committee which means that they all participated in the review of their respective committees.

**2.4.** Generally, the feedback from committees has been positive, which committee and lead officers have taken away to work on. There are a number of recommendations for improvement, as we would expect. The table below summarises the feedback from each committee.

| Committee | Recommendations | Areas to note or for improvement |
|---|---|---|
| Audit and Governance Committee (AGC) | Explore the option of bringing in additional independent non-executive members. | Add to the terms of reference an option for co-opting members with particular expertise when required (Change to Standing Orders.) |
| | Identify any skills gap. | Populate a self-assessment skills map before next year's annual review of effectiveness. |
| | Review of near misses | For future consideration as and when any examples of near misses arise, particularly in |

| Committee | Recommendations | Areas to note or for improvement |
|---|---|---|
| | | relation to our strategic risks or any major pieces of work that are reporting into AGC. This could also be considered under future deep dive topics.<br><br>In addition, when we produce the annual forward look paper on risk management, we could incorporate information about incidents and near misses. |
| Licence Committee (LC) | The legal training on induction did not fully identify the limitations on the committee's decision-making, and the relative lack of options. This could usefully be fed back into future training. | This will be fed back to the trainer for future training, to further improve it. |
| | As well as observing a meeting, it might be useful to send some past minutes for reading as part of induction. A range of examples including challenging cases would be best, since this would help new members to better understand the range of item types and the variability between items of different complexity. | The committee staff to develop a sample set of minutes that show the variation between item types and illustrate the range of complexity in the decision-making. This will then be given to future new members as part of their induction. |
| | Abbreviations – it would be good to have a list of what they all mean. | The Head of Planning and Governance to lead on this - done. |
| | It would be helpful for lay members in particular to get more of a feel for the sector, including through visiting a clinic. | The Compliance team to arrange for clinic visits for all new Authority members, particularly lay Licence Committee members - in progress. |
| | Some advance notice of items coming to the meeting would be good. Perhaps a note a week in advance of the papers going out, giving an indication of what we expect to be posting to them. | The Licensing team have taken this away to consider. |
| | It would similarly be helpful if we could provide some indication of | Members to note the proviso that there will be times when a discussion takes longer |

| Committee | Recommendations | Areas to note or for improvement |
|---|---|---|
| | likely duration in advance. This would help with diary management. | than anticipated, and the importance of maintaining quoracy. |
| | In complex cases, where a range of possible recommendations might have been considered by the inspectorate, in line with the compliance and enforcement policy, committee papers to give insight into the reasoning behind the Executive recommendation. | To be considered in future papers, particularly for complex items. |
| Executive Licensing Panel (ELP) | Follow up meetings with the Licence Committee may be useful. | To be discussed with the Licence Committee Chair. |
| | It could be useful to seek feedback from the Compliance team on ELP decisions. | Feedback to be sought at regular Compliance and Licensing team meetings. |
| Statutory Approvals Committee | A precedents library of decisions could be useful. | This will be kept under review and a report will go back to the committee if future IT/software or resources change and it becomes possible to track precedents. The Head of Planning and Governance agreed to discuss with the Compliance team whether future examples where there were relevant previous decisions could be highlighted where possible in the papers. |
| | The committee wondered whether, in those cases where the only issue was that testing was not done in the overseas clinic at the time of gamete collection, there might be a simpler way of handling certain Special Direction items. However, the committee was also cognisant of its legal advice during the earlier meeting, which was that the decision tree should be followed in the normal way. | Staff agreed to discuss this further with the Compliance team. |
| | There is the need to ensure quoracy at all meetings. | Staff to consider adding additional members to meetings if necessary to maintain quoracy. |
| | The change to meeting days is manageable but not ideal for all members. It was agreed that it helps | Consider again in 2023 when setting the calendar for 2024. |

| Committee | Recommendations | Areas to note or for improvement |
|---|---|---|
| | to ensure quoracy and a good mix of people. | |
| Scientific and Clinical Advances Advisory Committee | It would be helpful to have some written clarification on the outputs of the committee in terms of action items of previous meetings and if these have been followed up on/ the outcome when taken to the Authority. | Consider longer term follow-up of actions to be raised during 'matters arising' agenda item. |
| | Periodic reminder of the role and function of SCAAC to its members. | Consider refresher session for members. |
| | At times patients are unaware of the SCAAC or what its function is. | Continue to increase transparency of the committee.<br>More information back to patients on the website about how decisions are made. |
| Register Research Panel | Key issues could streamline the discussion if they are raised at the start – this could highlight any major issues straight away. | Data Protection Officer to attend/observe.<br>Legal advisor to prepare list of key advice in advance of meeting. |
| | There are some members who have essential skills/knowledge and so absences can have a big impact on the panel. | Executive to be notified early on and re-arrange meetings if need be, or written input can be provided.<br>Identify substitutes for key members/skills including the:<br>*Chair –<br>*Deputy Chair<br>*Data protection officer. |
| | While significant progress has been made with the forms/data specification/decision tree, there are still some outstanding issues with these documents which need addressing. | The Executive will continue work on these documents. |
| Remuneration committee | *Formal review not undertaken due to infrequency of meetings.* | |

**2.5.** Members are asked to note the summary of the annual reviews of committee effectiveness.

## 3. Review of Standing Orders

**3.1.** In addition to the review of committee effectiveness we are proposing a change to the Audit and Governance Committee's terms of reference in Standing Orders.

**3.2.** The Authority is asked to review and approve the proposed change to Standing Orders, as set out below in section 4. If approved, the new Standing Orders would come into effect on 1 April 2023.

## 4. Audit and Governance Committee

**4.1.** During the discussion of committee effectiveness, it was observed that it would be worthwhile to enable the committee to have the option of bringing in additional independent non-executive expertise, if required in relation to particular subjects.

**4.2.** There is nothing to preclude us from adding this option to the committee's terms of reference.

**4.3.** To accommodate this, the proposed change is in section 2.7 , with the entire section appended to this report:

> "The committee shall have the power to co-opt additional members for particular expertise if needed. Any such appointment, and the term of office, shall be at the discretion of the Chair of the HFEA".

## 5. Recommendation

**5.1.** The Authority is invited to:

- Approve by a majority vote, revised Standing Orders (see section 1.3 in Standing Orders), to come into effect from 1 April 2023.
- Note the feedback from the annual reviews of committee effectiveness and the action points for each committee.

# Annex 1

## 2. The Audit and Governance Committee

## Purpose of the committee

**2.1.** The purpose of the Audit and Governance Committee is to oversee corporate governance, risk, audit arrangements and financial matters.

## Delegated powers and functions of the Audit and Governance Committee

**2.2.** The Authority delegates to the Audit and Governance Committee, the following powers:

a) approval of the internal audit programme, and

a) approval of the statement on internal control or equivalent annual governance statement included in the annual accounts.

**2.3.** The functions of the Audit and Governance Committee shall be to:

a) oversee the general corporate governance of the Authority (including supervision and review of the operational effectiveness of the Authority's internal control and risk management procedures)

b) ensure that the Authority complies with its statutory functions, and with the requirements of the regulators' code, requirements applicable to arm's length bodies, and the principles and best practice guidance issued by the Better Regulation Executive

c) meet regularly with the Authority's internal and external auditors to ensure that the Authority is complying with statutory requirements and best practice relating to internal control systems risk management, audit, and financial reporting requirements

d) review the annual financial statements before their submission to the Authority focusing particularly on changes in, and compliance with accounting policies and practices, and

e) review and manage the effectiveness of the Authority's whistle-blowing policy.

**2.4.** In particular, the Audit and Governance Committee shall:

a) review the adequacy of all risk and control related disclosure statements, together with any accompanying statement from the internal auditors, prior to endorsement by the Authority

b) review the adequacy of structures, processes and responsibilities for identifying and managing key risks facing the Authority

c) review the adequacy of internal audit policies to ensure compliance with the controls assurance standards and other relevant guidance

d) review the adequacy of policies and procedures for all work related to fraud and corruption as set out in the Secretary of State directions and as required by the National Health Service Counter Fraud Service

e) make recommendations to the Authority about the appointment (including renewal) and, where necessary, dismissal of the internal audit service and the audit fee payable

f) manage the relationship with the external auditor (the Comptroller and Auditor General), and ensure that any chargeable non-audit services provided do not compromise the auditors' independence or objectivity

g) review the planning, conduct and conclusions of the external audit process (including review of all reports and annual audit letters, together with the associated management responses)

h) receive reports from the tender panel established in accordance with the financial procedures approved by the Authority, and

i) receive reports about all consultancy contracts made by the Authority.

**2.5.** In pursuance of these functions, the Authority authorises the Audit and Governance Committee to:

a) require a review or investigation of any procedures and activities undertaken by the Authority that fall within its remit

b) obtain from any employee, such information as it considers relevant to the carrying out of its functions (all employees are directed to co-operate with any request made by the Audit and Governance Committee)

c) obtain such external legal or other professional advice as it considers necessary to enable it to fulfil its functions, and

d) provide such advice or recommendations to the Chair, the Authority members and the Authority's Chief Executive, as it considers necessary or appropriate.

## Membership of the Audit and Governance Committee

**2.6.** The Audit and Governance Committee shall consist of up to six members including:

a) a Committee Chair (who shall be an Authority member)

b) a Deputy Committee Chair (who shall be an Authority member)

c) up to two other Authority members

d) two persons who shall not be Authority members and who have relevant legal, financial, public sector or other corporate governance expertise, if required.

**2.7.** The committee shall have the power to co-opt additional members for particular expertise if needed. Any such appointment, and the term of office, shall be at the discretion of the Chair of the HFEA.

**2.8.** The Chair of the HFEA shall appoint the members of the Audit and Governance Committee.

**2.9.** Members of the Audit and Governance Committee shall usually be appointed for a term of three years.

## Meetings of the Audit and Governance Committee

**2.10.** The quorum for a meeting of the Audit and Governance Committee shall be three, providing that two are Authority members, including the Committee Chair or Deputy Committee Chair.

**2.11.** The Audit and Governance Committee shall usually meet no fewer than four times a year.

## Attendance at meetings of the Audit and Governance Committee

**2.12.** In addition to members of Audit and Governance Committee, the following persons shall usually attend its meetings:

a) the Chief Executive (or his delegated representative)

b) the Director of Finance and Resources

c) the Head of Planning and Governance

d) the Committee Secretary

e) a representative from the Department of Health

f) a representative from the Authority's internal auditors, and

g) a representative from the Authority's external auditors.

**2.13.** The Committee Chair may invite such other persons (including employees) as he/she considers appropriate, to attend the meetings of the committee and/or to provide advice to inform the deliberations of the committee.

The Committee Chair may determine when and whether it is necessary or desirable for any non-members of the Audit and Governance Committee to withdraw from the meeting to enable the committee to deliberate in private.

# Code of Practice update, October 2023

## Details about this paper

| | |
|---|---|
| Area(s) of strategy this paper relates to: | The right information |
| Meeting: | Authority |
| Agenda item: | 7 |
| Meeting date: | 22 March 2023 |
| Author: | Niamh Marren, Regulatory Policy Manager |
| Annexes (see separate document) | Annex 1: Guidance note 2 - Staff<br>Annex 2: Guidance note 3 – Counselling and patient support<br>Annex 3: Guidance note 4 – Information to be provided prior to consent<br>Annex 4: Guidance note 5 – Consent to treatment, storage, donation, training and disclosure of information<br>Annex 5: Guidance note 6 – Legal parenthood<br>Annex 6: Guidance note 11 – Donor recruitment, assessment and screening<br>Annex 7: Guidance note 12 – Egg sharing arrangements<br>Annex 8: Guidance note 15 – Procuring, processing and transporting gametes and embryos<br>Annex 9: Guidance note 17 – Storage of gametes and embryos<br>Annex 10: Guidance note 19 - Traceability<br>Annex 11: Guidance note 22 – Research and training<br>Annex 12: Guidance note 25 – Premises, practices and facilities<br>Annex 13: Guidance note 26 – Equipment and materials<br>Annex 14: Guidance note 28 - Complaints |

## Output from this paper

| | |
|---|---|
| For information or decision? | For decision |
| Recommendation: | Authority members are asked to decide between:<br>1. Publishing the Code this year with the recommendations made throughout this paper and acknowledge that parts of the Code may be redundant as outlined in paragraphs 5.2. However, if the necessary additional changes are known prior to the Secretary of State for Health and Social Care's approval these changes will be communicated to Members outside of an Authority meeting for consideration and approval.<br>2. Postponing publication until after the changes to storage law Transitional Period (30 June 2024) so we receive further clarification on the potential MHRA guidance, professional body guideline changes and the Windsor Framework to prevent our Code being out of date so soon after publication, needing to strikethrough any redundant guidance and continue to refer the sector to the Clinic Guide for storage information. |
| Resource implications: | Within budget |
| Implementation date: | We are preparing for publication in October 2023. 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, LCP |
| 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 (the Code) which provides guidance to help licensed clinics comply with the Act and relevant legislation. This Code 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.** The focus of this update is to incorporate legislative changes that have come into force since the last Code publication in 2021, 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) other changes, and

3) least substantive changes.

**1.3.** The legislative changes are:

- From 1 July 2022 the Health and Care Act 2022 introduced amendments to the Human Fertilisation and Embryology Act 1990 (the Act) changing the statutory storage limit and consequential arrangements of gametes and embryos.
- The Medical Devices Act 2002, which had introduced new requirements for the marking of medical devices from 30 June 2023 received an extension in relation to medical devices needing to be UK Conformity Assessed (UKCA).

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

**1.4.** The other changes are:

- Reference to Competition and Markets Authority (CMA) recommendation to amend our Code following their review of fertility services
- Cancelling a benefit in kind arrangement

**1.5.** The least substantive changes are:

- Counselling qualifications and equivalence
- Pre-employment health screening
- Chaperone guidance
- Medical and laboratory guidance
- Safe-sedation guidance
- E-consent platforms

**1.6.** The following sections of this paper outline the rationale for amendments to the proposed new edition of the Code. 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 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 the accessibility check, however, any changes will not affect the meaning behind the proposed guidance in the annexes.

**1.7.** Following Authority approval, we will put the submission to Secretary of State for Health and Social Care in May 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 was last updated in 2021 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, Clinic Focus and the requirements are already in force.

### Health and Care Act 2022 - Storage changes

**2.2.** These changes enable patients to consent to embryos being stored for treatment purposes for a maximum of 55 years; gametes will be able to be stored for up to 55 years for treatment, research or training purposes, and embryos and human admixed embryos will be able to be stored for research or training purposes for up to 10 years. There are also new provisions relating to storage for posthumous use and in the event of mental incapacity.

**2.3.** To reflect the legal changes we have made substantive changes in guidance note 17 (Storage of gametes and embryos), which includes information on the Transitional Period which is contained within light blue boxes. We amended guidance box 3A, paragraphs 3.1, 3.10 and mandatory requirements in guidance note 3 (Counselling and patient support), mandatory requirements, box 4A, paragraphs 4.7, 4.18, 4.20 in guidance note 4 (Information to be provided prior to consent), mandatory requirements, box 5A, box 5B,box 5H, paragraphs 5.20, 5.23 and 5.33 in guidance note 5 (Consent to treatment, storage, donation, training and disclosure of information), mandatory requirements in guidance note 6 (Legal parenthood), paragraph 11.36 in guidance note 11 (Donor recruitment, assessment and screening), mandatory requirements, 15 (Procuring, processing and transporting gametes and embryos), paragraph 19.2 in guidance note 19 (Traceability) and mandatory requirements, and box 22G in guidance note 22 (Research and training).

### Recommendation

**2.4.** The amendments to guidance notes 3, 4, 5, 6, 11, 15, 17, 19 and 22 can be found at Annexes 2, 3, 4, 5, 6, 8, 9, 10 and 11. As these follow the new statutory requirements the amended guidance notes are included for information only.

### Medical Device Regulations 2002 – UKCA marking

**2.5.** To reflect the extension to the Medical Device Regulations 2002, we have made amendments to the mandatory requirements in guidance note 11 (Donor recruitment, assessment and screening), guidance note 15 (Procuring, processing and transporting gametes and embryos), guidance note 17 (Storage of gametes and embryos), and above paragraph 26.4 in guidance note 26 (Equipment and materials) that refer to SLCs T30, T51, and T53 where manufacturers will be able to continue to place CE marked devices on the Great Britain market after 1 July 2023. From July 2024, the transitional arrangements will apply for CE and UK Conformity Assessed (UKCA) marked devices placed on the Great Britain market. MHRA will be issuing further guidance on this and SLCs will be updated at a later date to be in line with this extension.

### Recommendation

**2.6.** The amendments to guidance notes 11, 15, 17 and 26 can be found at Annexes 6, 8, 9 and 13. As these follow the new statutory requirements the amended guidance changes are included for information.

## 3. Other changes to guidance

**3.1.** The following sections outline the more substantive changes to guidance which will be added to the Code 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.

### Reference to CMA recommendation

**3.2.** The CMA and the Advertising Standards Authority (ASA) published a recommendation in their 2022 Compliance Review Findings Report. We have added guidance based on their recommendation to mandatory requirements and paragraphs 28.12-28.14 in guidance note 28 (Complaints). This explains that clinics should subscribe to Alternative Dispute Resolution (ADR) schemes. We also make clear the options for self-funded and NHS funded patients. This can be seen in Annex 14.

### Cancelling a benefit in kind arrangement

**3.3.** A clarification was added regarding who bears the financial burden if a benefit in kind arrangement breaks down. We made clear that gamete providers can withdraw or vary their consent and to ensure that they understand the implications of withdrawing from a benefit in kind arrangement. We also clarified the additional information that should be documented in the patient's information and in the agreement. These can be seen in paragraphs 12.11, 12.13 and 12.22 in guidance note 12 (Egg sharing arrangements) in Annex 7.

### Recommendation

**3.4.** The Authority is asked to approve the proposed changes.

## 4. Least substantive changes to guidance

**4.1.** The following section outlines the smaller proposed additions to the Code, mostly incorporation of guidance or information previously communicated through our Clinic Focus newsletter, Chair's letters or minor clarifications.

### Counselling qualifications and equivalence

**4.2.** In April 2022 we published a Clinic Focus article to indicate that there is a list of professional counselling/accreditation schemes held by the British Infertility Counselling Association (BICA) Accreditation Board and added a link to the BICA counsellor accreditation scheme guidance handbook. This has been added to paragraphs 2.15-2.16 in guidance note 2 (Staff) in Annex 1.

### Pre-employment health screening

**4.3.** In September 2022 we published a Clinic Focus article that included information on pre-employment health screening for staff, including exposure prone procedures and added links to professional guidelines published by Health and Safety Executive and the UK Advisory Panel for Healthcare Workers. This has been added to paragraph 2.13 in guidance note 2 (Staff), which can be seen in Annex 1.

### Chaperone guidance

**4.4.** In October 2021 we published a Clinic Focus article that provided guidance on clinics offering a chaperone to a patient who is having an intimate examination and added a link to the General Medical Council's (GMC) guidelines on this topic. This has been added to paragraphs 3.16-3.17 in guidance note 3 (Counselling and patient support), which can be seen in Annex 2.

### Medical and laboratory tests

**4.5.** In September 2022 we published a Clinic Focus article to provide guidance on carrying out and documenting risk assessments for donors that do not meet the criteria for additional testing or

professional body guidelines. This has been added to paragraph 11.24 in guidance note 11 (Donor recruitment, assessment and screening), which can be seen in Annex 6.

### Safe-sedation practice

**4.6.** In September 2021 we published a **Clinic Focus** article that provided information regarding the Academy of Medical Royal Colleges guidelines on safe sedation practice for healthcare procedures. This has been added to paragraphs 25.31-25.33 in guidance note 25 (Premises, practices and facilities), which can be seen in Annex 12.

### E-consent platforms

**4.7.** In February 2022 we published a **Clinic Focus** article for centres using e-consenting platforms to ensure that their records are retained in line with General Direction 0012. This has been added to paragraph 5.33 (g) in guidance note 5 (Consent to treatment, storage, donation, training and disclosure of information), which can be seen in Annex 4.

### Links

**4.8.** There are links to other Clinic Focus, Chair's letters and Chief Executive's letters that were added to this Code update which we have not included as Annexes to this paper. Any typos, formatting problems, updated regulations or broken/expired links that have been identified since the last update in October 2021 have also been corrected.

### Version control

**4.9.** This updated Code has also corrected the use of version control on the front cover and on the copyright page. This is to make it clearer for clinics and HFEA staff which version was active and when. The versions of the 9th edition Code of Practice are:

- Edition 9.1 – first published 2nd January 2019
- Edition 9.2 – revised 16th December 2019
- Edition 9.3 – revised 26th October 2021
- Edition 9.4 – to be published in October 2023.

### Recommendation

**4.10.** The Authority is asked to approve the proposed changes.

## 5. Recommendation and next steps

**5.1.** Our planned timetable is based on the revised Code coming into force in the year. However, there may be further guidance changes that we will need to make to this Code update following recent decisions outside of our control. Should further guidance be necessary we will ask Members to review and approve those changes outside of an Authority meeting as they will need to be incorporated as early as possible to ensure that the guidance we provide to the sector is current and valid. These changes may include, but are not limited to:

(a) the MHRA guidance based on the Medical Device Regulations 2002 extension as mentioned in paragraph 2.5,

(b) updated professional body guidelines e.g. ICSI, SaBTO, and

(c) the Windsor Framework relating to the regulatory or other consequent impacts of relationships between Great Britain, Northern Ireland and the European Union.

**5.2.** The current plan is to seek approval from the Secretary of State for Health and Social Care before the summer recess, lay the Code in Parliament in September and publish in October 2023. If additional changes are required for this update that are not in line with the project plan, we may need to:

- strikethrough parts of the Code guidance because they will be redundant e.g., the guidance specific to Northern Ireland as a result of the Windsor Framework or updated ICSI or SaBTO guidelines. Using strikethrough on some parts of the guidance may make it difficult to read and is likely to cause accessibility issues.
- communicate the additional changes clearly to the sector via Chair's letters, Clinic Focus articles and attend relevant stakeholder meetings. This additional communication may cause confusion in the sector initially, but we can publish Clinic Focus regularly and answer questions that clinic staff may have about the new guidance.
- postpone publication until we are certain of the potential new guidance that is required, however this increases the risk to the sector of not having up to date storage guidance in the Code. The current draft guidance includes details on the Transitional Period, which we have placed in light blue boxes in guidance note 17 and this period ends on 30 June 2024 which means that from 1 July 2024 it would be redundant. If publication was postponed the sector would continue to refer to the Clinic Guide and FAQ on the Portal.

**5.3.** The Authority is asked to decide between:

1. Publishing the Code this year with the recommendations made throughout this paper and acknowledge that parts of the Code may be redundant as outlined above. However, if the necessary additional changes are known prior to the Secretary of State for Health and Social Care's approval these changes will be communicated to Members outside of an Authority meeting for consideration and approval.

   This has the advantage of ensuring the Code reflects the large changes resulting from the Health and Social Care Act and enables all users of the Code to have the most up to date information within the Code. However, other areas of the Code may become out of date as per the issues outlined in paragraph 5.2.

   If option 1 is agreed, then all changes will be incorporated in the next update of the 9th edition of the Code of Practice (version 4). This will come into in force, subject to Secretary of State for Health and Social Care approval, in October 2023. 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.

2. Postponing publication until after the Transitional Period (30 June 2024) so we receive further clarification on the potential MHRA guidance, professional body guideline changes and the Windsor Framework to prevent our Code being out of date so soon after publication, needing to strikethrough any redundant guidance and continue to refer the sector to the Clinic Guide for storage information.

   This has the advantage of ensuring all the potential changes to the Code that we are aware of at this time, that may come to light over the next few weeks or months, are encapsulated within this Code update. However, it would mean that users of the Code must continue to rely on non-Code of Practice information in relation to the storage changes as per the current arrangements.

Human Fertilisation & Embryology Authority

# Opening the Register – update

**Rachel Cutting and Clare Ettinghausen**

22 March 2023

www.hfea.gov.uk

# Opening the Register activity 2023

**Activity since January 2023 Authority meeting**

- Continued national media interest in the area including since January 2023, coverage in the I newspaper on the OTR process and 2023, Women's Hour and ITV Evening news following the broader HFEA report on donation and New Scientist on the changes this year
- Ongoing activity in the three workstreams
- Focus on resourcing these fully for the new financial year

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# Opening the Register activity 2023

**Overview**

- Update on activity since January 2023 Authority meeting
- Workstreams update
- Risks
- Next steps

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# HFEA activity during 2023

**Three workstreams**

| OTR service | Future of support service | Communications |
| --- | --- | --- |
| Ensuring our staffing levels and team structure are appropriate for the demand and systems are effective in processing applications | To report back to the Authority on next steps for a multi-layered support service | To ensure patients, clinic and public communications are timely, informative and relevant throughout 2023 |

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# OTR service

**Workstream update**

- Good progress on the integration the new IT system for managing applications (testing phase)

- Continued work on updating policies and legal advice to inform processes.

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# Future of support service

## Workstream update

- Develop options for a financially viable multi-layered support service for review later in the year by Authority
- Business case will be presented to CMG in March
- Project work will include
  - Literature review and international comparison of other models of support services
  - Explore funding options
  - Targeted engagement with key stakeholders
  - Option appraisal of different support mechanisms including for example professional counselling, peer support, intermediary services and information provision.

Human Fertilisation & Embryology Authority

# Communications

**Workstream aims**

- Planning now underway for delivery of this workstream in a cost effective and timely way
- Ongoing media interest including large factual pieces in the i newspaper and much interest surrounding the law reform consultation work on issues relating to donation
- Balance to be had between wide public interest in this and ensuring effective communication to clinics, former and current donors, donor conceived individuals and their families.

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# Risks

- Unrealistic expectations of DCI, donors and clinic staff to what the HFEA can do
- Clinics not signposting donors or donor conceived individuals to the HFEA and OTR service
- Not all DCI will have the relationship they may wish for with their donor
- Reputational risk is high both for those elements we are responsible for, and those we aren't
- HFEA resources may not meet demand of applications (prediction of number of applicants very difficult)
- Unlawful practices undertaken if clinics and HFEA do not fully understand the law
- Donors and DCI not having access to information and support
- Limits of what information we can provide

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# Next Steps

- Through the work streams mitigate the risks where possible
- Provide internal updates at the Project Assurance Group to ensure progress is timely
- Present options for a support service for an Authority decision later in 2023 to commission new service later in 2024
- Provide updates and engagement as needed to Authority and external stakeholders

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# Modernising Fertility law - update

**Clare Ettinghausen**
Director of Strategy and Corporate Affairs
22 March 2023

www.hfea.gov.uk

# Overview

- Background
- Current position
- Risks
- Next steps

Human Fertilisation & Embryology Authority

# Background

- Identified the need to look at updating the Act as part of the HFEA at 30 activities in 2020. Further work was delayed at that point due to Covid.
- A number of Authority discussions refined the areas of focus
- Previous updates to the Authority in February 2022, May 2022, July 2022 and September 2022 outlined the different areas of focus and developments during those periods
- Law Reform Advisory Group set up in March 2022 to help to further refine broad topics
- All refined into a consultation that was launched on 28th February
- Public ministerial support for the HFEA to look at areas where the law should be modernised

Human Fertilisation & Embryology Authority

# Current position

**Consultation launch**

- Public consultation looking at four key areas running 28th February – 14th April 2023
  - Patient safety and promoting good practice
  - Access to donation information
  - Consent
  - Scientific developments
- In each area we provide a short summary of the current situation, then set out the issues with the Act, and describe our proposals for change.

Human Fertilisation & Embryology Authority

# Current position

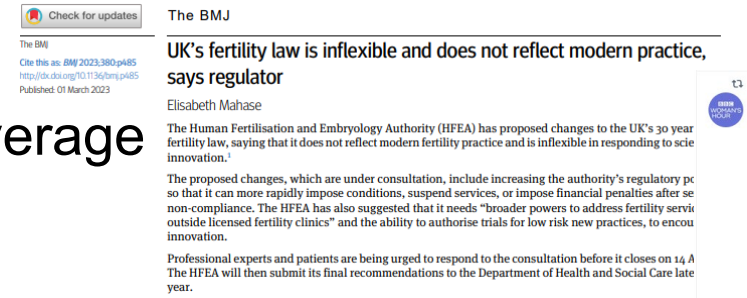
**Consultation to date**

- Widespread media and social media coverage and commentary
- Very positive feedback on the consultation
- Not seeking a representative sample but interested in a wide range of views to inform Authority thinking
- Engagement with professional and patient groups plus a wide range of stakeholders, experts, patients and interested individuals
- Speaking at Fertility Network, and other events
- Planning for report drafting – to come to Authority for review

Human Fertilisation & Embryology Authority

# Media/social media coverage

- Media coverage:
  - 352 total pieces of coverage
  - 17 pieces of national coverage
- Most articles focus on donor anonymity. The BMJ was one of the few that didn't headline the proposed removal of donor anonymity.
- Top performing social media posts:
  - The consultation launch post
    - Twitter and Instagram
  - 'Areas we think need modernisation' post
    - LinkedIn


Check for updates

The BMJ

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The BMJ

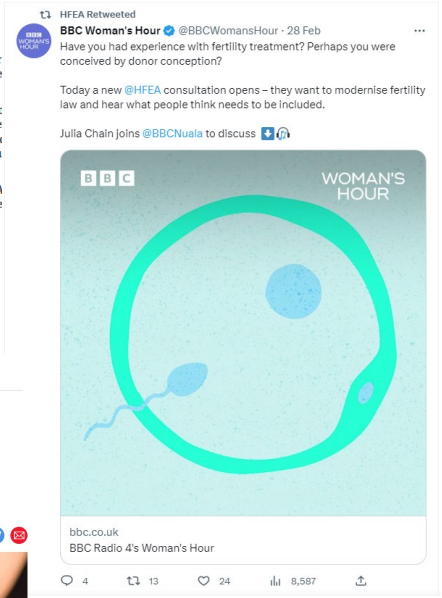
**UK's fertility law is inflexible and does not reflect modern practice, says regulator**

Elisabeth Mahase

The Human Fertilisation and Embryology Authority (HFEA) has proposed changes to the UK's 30 year fertility law, saying that it does not reflect modern fertility practice and is inflexible in responding to scie innovation.[1]

The proposed changes, which are under consultation, include increasing the authority's regulatory pc so that it can more rapidly impose conditions, suspend services, or impose financial penalties after se non-compliance. The HFEA has also suggested that it needs "broader powers to address fertility servi outside licensed fertility clinics" and the ability to authorise trials for low risk new practices, to encou innovation.

Professional experts and patients are being urged to respond to the consultation before it closes on 14 A The HFEA will then submit its final recommendations to the Department of Health and Social Care late year.


HFEA Retweeted

**BBC Woman's Hour** @BBCWomansHour · 28 Feb

Have you had experience with fertility treatment? Perhaps you were conceived by donor conception?

Today a new @HFEA consultation opens – they want to modernise fertility law and hear what people think needs to be included.

Julia Chain joins @BBCNuala to discuss



bbc.co.uk
BBC Radio 4's Woman's Hour

4 13 24 8,587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**Call for sperm and egg donors to be identifiable after the birth of a child**

At present children can only find out the identity of their biological parent when they are 18.

Ella Pickover • Tuesday 28 February 2023 00:01




There are four areas where we think modernisation is most needed:

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Patient safety


Access to donor information


Consent


Scientific developments


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**Sperm and egg donors could be named as soon as the baby is born, with children not having to wait until they are 18 to identify their biological parents, fertility watchdog says**

- Watchdogs say age a child can find their biological parent should be lowered
- Currently children born from fertility clinics must wait until they're 18

By JOHN JAMES FOR MAILONLINE

PUBLISHED: 10:19, 28 February 2023 | UPDATED: 11:32, 28 February 2023

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# Current position

**Risks**

- A number of risks were outlined in July 2022 which still stand
- In summary:
  - the timetable to do this work and pressures on that;
  - criticism of the issues/focus of the consultation;
  - lack of consensus on the issues; and
  - challenge from a minority to the idea of regulation in principle

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# Next steps

- Ongoing promotion through blogs, social media and events of the consultation
- Analysis of consultation responses to begin and report set out
- Authority overview of recommendations will be ongoing with plan to seek final approval in July
- **Authority are asked to review the progress to date and comment on next steps**

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