Authority meeting

Date: 13 September 2023 – 1.00pm to 4.15pm

Venue: HFEA Office, 2nd Floor 2 Redman Place, London E20 1JQ

Agenda item	Time
1. Welcome, apologies and declarations of interest	1.00pm
2. Minutes of the meetings held on 12 & 17 July 2023 and matters arising For decision	1.05pm
3. Chair and Chief Executive's report For information	1.10pm
4. Committee Chairs' reports For information	1.15pm
5. Performance Report For information	1.35pm
6. Opening the Register For information	2.05pm
Break (2.30pm)	
7. Modernising Fertility Regulation - proposals For decision	2.40pm
8. Draft Business Plan 2024-25 For decision	3.50pm
9. Any Other Business	4.10pm
10. Close	4.15pm

Minutes of Authority meeting held on 12 July 2023

Details:			
Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society		
Agenda item	2		
Meeting date	13 September 2023		
Author	Alison Margrave, Board Governance Manager		
Output:			
For information or decision?	For decision		
Recommendation	Members are asked to confirm the minutes of the Authority meeting held on 12 July 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 12 July 2023

Members present	Julia Chain Zeynep Gurtin Tim Child Alison Marsden Alison McTavish	Gudrun Moore Alex Kafetz Geeta Nargund Catharine Seddon
Apologies	Graham James Frances Flinter Jonathan Herring	Christine Watson Jason Kasraie
Observer		Online Steve Pugh (Department of Health and Social Care – DHSC) Amy Parsons (DHSC)
Staff in attendance	Peter Thompson Clare Ettinghausen Rachel Cutting Paula Robinson Shabbir Qureshi Debbie Okutubo	

Members
There were nine members at the meeting – six lay and three professional members.

1. Welcome and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members, HFEA staff and DHSC colleagues present.

1.2. The Chair also welcomed observers 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.

1.3. The Chair commented that in view of the relatively large number of apologies, a decision had been taken to reschedule our consideration of our proposals for legislative reform to a separate additional meeting, which would be held on Monday, 17 July. It was noted that the meeting would be online, and as usual would be open to the public to observe.

1.4. Declarations of interest were made by:

- Tim Child (PR at a licensed clinic)
- Alison McTavish (Trustee at Progress Educational Trust (PET) and British Fertility Society (BFS))
- Geeta Nargund (Clinician at a licensed clinic) and
- Catharine Seddon declared recent appointments to the Disciplinary Committee for Royal College of Veterinary Surgeons, and to non-executive Director roles at the Personal Finance Society and the Chartered Insurance Institute. It was noted that these positions did not constitute any conflict of interest.

2. Minutes of the last meeting and matters arising

2.1. Members agreed that the minutes of the meeting held on 17 May 2023 were a true record and could be signed by the Chair.

Matters arising

2.2. Members were advised that matters arising where either being actioned or on the agenda.

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 events and the decision-making committees of the Authority.

3.2. The Chair commented on the all-staff event that she attended on 10 July 2023 and noted that it was an opportunity for staff, both home and office based to come together in person. It was a well-attended day and something that she took away from it was how the board could usefully have more time with members of staff.

3.3. On the Code of Practice, it was noted that there were some minor changes which did not change the policy positions of the code and that these changes had been signed off by the Chair. The Code of Practice will be sent to the Secretary of State for Health and Social Care for approval before it is can be published.

3.4. The Chief Executive provided an update on the key external activities and commented on the all-staff event, noting that it was an opportunity to reflect on what staff found most valuable.

3.5. Members were advised that we had appointed a new shared Director of Finance and Resources, Tom Skrinar, joining us near the end of August 2023. The Chief Executive thanked the Head of Finance for the enormous work she continues to do with her team since the departure of the previous Director of Finance and Resources, Richard Sydee, in July and before Tom Skrinar starts in August.

3.6. The Remuneration Committee had met and members were advised that following new Government guidance an additional non-consolidated payment of £1,500 was to be paid to all staff below the senior management team in July. The Chief Executive commented that this was a good thing for staff, however it was not centrally financed so would have to be found from HFEA budgets. The one-off payment was in addition to the annual pay award business case which had been sent to the DHSC for consideration. Any pay rise, once approved, will be backdated to August if not paid that month.

3.7. On the public body review it was noted but this should be concluded in the Autumn.

Decision

3.8. 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), gave an overview of the last committee meeting. She thanked the Deputy Chair of the committee (Graham James) for the work he and other committee members were doing and the high volume of work they continued to take on.

4.3. In the absence of the Statutory Approvals Committee (SAC) Chair (Jonathan Herring), the Deputy Chair of the Committee (Gudrun Moore) commented on the meeting held in June and stated that they had a straightforward meeting with nothing exceptional to report.

4.4. The Audit and Governance Committee (AGC) Chair, Catharine Seddon gave a summary of the meeting held in June and informed members that the Authority was given a 'moderate' assurance rating by the internal auditors to the organisation's governance arrangements, risk management and systems of internal control. Continuing, the AGC Chair noted that the committee was particularly pleased to hear about the progress made on meeting the requirements of the DSPT. On recruitment of the AGC external member, one new committee member will take up position on the 1 October 2023 and Mark McLaughlin and Geoffrey Podger, the two external committee members were thanked for their contributions as their terms of office were coming to an end.

Decision

4.5. Members noted the Committee Chairs' reports.

5. Annual Performance report 2022/2023

5.1. The Risk and Business Planning Manager presented this item. Members were advised that staff sickness absence rates over the last year were mostly below the key performance indicator of 2.5%. When it did peak it was partly due to seasonal coughs and colds and three staff members being on long term sickness.

5.2. On turnover, it was noted that this improved steadily throughout the year, but members were advised that for June 2023 this might peak again due to a higher number of leavers that month.

5.3. Members were informed that OTR performance had been complicated by staff turnover and the need to develop and test a new case management system. The new system is due to go live in August 2023 and it is anticipated to make the process more efficient and reduce the turnaround time of OTR requests. Members were also assured that there will be a clearer understanding of how quickly the backlog would be reduced once the new system was in use and had been embedded. A new team structure was also in place which should bring stability and, together with the new case management system and improved PRISM tools for data extraction, greater productivity in future.

5.4. On parliamentary questions and freedom of information (FoI) requests members were advised that all these were processed within the agreed required timescales.

5.5. The Licensing team had dealt with high volume of activity (both Committees and Licensing Officer). Some items had been complex and protracted, requiring more than one meeting with some extending into the 2023/24 business year. Members noted that most minutes were delivered within our KPI.

5.6. Delivery of the 2022/23 inspection schedule was challenging for several reasons. The effect of extension of licences and deferment of inspections during the pandemic increased the number of inspections to complete. There was also a need for extra inspections to be fitted into the schedule where significant compliance concerns or whistleblowing allegations arose.

5.7. In response to a question on whistleblowing, the Director of Compliance and Information commented that Inspectors leave cards at clinics for clinic staff to contact the HFEA should they have concerns.

5.8. Members were also informed that there was increased sickness (including long term sickness) and an unusually high turnover in the inspection team in the year under review. Inspectors had had to take responsibility for extra clinics into their portfolios which increased their workload in relation to additional inspections, clinic enquiries, incidents, and patient complaints.

5.9. Members noted that the inspection reporting KPIs were under review. However, despite the challenges outlined above, it was noted that all clinics had their licences issued within the timescales required, even when the end-to-end licensing KPI had been missed. Looking ahead, staff recruitment and training as well as use of external inspectors were all in the pipeline and would help ease pressures in the medium to long term. Scheduling would also be reviewed for the next inspection year.

5.10. On debt collection within 40 working days, members were advised that we issued estimated invoices in July covering a 3-month period. This caused an increase in the 40 working days KPI as clinics delayed payment to better understand the basis for invoices raised. It was noted that this was improving slowly as more focus was applied after year end had been finalised.

5.11. In response to a question on debt collection performance, members were informed that treatment cycles were down but it was too early to say if this was a trend. Looking ahead to 2023/24, we currently overspent – a position exacerbated by the non-consolidated payment to staff referred to earlier. It was noted that if treatment cycle activity increased to its trend level then we would be in a stronger financial position. Members were reassured that this was being discussed at senior management team (SMT) level and was being actively managed.

5.12. On social media engagement, followers remained broadly stable on Facebook and Twitter but we were seeing a steady increase on LinkedIn and, from a low base, on Instagram where we aimed to engage with people going through or considering fertility treatment. Members congratulated the team on social media engagement.

5.13. Members asked about the high staff turnover. The Chief Executive responded that a lot of work had been put into engaging with staff and it was therefore difficult to point to particular things that were causing staff to leave the organisation beyond a desire for pay and promotion opportunities that were limited at the HFEA due to the small size of the organisation.

5.14. The Chair commended the Inspectorate team, whom she said were doing a great job especially with staff absences and the remaining staff having to cover for their colleagues as this team carried out core statutory duties.

Decision

5.15. Members noted the annual performance report.

6. Performance report

6.1. Turning to the latest monthly performance report, the Chief Executive commented on the four red indicators for the month of May, which are:

- HR1 –Staff sickness rate - Three employees remained on long term sick during May. All are being closely monitored and referred as necessary. Two employees have been absent this month due to work stress - both have returned.
- C2 –Inspection reports sent to PR within 20 working days - Sickness absence, maternity leave and staff turnover significantly impacted negatively this month.
- C4 –End to end licensing reports within 70 working days - Three reports were over their KPIs, two at 75 working days and one at 84 working days.
- F2 –Debtor days - Debt collection was the focus throughout the month of May and this continued into June to bring the outstanding debt figure down. Over 50% of the debtors balance relates to prior year(s) and would remain the top priority.

6.2. On PRISM, activity levels were now stable with an error rate of 3.8%. On Choose a Fertility clinic (CaFC), we are continuing to encourage clinics to address errors and we have reiterated our CaFC timescales and best-and worst-case scenarios.

6.3. Members were advised that on opening the register (OTR), the planned target was to complete the reports required for the OTR team by the end of July 2023. The Register Team have successfully tested the manual matching system.

Compliance and Information

6.4. The Director of Compliance and Information gave an update. Members were informed that resourcing remained a challenge due to staff turnover / recruitment, long term sickness, maternity leave and increased inspection numbers. A decrease in inspector team numbers meant each inspector working has an increased number of clinics in their portfolios. KPIs were therefore challenging to meet and are under review. It was noted that the schedule was being finalised for the period up to March 2024.

6.5. On OTR, PRISM tools should be ready by August when we will be switching over to a new IT system. OTR applications would then be easier to process.

6.6. We were also working on the business continuity plan. A member commented that beyond the DSPT, we had assurance that our IT was secure especially in relation to cyber security updates implemented regularly by the IT team.

6.7. The Director of Compliance and Information also commented that we regularly carry out penetration testing on our systems and filter out phishing emails.

Strategy and Corporate Affairs

6.8. The Director of Strategy and Corporate Affairs gave an update. Members were informed that we published our fertility trends report in June and it had received widespread media coverage. The Director thanked the Research and Intelligence and Communications' teams for their hard work in getting the report produced and published.

6.9. Members were also informed that the Licencing team and the Risk and Performance team in the wider Planning and Governance team have been extremely busy. Colleagues had also been working on progressing specific pieces of work, such as proposals on law reform.

6.10. Future planned publications included the annual State of the Sector Report in the Autumn, the proposals for law reform and an update on Ethnic disparities in fertility treatment report later in the

year. We are also working hard to publish data in different ways to ensure it can reach people in more easily accessible ways.

6.11. Members were reminded that the Competition and Markets Authority (CMA) started working with us on adherence to consumer law on fertility treatment about three years ago. It was noted that the final part of their work with clinics was now in progress to agree a way of providing information on prices that would enable patients to more easily compare different clinics.

6.12. On treatment add-ons, it was noted that SCAAC will review the add-ons using the new rating system at the meeting in July and our website would be updated after that and clinics and patients informed of the new system.

6.13. The Chair commented that there was an excellent working relationship with the CMA, and although they would not be working indefinitely in the fertility sector, we were appreciative of the work they had been undertaking.

Decision

6.14. Members noted the performance report.

7. Strategy 2024-25

7.1. The Head of Planning and Governance presented the report. Members were reminded that at the May 2023 Authority meeting members agreed:

- That the current strategy should be extended by one year and that the development of the new strategy should follow in 2024 and
- That we should develop and communicate a clear picture of the further work on the current strategy that will be done in the business year April 2024-March 2025.

7.2. Members were presented with a report outlining the activities we could include in the business plan for the one-year extension period.

7.3. Members suggested that under the ‘right information’ or ‘best care’ sections of the strategy, more work on ethnic disparity (in relation to planned work on the Government’s women's health strategy) would be welcomed, following on from work that has already begun. It was agreed that this should be broadened to cover wider health inequalities, informed by available data. This could be a potential theme in the next strategy.

7.4. Members discussed regulatory transparency and the need to develop further clarity on what this would mean in terms of the way we do our work. It was suggested that impact metrics may be useful to monitor the impact of our interventions over time.

7.5. Developing our position on the use of HFEA information and data, given the rise in online providers, was welcomed. The use of our data and how we make it available was also likely to form part of our next strategy.

7.6. Other proposals set out in the paper were agreed for further work as the business plan for 2024/25 was developed over the coming months. The Chair thanked the Head of Planning and Governance and her team for the planning work to date.

Decision

7.7. Members approved the approach set out in the report and noted that further development would be done shortly during the business planning process, in liaison with the Corporate Management Group (CMG).

8. Opening the Register - update

8.1. The Directors of Compliance and Information and Strategy and Corporate Affairs presented the update on Opening the Register (OTR).

8.2. The workstream update on the OTR systems was discussed. It was noted that good progress was being made on the integration of the new IT system for managing applications.

8.3. The ongoing risks associated with OTR were also noted.

8.4. Members requested that the questionnaire being developed to gather views from people affected by donation issues on the future of support services which would be launched by the end of July be circulated in draft form to some members.

8.5. In response to a question on PRISM the Director of Compliance and Information commented that once we get the register tools required to extract data from the register and the case management system in place and embedded, we will be able to assess how long it takes to respond to applications.

8.6. The Chair commented that at the all-staff event on 10 July, we had a presentation from DCN (Donor Conception Network) which was on the user perspective and that the HFEA continued to work with them.

Action

8.7. The questionnaire being developed to gather views from people affected by donation issues on the future of support services which would be launched by the end of July be circulated in draft form to some members.

Decision

8.8. Members noted the update on OTR.

9. Any other business

9.1. The Chair commented that there will be a Board away day later in the year, most likely in November. The Chair stated that this will be over two days and asked that members please make themselves available.

9.2. The Chair also mentioned that we were looking at a future Persons Responsible (PR) event and were considering both timing and content.

9.3. The Chief Executive commented that this was the last meeting of the Governance Manager, Debbie Okutubo, as she would be leaving the HFEA at the end of the month. Debbie was thanked for her support to the Board over the last four years. The Chair reiterated this on behalf of the Board.

9.4. Members were advised that Alison Margrave will be replacing Debbie and she would start shortly.

9.5. Lastly, members were reminded that the discussion on our law reform proposals would take place on Monday 17 July.

Chair's signature

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

Signature

Chair: Julia Chain

Date: 13 September 2023

Minutes of Authority meeting held on 17 July 2023

Details:			
Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society		
Agenda item	2		
Meeting date	13 September 2023		
Author	Paula Robinson		
Output:			
For information or decision?	For decision		
Recommendation	Members are asked to confirm the minutes of the Authority meeting held on 17 July 2023 as a true record of the meeting.		
Resource implications	-		
Implementation date	13 September 2023		
Communication(s)	For publication on the website		
Organisational risk	☐ Low	☒ Medium	☐ High

Minutes of the Authority meeting on 17 July 2023

Members present	Julia Chain Jason Kasraie Tim Child Graham James Frances Flinter	Gudrun Moore Alex Kafetz Geeta Nargund Catharine Seddon Christine Watson Alison McTavish
Apologies	Jonathan Herring Alison Marsden Zeynep Gurtin	
Observers	Steve Pugh and Amy Parsons (DHSC)	
Staff in attendance	Peter Thompson Clare Ettinghausen Rachel Cutting Ana Hallgarten Angharad Thomas	Paula Robinson Allison Margrave

Members

There were 11 members at the meeting – 6 lay and 5 professional members.

1. Welcome and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members and Department of Health and Social Care (DHSC) colleagues present.

1.2. The Chair also welcomed staff who were present and observers 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.

1.3. 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).
- Alison McTavish (British Fertility Society Trustee and Progress Educational Trust Trustee)
- Frances Flinter (Progress Educational Trust Trustee)

1.4. Catharine Seddon also placed on record her recent appointments to the disciplinary committee of the Royal College of Veterinary Surgeons and as an Institute Director of the Chartered Insurance Institute. In that capacity she has also been appointed as a Board Director for the Personal Finance Society, which entailed also becoming a company director. The Chair congratulated her on these recent appointments.

2. Modernising Fertility Regulation - update

2.1. The Director of Strategy and Corporate Affairs introduced the report, which followed several Authority discussions and input from experts. This also included several meetings with the Legislative Reform Advisory Group and a targeted public consultation held earlier in 2023.

2.2. At its meeting in May, the Authority had discussed the initial quantitative results from the public consultation and heard that there had been widespread support for most of the proposals. However, the initial qualitative analysis showed that four of the draft proposals required further work either to clarify wording or identify a preferred way forward. The paper before the Authority today presented draft proposals, together with background information where further discussions had taken place since the May Authority meeting. The report included an outline of where further discussions were needed, the risks relating to this work, and the proposed next steps after today's discussion. A confidential draft proposal document for submission to the Department of Health and Social Care was circulated to Authority members only, prior to the meeting.

2.3. Members noted the report as a whole, and discussed the following points:

Annex A: Proposals

2.4. Members confirmed their agreement to proposals 1-13 set out in Annex A, which were as follows:

Patient safety and promoting good practice:

1. The HFEA should have greater freedom to decide the regularity and form of inspections.

2. There should be more flexibility in the appointment of clinic leaders, for example introducing the option of a deputy PR, and broadening the criteria for the qualifications and experience required to be a PR.

3. The HFEA should have a broader, more effective range of powers to tackle non-compliance.

4. The HFEA should have a broader range of powers to impose financial penalties across the sector.

5. There should be an explicit duty on the HFEA and clinics to act to promote patient care and protection.

6. The Act should be revised to accommodate developments in the provision of related fertility services in order to have a broader range of powers to tackle related fertility services not taking place in licensed clinics.

7. The Act should be amended to allow the HFEA to determine and set a more proportionate appeals process.

8. The HFEA should have the ability to make rules governing how standard licence conditions are made and revised, there should be more flexibility for the HFEA to make rules governing the setting of standard licence conditions.

Access to donor information:

9. Clinics should be required by law to inform donors and recipients of the potential for donor identity to be discovered through DNA testing websites.

10. The Act should require all donors and recipients to have access to information about the implications of their decision before starting treatment.

Consent:

11. The sharing of fertility patient data in a non-fertility medical setting should be brought in line with the current regulations for the sharing of other patient/medical data between healthcare providers.

12. Consent for donating embryos should be extended to allow patients who wish to, to give consent to research embryo banking.

Scientific developments:

13. The Act should explicitly give the HFEA greater discretion to support innovation in treatment.

Annexes B, C and D: Policy proposals in progress

2.5. It was agreed at the May 2023 Authority meeting that four areas required further examination following the consultation. These were:

- Ways in which to simplify the current consent process
- Potential changes in donor information provision
- The potential use of secondary legislation and other mechanisms for changes to the regulation of scientific developments
- Elements of the HFEA's regulatory powers, most notably the regulation of allied services – the issue here was in better explaining, rather than reviewing options for reform.

2.6. Further discussions on three of these proposals (donor information, scientific developments, consent) was outlined in Annexes B, C and D. The further description on regulation of allied services would be incorporated into the full response as the requirement was for better explanation, rather than for decision and as such did not require discussion at today's meeting.

Simplifying the consent process

2.7. Members noted the options set out in Annex B, namely:

1. Keep current system and make no recommendations for change
2. Recommend 'opt-out' model (proposed in the consultation)
3. Keep current system and make recommendations for changes that don't overhaul the whole system
4. Recommend a thorough overhaul of consent regime, possibly identifying areas where opt-out might be appropriate, but say we will work closely with DHSC and others to make detailed recommendations at a later stage
5. Recommend a change to legal parenthood as set out in a recent academic paper by Jackson/Horsey.

2.8. The Chief Executive noted the centrality to the legal framework of consent, and its complexity owing to the many possible scenarios patients might face. Both patients and clinic staff find the law complex, and the complexity can lead to the possibility of error. However, simplifying the consent regime is not straightforward.

2.9. A significant proportion of patients are couples in a formal relationship using their own gametes. The 'opt-out' model would enable a simpler regime for such patients. However, this proposal received mixed support in the consultation. The paper therefore looks at the five possible options set out above, one of which would be to retain the status quo. The other options represented other potential ways to address existing problems with the regime. Option 4, an overhaul of the

regime, would take longer to achieve. Similarly, option 5 would require further work, after the submission of our recommendations to the DHSC.

2.10. Members questioned how prescriptive the Act needed to be in relation to consent, since the scenarios requiring consent do tend to evolve. It was felt that there was some flexibility in how the Act could be redrafted in future to allow for change over time.

2.11. Consent was acknowledged as a major issue for the sector. Safeguards are needed that cover the unlikely events that can happen from time to time, as well as common scenarios. Consent, or the lack thereof, has been at the root of many legal cases. Mistakes and oversights could have far-reaching consequences for people.

2.12. Members agreed that an overhaul of the regime (option 4 and/or 5) was the most appropriate response, while acknowledging that either option would require a lot of further work, preferably in collaboration with the sector. Option 5 would make legal parenthood more straightforward in the future and be more equitable for different family types. It was suggested that considerations raised about legal parenthood could perhaps be explored at a later stage, after further detailed work on option 4 had taken place.

2.13. It was noted that the sector is used to the current complexity of the regime, and that any change would carry risks and difficulties as well as advantages, but it was felt that this was the right thing to do. In relation to potentially defining legal parenthood in a different way, this might be the right thing to do in law, although it may not be supported by all the general public. It would be important to work with others on this to ensure as much consensus and understanding as possible.

2.14. The Authority agreed developing and proposing option 4 and further consideration of a link with option 5.

Donor information provision

2.15. The Director of Strategy and Corporate Affairs introduced the discussion. Members noted that the most challenging issues concern the proposals on access to donor information. Each of these proposals has a host of potential consequences which would raise numerous tricky policy questions.

2.16. Members were reminded of the range of options that were considered prior to the consultation:

1. Status quo plus – keep the current statutory position where all donors remain anonymous until the resulting child reaches the age of 18 after which the donor-conceived person may seek information about their identity from HFEA if they wish to.
2. Early identification by consent – introduce a voluntary system for donors to become identifiable earlier on, perhaps under agreed terms about the level of contact/localised arrangements (either from the outset or at any point before children born from their donation reach 18 with the consent of the parents, or consent varied by the child after a certain age).
3. Remove anonymity completely – amend the Act so that donors are identifiable to the recipients from the outset: whether from the time of considering all donors, so donor details are always identifiable, or after selecting a specific donor, or when treatment commences, or upon pregnancy, or birth.
4. Double track system – in which donors must choose between the status quo (i.e., donor identifiable information available when the child turns 18) and being identifiable from the

outset (to be defined in new legislation). Under this option patients could choose between donors who wish to be identifiable and those who do not.

2.17. Members were reminded of current legal requirements in relation to information access for donors and donor-conceived people. Several further issues were raised by consultation respondents as outlined in the paper. The current system has also been overtaken by developments such as DNA websites and social media. Retrospective opening of the register was also proposed by some respondents, as was the removal of anonymity completely.

2.18. It was not yet possible to know what the public appetite would be for the full range of options, including the complete removal of anonymity and what any unintended consequences of the options were at this stage.

2.19. It was suggested that the status quo should perhaps be maintained while there is some investigation into the possibility of complete removal of anonymity in the future, which is a route some other countries have already gone down. Options 2 and 4 may be seen as too complex and result in a great increase in the need for implications counselling.

2.20. People have a right to know their genetic origins, and this could be important information in certain medical situations (including at a younger age than 18). It was noted that this may create a discrepancy between the rights of adopted children and donor-conceived individuals.

2.21. A question was raised about whether anyone from particular ethnic minority groups had expressed a distinct view on this issue. A breakdown of responses by ethnicity had not been carried out but broadly, there was no specific support from consultation respondents on any alternative proposal than the one that had been in the consultation, although there was some support for option 3.

2.22. In discussing the potential for a double-track system, option 4, it was acknowledged that while it had merit at the present time, it may not be the right option for the future, given that there is perhaps now more of a public appetite for the removal of anonymity and greater transparency. The Act in 1990 was grounded in the principle of the anonymity of the donor; however, most donors now realise (and accept) that their anonymity will not be guaranteed, and donor numbers are still rising. Given ongoing changes in the world, if a double track system, as a temporary measure, was not felt to be truly viable, option 3 should be chosen.

2.23. It was observed that option 3 would require a lot of further work and have a lot of implications, but that it may be the most appropriate option given wider developments, if it was agreed in principle that we should try to future-proof the legislation. Given how easily donor conceived individuals can access DNA databases and feasibly identify, by triangulation, their donor or someone closely related to them, it was agreed after discussion that the favoured option should be option 3, even if it takes some time to get there.

2.24. The proposal could be to change the law such that over the next 5-10 years, for example, anonymity would be removed, i.e., not with immediate effect. This would give more of a chance to obtain the views of the public, donors and donor-conceived individuals on this and consider possible unintended consequences. If the change of circumstances being brought about by DNA testing and social media means that anonymity effectively cannot be maintained, the law should reflect that. It was pointed out that not everyone would be able to use DNA testing sites or social media in this way, and that we should ensure that the approach adopted is socially fair. With

regard to social inequality, this may apply more to some groups, and this would require an eventual equality impact assessment.

2.25. The immediate removal of anonymity would be a huge change compared to current practice, and we do not currently know what the public would think about that. It was also pointed out that not all donors are UK-based, and that those in the UK may have a different view to overseas donors. Therefore, a stepping stone approach, over time, may be appropriate.

2.26. It was acknowledged that extra work would be needed as a result of recommending option 3 when any change in the law occurred. This would require close working with our stakeholders and providing clear information for clinics and support for donors.

2.27. We should also bear in mind the effect on those who are considering using donated gametes, some of whom might seek treatment abroad in the event of complete removal of anonymity.

2.28. It was agreed that a fuller proposal would be produced for the September Authority meeting.. There could also be a step involved that would reduce the age of 18 for accessing identifiable information within the present system to a lower age, although we have not consulted on that.

2.29. In summary, since donors are likely to be found in any case, through other information routes, it was agreed that option 3 was the right option, with consideration given as to how best it might be introduced. The proposal would therefore indicate the stages that may be needed so as to reach this point and consider a potential timetable for ultimate removal of anonymity.

Regulation of scientific developments

2.30. Members considered whether to make a recommendation on the need to 'future-proof' the Act so that it could better accommodate novel scientific developments as they occur (as proposed in our consultation); or whether to go further (as some of the responses to our consultation suggested), and make recommendations that certain specific advances, as laid out in further detail in the report, should be considered in any revision of the Act. This might include several particularly pressing issues - new categories of cells, the 14-day rule for the use of embryos in research, and heritable nuclear germline genome editing.

2.31. The Public Policy Manager presented this part of the report. Greater discretion to support innovation in treatment received positive feedback in the consultation. Annex D of the report set out ways in which the Act could be future-proofed. There were questions and reservations from some respondents about what this would mean in practice and what safeguards would be put in place.

2.32. In relation to the broad question of future-proofing, members felt the HFEA needed to be more nimble since we operate in a fast-moving area of science. Such advances occur frequently and would be very difficult for Parliament to respond to in a timely way. Therefore, this could be better addressed by the HFEA having more discretion. Aspects that are likely to be more controversial, such as the 14-day rule, might be reserved to Parliament itself. In relation to new categories of cells, which are not currently regulated at all, the question was should they be regulated, and if so, how. They do not fall under the current definition of a 'permitted' embryo in the Act. They could potentially be referenced separately, although this would require further work to resolve – this would be a challenging area, with many ethical and philosophical issues. Regardless of the system ultimately chosen, there remains a necessity for us to be able to be responsive to new developments as and when they arrive.

2.33. Although no recommendation specifically looking at the 14-day rule was proposed in our consultation, members raised the following points in relation to the general area as this is a live topic of discussion for some researchers. . Were the Government to decide to look at this area in the future then consideration would need to be given to: the possibility of having a scientifically derived limitation rather than specifying the number of days; and a proposed number of days that was both appropriate and acceptable to the wider public. Fourteen days was considered to be the point of pre-sentience when it was first agreed, and this should be borne in mind. It would also be important to explain to the public the reason, and the importance, of any future extension to the 14-day rule, and to explain the stages of embryo development over time. It was also acknowledged that any Parliamentary discussion would likely include voices who would argue for the 14-day limit to be reduced, rather than extended, since some do not agree with embryo research at all. The views of scientific researchers' are not the only important ones and ethical arguments should form part of any additional future work. These considerations were not for the current HFEA work on law reform.

2.34. More work might also be needed on new types of cells.

2.35. There was a general view that heritable nuclear germline genome editing was not so developed that there was a case to depart from the current status quo, it was noted that it may be judged to be safe and effective at some time in the future. Therefore, further work may also be required on this at some stage, and we should perhaps set out some principles for the DHSC in relation to this and other potential future developments that will arise. Broadly, consideration should be given to the governance framework around any future decision-making, including the use of expert advisory groups.

2.36. Inevitably, any review of the Act would be subject to much Parliamentary scrutiny and public discussion, so incorporating the 14-day rule and new cell types could be part of that public process, if that is what a future Government decided.

2.37. It was noted that scientific advances are always likely to outstrip the particulars of any legislation if it is not future-proofed (or made more resilient) in some way. Even so, dealing with particular scientific developments directly within legislation will always be difficult to achieve and new wording could be overtaken by events even while it was still being discussed by Parliament.

2.38. It would be important to express in our proposals how an appropriate balance would be maintained so that the HFEA was not seen to be 'writing its own rules' on a range of matters.

Decision

2.39. Members approved the proposals for change to the Human Fertilisation and Embryology Act 1990 (as amended) as set out in 1-13 in Annex A noting that minor drafting changes may occur in wording on these proposals over the summer.

2.40. Members also agreed the following in relation to consent, release of donor information and scientific developments (set out in Annexes B, C and D):

2.41. **Consent:** Option 4 (overhaul of the regime), with the possibility of further work in the future on option 5 (legal parenthood), was agreed as the best approach.

2.42. **Release of donor information:** It was agreed that option 3 (removal of anonymity) was the right option, with consideration given to how this could be best implemented over time.

2.43. **Scientific developments:** It was agreed broadly that some level of resilience was needed in the Act, in order to address fast-changing areas of science. Given the speed of developments, the 14-day rule and new types of cells, might require further work in the not-too-distant future.

Next steps

2.44. It would be important to engage with the DHSC and agree a plan with them in respect of how best to deal with areas where there are unresolved questions and where further work would be necessary in the future.

2.45. A report on the consultation will also be published, setting out the overall quantitative and qualitative responses. The final HFEA proposals will be published with full communications support, in due course.

2.46. A further paper would be brought to the Authority's September meeting. It was agreed that some sections could usefully be shared with members, for their expertise, in the intervening period.

3. Any other business

3.1. No further items of business were raised.

Chair's signature

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

Signature

Chair: Julia Chain

Date: 13 September 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 The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science, and society		
Meeting	Authority meeting		
Agenda item	2		
Meeting date	13 September 2023		
Author	Alison Margrave, Board 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	2023/24 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 17 July 2023			
2.44 Engage with the DHSC and agree a plan with them in respect of how best to deal with areas of law reform where there are unresolved questions and where further work would be necessary in the future.	Director of Strategy and Corporate Affairs	December 2023	No progress to be reported until after final proposals are submitted to DHSC.
2.45 A report on the consultation on law reform will also be published, setting out the overall quantitative and qualitative responses. The final HFEA proposals will be published with full communications support, in due course	Director of Strategy and Corporate Affairs	December 2023	No update due.
2.46 A further paper would be brought to the Authority's September meeting. It was agreed that some sections could usefully be shared with members, for their expertise, in the intervening period	Director of Strategy and Corporate Affairs Public Policy Manager	September 2023	Paper with further proposals brought to the September Authority meeting.
Matters arising from the Authority meeting – actions from 18 May 2022			
3.6 Some members are yet to complete their cyber security training.	Board 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 also required to complete a module on Equality, Diversity and Inclusion. As at end of June 2023, 13 of the 14 members had completed their training in 2023. The 14th member completed their training in November 2022 but without the EDI module.

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:	13 September 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 meetings in July 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:

    - 25 July – Peter and I attended the SCAAC meeting in the morning only to hear the update from the team at the Newcastle Centre for Life regarding their Mitochondrial Donation programme.
    - 6 September – introductory meeting with Amanda Davies, Deputy Director – Health Ethics, NHS Quality, Safety, Investigations at DHSC

2.2 Chief Executive

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

    - 19 July – HFEA Annual Report and Accounts laid in Parliament.
    - 25 July – attended the morning session of SCAAC meeting.
    - 21 August – Introductory meeting with Tom Skrinar our new Finance Director.
    - Ongoing liaison with lead reviewer on the Public Bodies Review.

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:	13 September 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:		
29 June	1 Research initial 3 Executive updates	All approved
31 August	2 Executive updates	Minutes not yet finalised
Other comments:	Following an unusually busy period that has included additional meetings and unusual licensing situations, business has returned to a more normal level. It is too early to say if this will continue.	
Executive Licensing Panel:		
11 July	3 Research renewals 1 Variation of premises 1 Change of PR 1 Special direction for licence continuation	All approved
20 July	4 Interims 1 Change of LH 1 Variation of premises	All approved
8 August	2 Renewals 1 Interim 1 Variation of activities	All approved
22 August	2 Renewals 1 Interim 5 Changes of PR 1 Variation of activities	All approved
5 September	3 Renewals 1 Change of PR 1 Variation of activities 1 Variation of premises	Minutes not yet approved
Other comments:	None.	
Licensing Officer decisions:		
July 2023 – August 2023	20 ITE import certificates 1 Change of centre name	All granted

Meetings held	Items considered	Outcomes
Other comments:	None.	
Statutory Approvals Committee:		
20 June	4 PGT-M 1 special directions for import	All approved
31 July	4 PGT-M 2 special directions for import/export	1 PGT-M refused; 5 items approved
29 August	5 PGT-M 1 special directions for export	Minutes not yet approved
Other comments:	None.	
Audit and Governance Committee:		
The next meeting will take place on 3 October 2023.		
Other comments:	None.	
Scientific and Clinical Advances Advisory Committee:		
25 July	The team at Newcastle Fertility Centre at Life gave an update to the committee on progress in the mitochondrial donation programme.	Minutes of the discussion will be published on the HFEA website. The team at Newcastle Fertility Centre at Life will be invited to the February 2024 SCAAC meeting to give a progress update.
	Evidence base for treatment add-ons.	New ratings were allocated. The patient information on treatment add-ons on our website will be updated to reflect the new ratings in October 2023.
Other comments:	None.	

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

Up to July 2023

Evgenia Savchyna
Corporate Performance Officer
25/08/2023

www.hfea.gov.uk

About this paper

Details about this paper	
Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	CMG, Authority
Agenda item:	Item 5 (Authority)
Meeting date:	23/08/2023 (CMG), 13/09/2023 (Authority)
Author:	Evgenia Savchyna, Corporate Performance Officer
Contents	Latest review and key trends Management summary Summary financial position 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. The Authority receives this summary paper at each meeting, enhanced by additional reporting from Directors. Authority's views are discussed in the subsequent SMT meeting. The Department of Health and Social Care reviews our performance at each DHSC quarterly accountability meeting (based on the SMT paper).
Organisational risk:	Medium

Human Fertilisation & Embryology Authority

Latest review and key trends

Latest review

- The attached report is for performance up to and including July 2023.
- There were seven Green, three Amber, four Red, and three Neutral indicators.

Key trends

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

May (4)	June (5)	July (4)
Inspection reports sent to PR within 20 working days	Inspection reports sent to PR within 20 working days	Inspection reports sent to PR within 20 working days
End to end licensing reports within 70 working days	End to end licensing reports within 70 working days	Staff sickness rate
Staff sickness rate	Staff sickness rate	Debt collection
Debtor days	Debt collection	Invoices paid within 10 working days
	Debtor days	

Management summary

IT and register performance reporting

- PRISM activity: 474k units from 104 clinics. The error rate is 3.3%, down from 3.5% last month.
- The developers have completed the new OTR and 10 family unit reports and these are now being tested by teams.
- The key priority for clinics is to fix the CaFC related errors which we have been releasing to clinics in batches over previous months. As previously reported, clinics fixed registration errors quickly, the pace of fixing cycle errors was much slower.
- The final batch of errors was released in July, progress will be monitored through to September.
- We are on track for the first CaFC to be delivered by the end of the first half of 2024 (the backstop date that has been previously given to AGC).

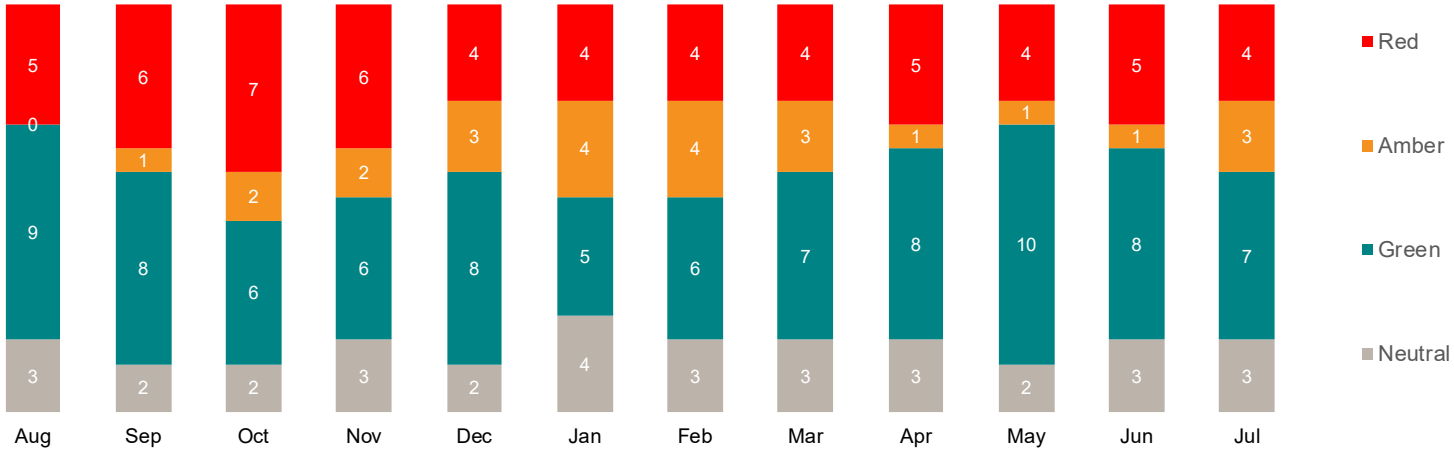
Management commentary

- Performance has been variable across KPI indicators with four Red, three Amber, seven Green and three Neutral indicators.
- Compliance KPIs are showing a more positive trend. More reports have been sent to PR within KPI compared to the previous two months and 75% of inspection reports were sent to the relevant committee in time. The ‘End to End licencing’ indicator is now Green with all items processed within the 70-working days KPI.
- Testing and training on the new case management system was prioritised with the OTR team in July which resulted in fewer OTR cases being actioned. The system went live at the beginning of August, ahead of schedule.
- There's a steady increase in social media followers across our channels with the largest rise on LinkedIn. Our blog for the World Embryologist Day was our highest performing social media post.
- Staff sickness is at its highest level for some time (four staff members are on long-term sick and one was absent for most of the month but has now returned). The turnover indicator remains Amber with one leaver in July.
- Debt collection remains Red with 72% within 40 days, however, there has been a 24% reduction in debtor balance from the previous year. 80% of invoices were paid within 15 working days (KPI is 10 working days).

Key performance indicators

Human Fertilisation & Embryology Authority

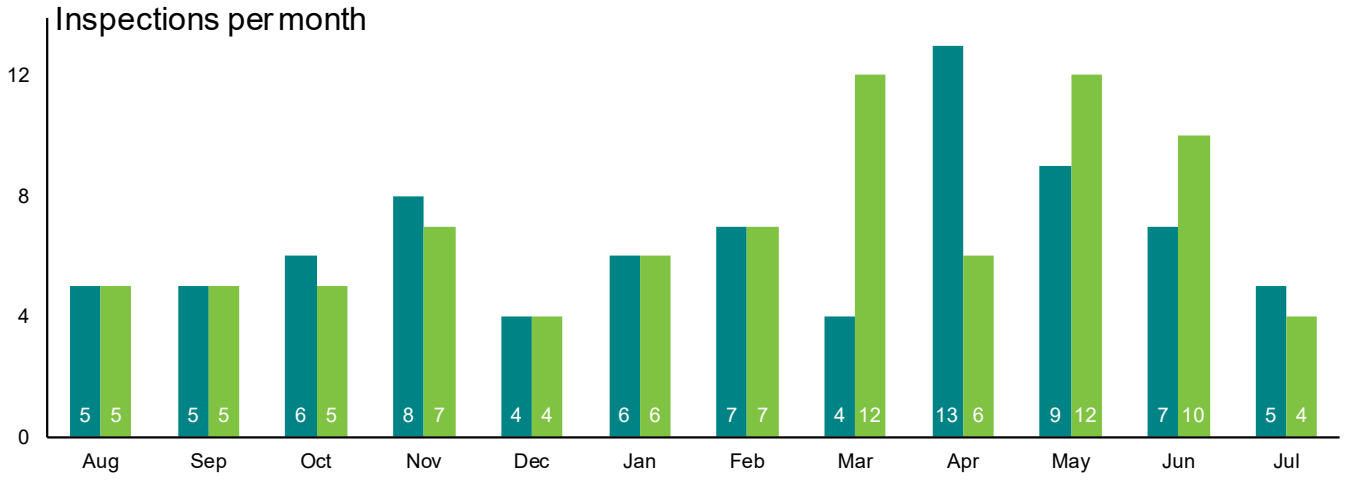
RAG status over last 12 months



RAG status over last 12 months

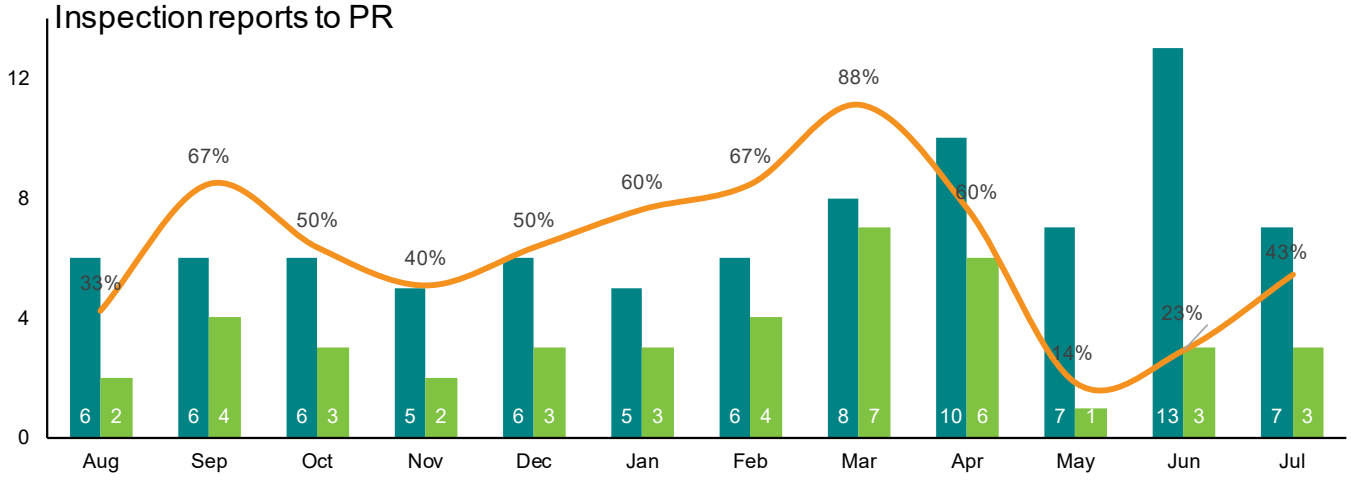
17 KPIs in total for each month

For July, the **4 Red indicators** are in these teams: **Compliance - 1; Finance - 2; HR - 1.**



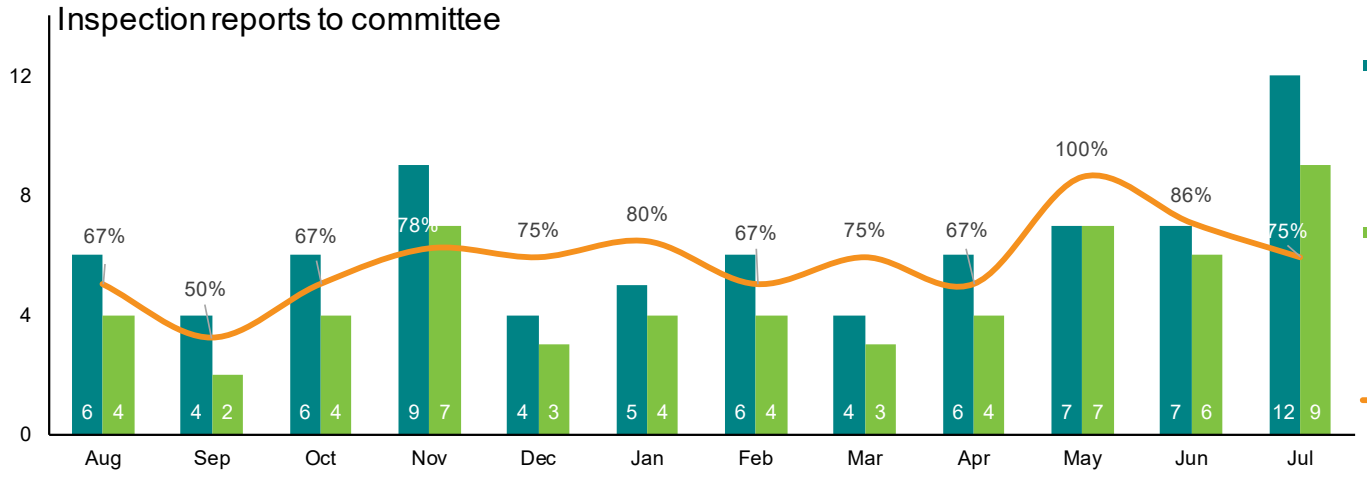
Status:	N/A
Compliance	
Inspections delivery	
Target: **not defined**	

Reduced number of inspections due to availability of trained inspectors because of long term absence (sickness and maternity leave) and staff turnover. New inspectors now in post and training has commenced. Train strike resulted in rescheduling of an inspection.



Status:	Red
Compliance	
Inspection reports sent to PR	
Target: **100% sent within 20 working days**	

KPI impacted by reduced capacity in inspection team (long term absence, turnover and availability of trained inspectors). Delays also caused when a management review meeting needs to be held with the legal and senior compliance staff (C&E policy). Whilst this may impact the KPI it ensures a more consistent and robust approach to making recommendations.



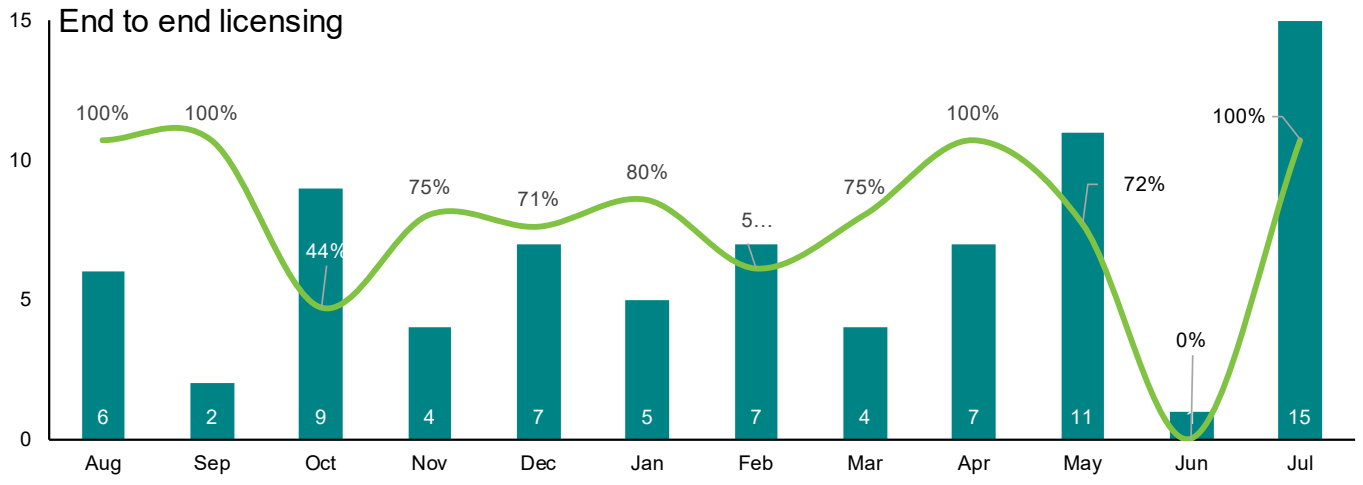
Status: **Amber**

Compliance

Inspection reports sent to relevant licensing committee

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

Reduced capacity due to long term absences within the team (sickness and maternity leave), turnover and availability of trained inspectors. Complex reports can be subject to further C&E assessments and management reviews which can delay the progression of a report.



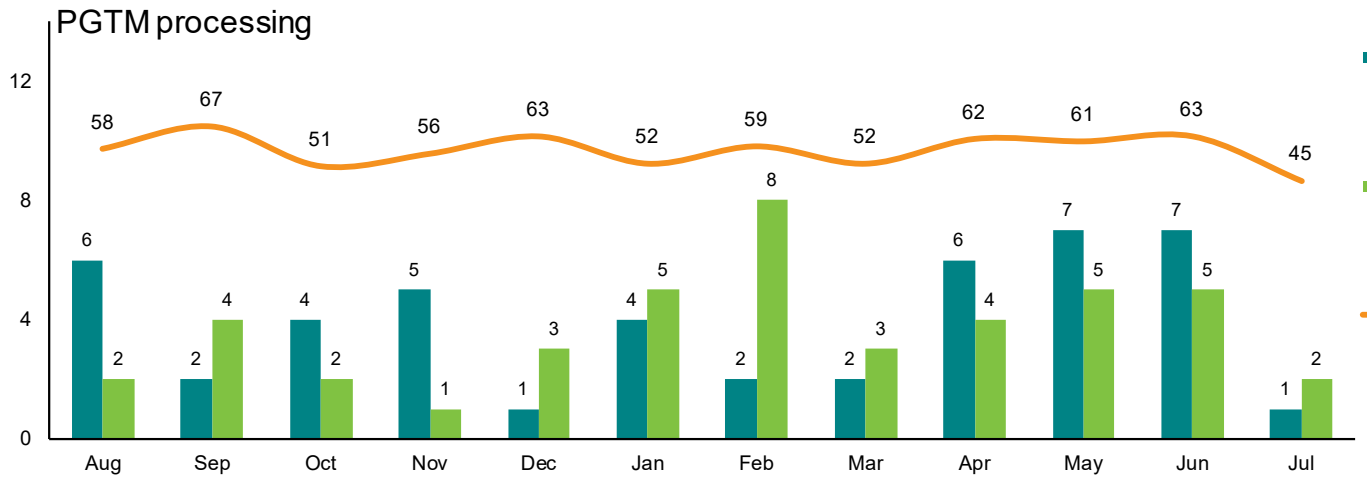
Status: **Green**

Compliance

End to end licensing process

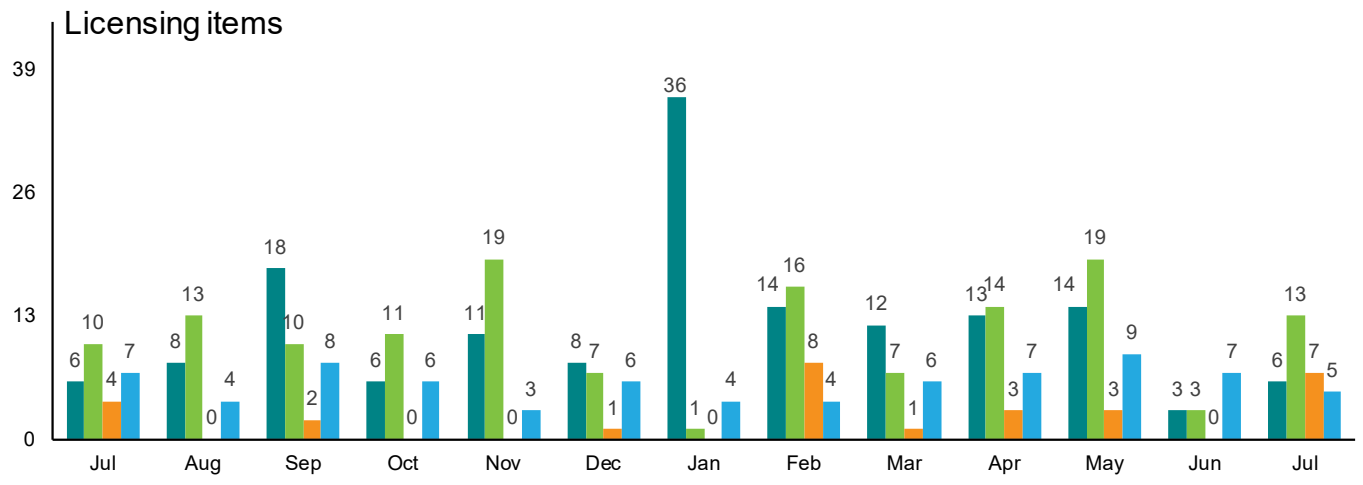
Target: **100% items completed within 70 working days**

All items processed within KPI.



Status:	Green
Compliance	
PGTM processing efficiency	
Target: **100% within 75 working days**	

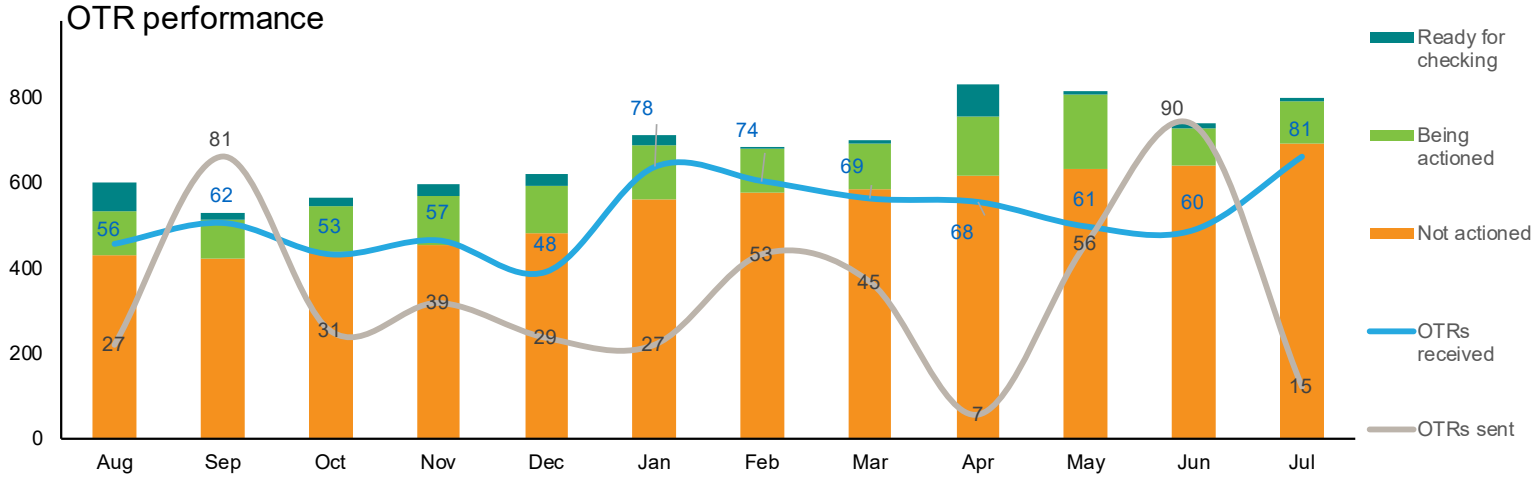
All PGTMs have been processed within KPI.



LO:	Green
ELP	Green
LC	Green
SAC	Green
PlanGo	
Licensing efficiency	
Targets: **LO - 5 WD; ELP - 10 WD: LC - 15 WD; SAC - 20 WD.**	

The LC meeting pattern was changed this year - the meeting that used to fall in July now falls at the end of June. This, combined with an increase in the number of LO and ELP items compared to last month, meant that the month was busier than usual. SAC had a steady number of items. Targets were met for all items, which is an achievement.

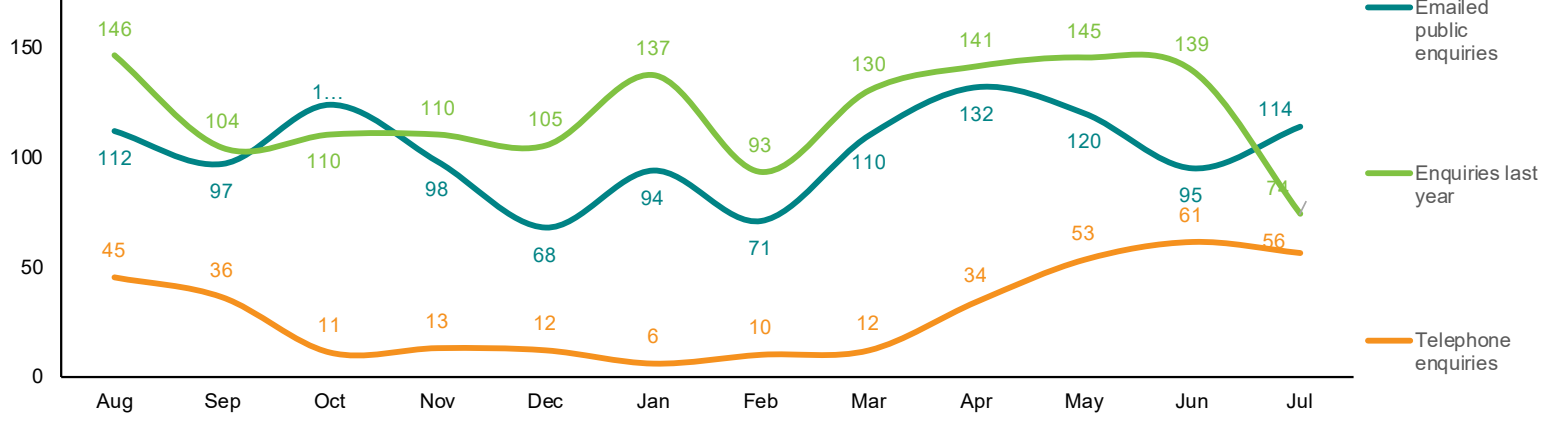
OTR performance



Status:	**N/A**
Information	
OTR performance	
Target: **to be developed**	

High number of applications received in July. Testing and training on the new case management system was prioritised with the OTR team in July which resulted in fewer OTR cases being actioned. The system went live at the beginning of August, ahead of schedule.

Emailed public and telephone enquiries

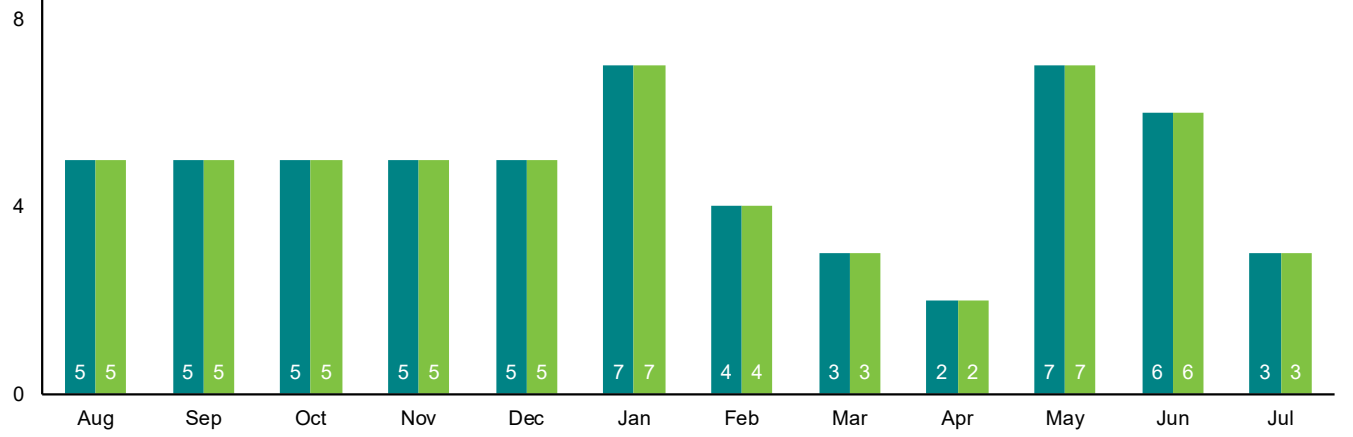


Status:	**N/A**
Policy	
Emailed public and telephone enquiries	
Target: **not defined**	

114 enquiries received in July 2023, and the majority of these enquiries were from patients.

The number of incoming phone calls remains high. **Main themes:** donation (24) and complaints related (5)

FOI requests



Status: **Green**

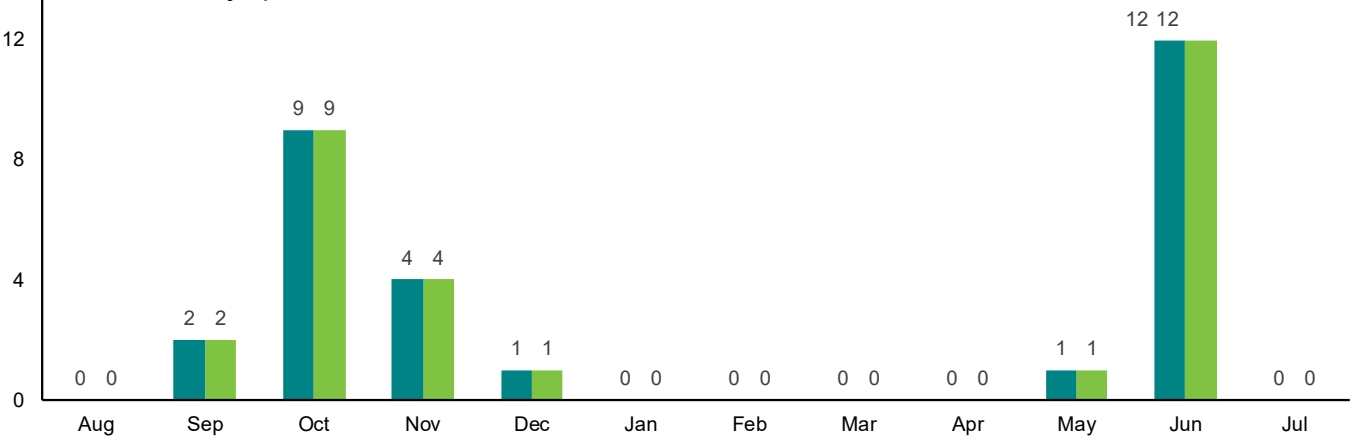
Intelligence

FOI responses

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

The FOIs due in July were about IT software, and regional clinic level data x2.

Parliamentary questions



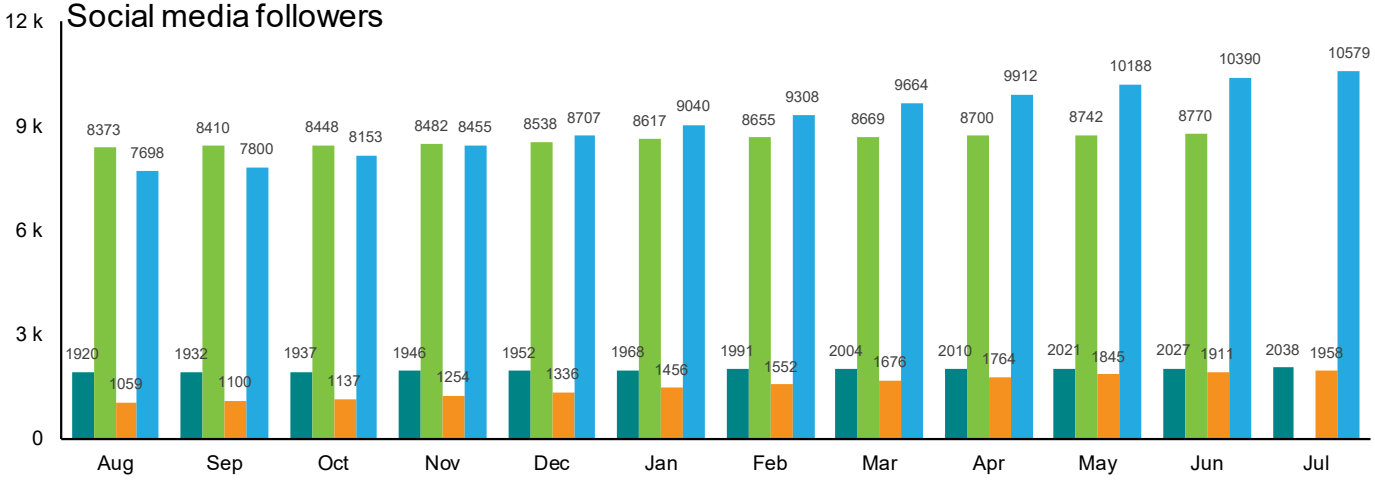
Status: **Neutral**

Intelligence

PQs responses

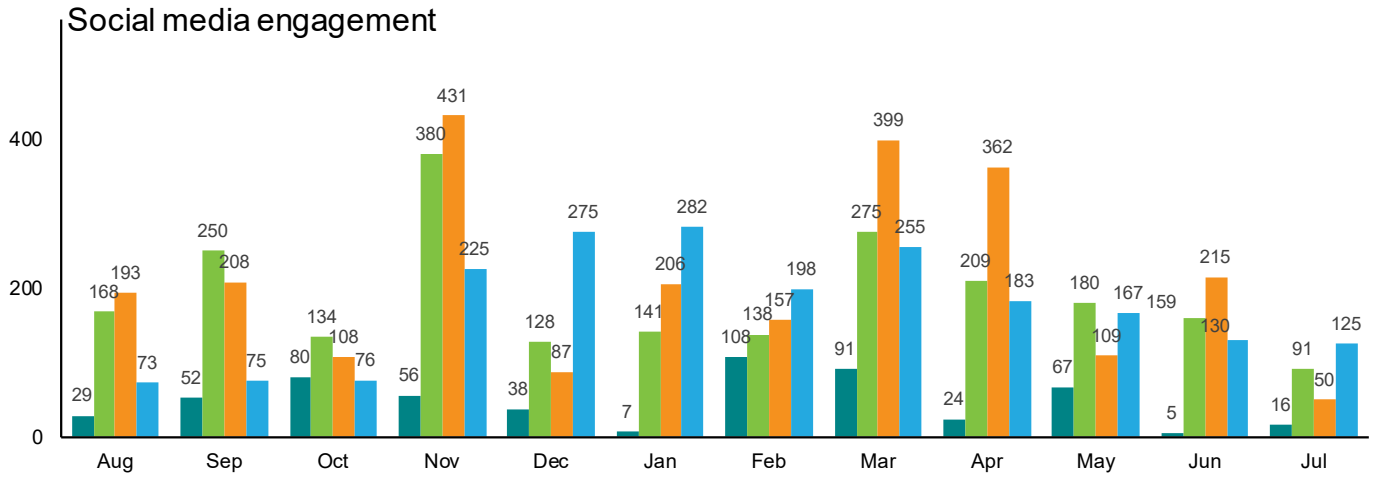
Target: **100% within deadlines set**

No PQs this month.



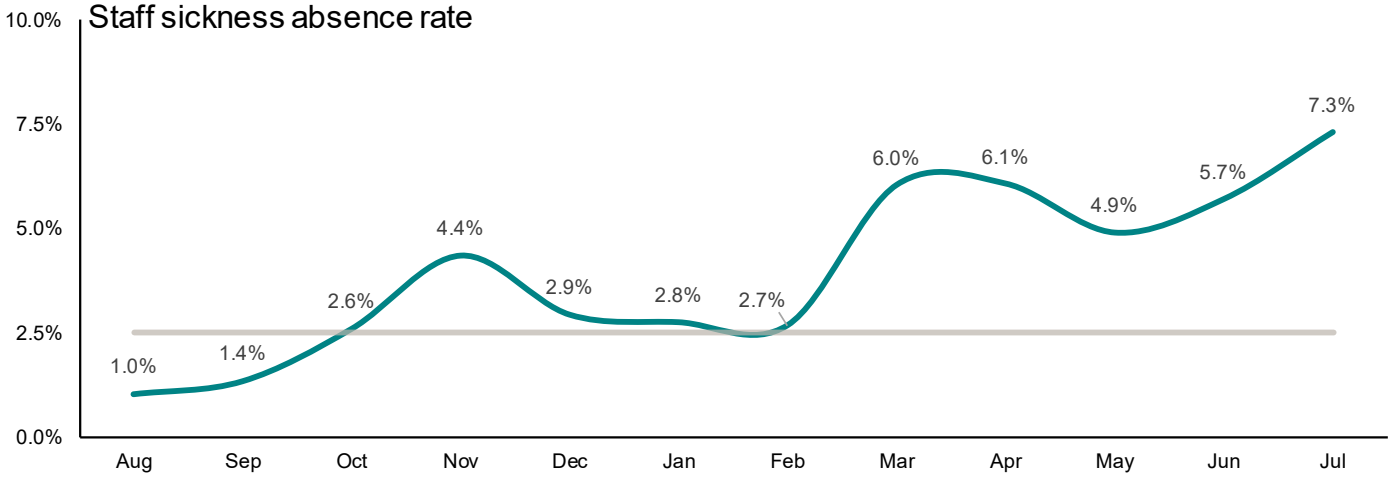
Status:	N/A
Comms	
Total number of followers across social media	
Target: **not defined**	

Same as last month, there's a steady increase in followers across our channels with the largest rise on LinkedIn. This month we cannot accurately report on Twitter's analytics due to changes with the transition to X.



Status:	N/A
Comms	
Engagement across social media	
Target: **not defined**	

In July, we posted content from our new blog for World Embryologist Day. It was one of the highest performing posts.



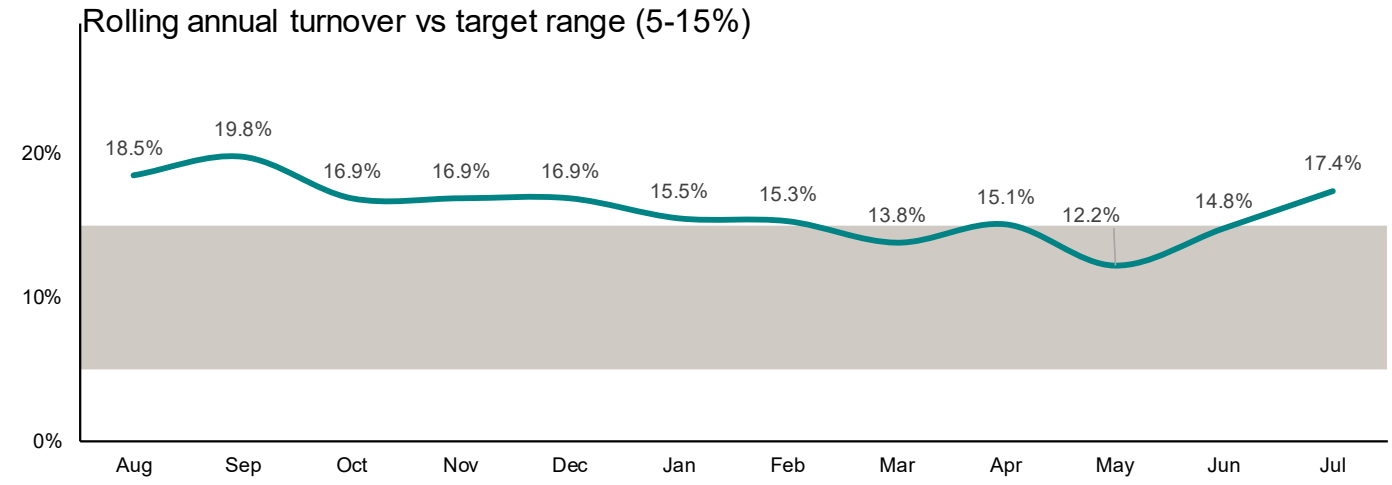
Status: **Red**

HR

Sickness

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

Sickness absence remains high with 4 employees on long term sick (all for different reasons). One other employee was absent for most of the month but has now returned.



Status: **Amber**

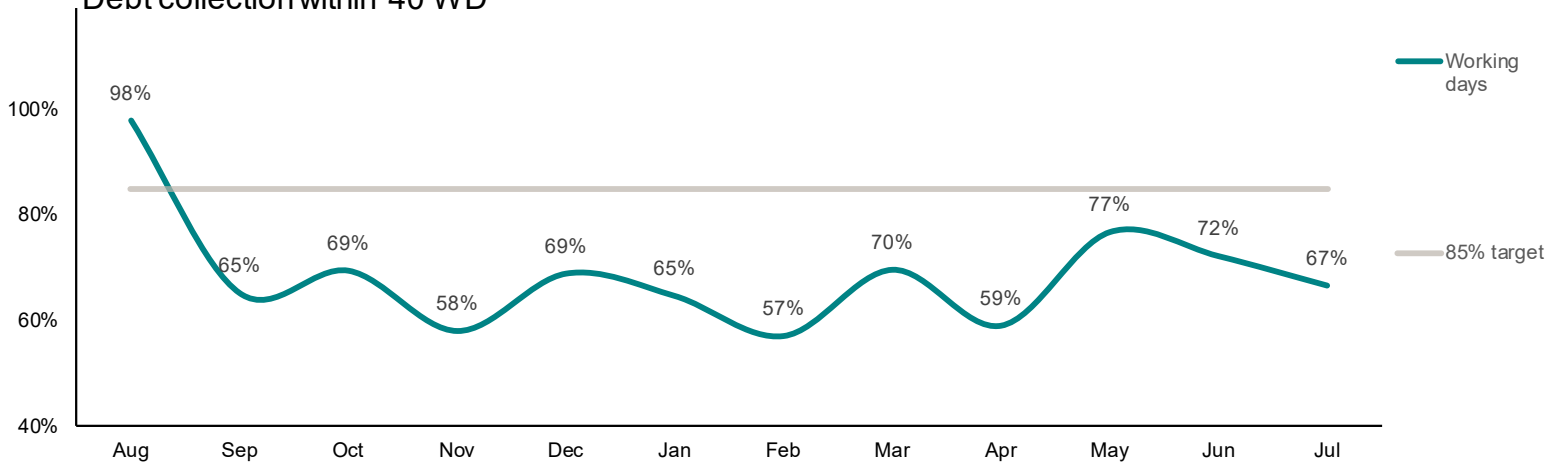
HR

Turnover

Target: **From 5% to 15%**

One leaver for July, however, the turnover from last month will have an overall effect on our rolling figures.
Supplementary HR data: **Headcount - 75; Posts - 76; Starters - 2; Leavers - 1**

Debt collection within 40 WD



Status: **Red**

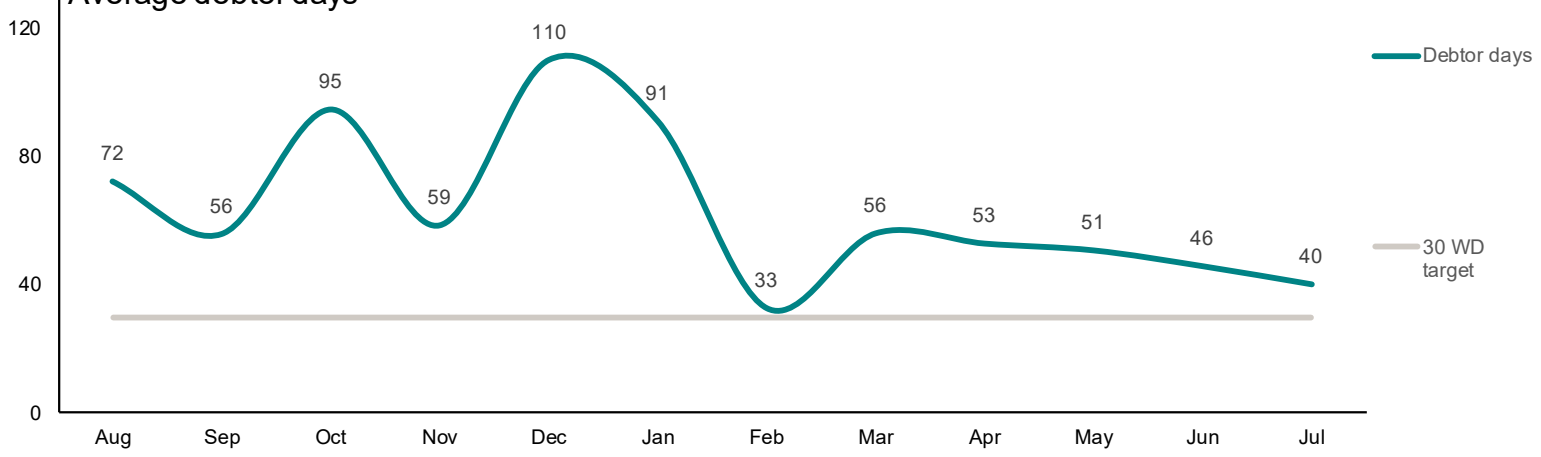
Finance

Debt collection

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

£72,000 of the payments received this month relate to prior year invoices. This is a 24% reduction in the prior year debt balance.

Average debtor days



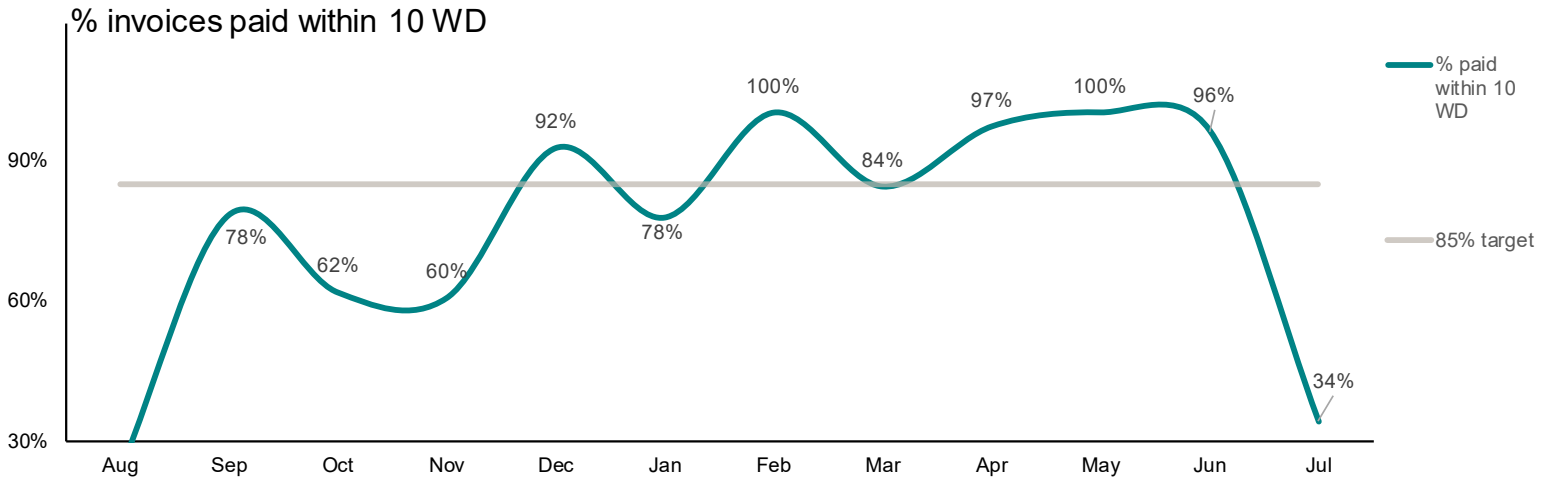
Status: **Amber**

Finance

Debtor days

Target: **30 working days or less**

The overall debtor balance has reduced by 9%. This is part of the ongoing drive to tackle the outstanding debt.



Status:	Red
Finance	
Prompt payment	
Target: **85% or more invoices paid within 10 working days**	

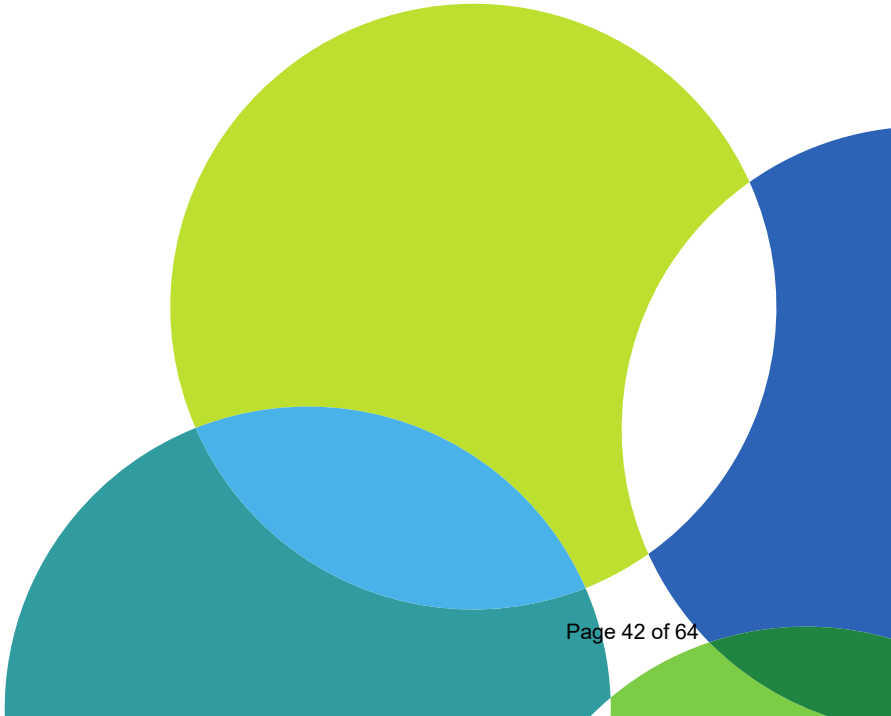
Despite the low percentage paid within 10 days, 80% of invoices were paid within 15 days. During the month there was a delayed pay run which contributed to the lapse in 10-day payment figures.

Human Fertilisation & Embryology Authority

Opening the Register – update

Rachel Cutting and Clare Ettinghausen

13 September 2023



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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

- New IT system for managing applications went live beginning of August (earlier than scheduled). Positive feedback received regarding use from the OTR team in terms of ease and efficiency

- Continued work on updating policies and legal advice to inform processes, incorporated Authority decision on contacting donors into operational protocol

- Development of register tools to aid extraction of data completed, now in testing phase with OTR team

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Future of support service

Workstream update

- Post donation support questionnaire now live
- Open to those over 16 personally impacted by the provision of post donation support services
- Aims to gain insights into what people who may access post donation support services want or need from these services. It also gauges opinion on meeting the costs of a support service
- Response numbers positive, as of 6 September, over 225 responses with a good representation across those impacted by donation
- Survey closes 12th September

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Communications

Workstream update

- Targeted public-facing communications will begin in September, informed by audience insight work
- We are applying lessons learned from previous website user testing to revamp our donation pages so people can access the right information
- Continued engagement with and management of interested media outlets and documentary makers
- Continued stakeholder engagement to agree sharing of information and collaboration where relevant
- Clinic communications planned via Clinic Focus special edition
- Internal communications so colleagues are aware and engaged
- Social media assets developed including video content and press opportunities continue to be found.

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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

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 a summary of findings in November regarding the future of support services for an Authority decision in January 2024
- Provide updates and engagement as needed to Authority and external stakeholders

Human Fertilisation & Embryology Authority

Modernising Fertility Regulation - proposals

Details about this paper

Area(s) of strategy this paper relates to:	Shaping the future
Meeting:	Authority
Agenda item:	7
Meeting date:	13 September 2023
Author:	Clare Ettinghausen, Director of Strategy and Corporate Affairs Ana Hallgarten, Public Policy Manager

Output from this paper

For information or decision?	For decision
Recommendation:	The Authority is asked to discuss and approve the proposals on law reform as set out in the paper and annexes on: ○ Consent ○ Release of donor information ○ Scientific developments
Resource implications:	Staff resources as planned in the current business plan
Implementation date:	October 2023 onwards
Communication(s):	As outlined in the paper – publication in October 2023
Organisational risk:	Medium

1. Introduction

1.1. The HFEA has long argued that the Human Fertilisation and Embryology Act 1990 (as amended) was, in places, in need of modernisation to reflect changes in the fertility sector, social attitudes and scientific developments. That work started in earnest in 2022.

1.2. Since then, there have been several Authority discussions and input from experts, a Legislative Reform Advisory Group was established in March 2022 and a public consultation took place in early 2023 to which we received over nearly 7,000 responses.

1.3. Previous updates to the Authority in **February 2022**, **May 2022**, **July 2022**, **September 2022**, **March 2023,** **May 2023,** and **July 2023** have noted the background to this work and developments to date.

1.4. At the Authority meeting on 17 July 2023, members agreed 13 proposals on law reform (as set out in Annex A) and discussed three proposals that required further work, identifying a preferred way forwards in each area.

1.5. This paper provides updated proposals in those three areas: consent, release of donor information and scientific developments (at Annexes B, C and D respectively). Section 2 outlines the work undertaken to the proposals discussed in July 2023; section 3 outlines the risks relating to this work and then the paper goes on to outline next steps in section 4.

2. Updated proposals

2.1. Following discussion and decisions made at the July 31st Authority meeting, work has been carried out on three areas to develop further the proposals in these areas. Given the timescale, this has not been in-depth policy or legal work but high-level overview of the issues raised by the Authority. The three areas are:

- Ways in which to simplify the current consent process
- Potential changes in donor information provision
- The potential use of mechanisms (secondary legislation, clinical trials type approvals, 'regulatory sandboxes') to provide greater flexibility to the regulation of scientific developments

2.2. The proposals for each of these areas are in Annexes B, C and D.

2.3. Each of these proposals relates to a 'direction of travel' and further policy analysis and public consultation will be needed in each area.

3. Risks

3.1. The risks outlined in the **May 2022 Authority meeting** are ongoing and include:

- The short time available to complete the work
- Criticism of the presented issues or focus
- A lack of consensus
- Wider challenges for or against the idea of regulation itself.

3.2. We know from the consultation responses that the risks outlined above were reflected in some of the responses we received.

3.3. The proposals have always been intended to be high level, rather than detailed drafting, and we recognise that should the government agree that the HFE Act be re-opened, there will need to be further policy work in some areas before the proposals are ready for legislative drafting.

3.4. It is also important to note that although the majority of our proposals received widespread support, it is inevitable that some of our proposals will go too far for some and not far enough for others. The Authority will therefore need to be content with a level of criticism from those that would hope for a different proposal or outcome.

3.5. The three proposals at annexes B, C and D are 'directions of travel' and require further work and detailed discussions with those affected by the changes and key stakeholders. This will not be completed before the proposals are published and should the Authority prioritise this work then this will impact other planned activities that are discussed in the draft business plan paper being discussed at the September 2023 Authority meeting.

3.6. Lastly, the consultation itself brought some criticism in terms of the HFEA and our remit. Our proposals are aimed at better supporting both clinics and patients (an umbrella term we use to mean all those affected by fertility treatment) and it is our strong belief that advocating for these changes will help the HFEA to be a modern up-to-date regulator that can best address the challenges from the changing fertility sector.

4. Next steps

4.1. Following the Authority decisions, we will submit the full suite of proposals to the Department for Health and Social Care and discuss follow up work with our sponsor team.

4.2. We will then publicise the proposals together with a short report on the consultation.

4.3. We know there is widespread interest in this area from the media, clinic staff, patients, stakeholders and the wider public. Any publicity of these issues is likely to also attract criticism from those who do not agree with either the direction of travel, the wider remit of the HFEA or the specific proposals recommended.

4.4. Any change to the law is likely to take place in the years to come and the HFEA will continue to advocate for these changes discussing the priority for this week alongside other priority areas for the HFEA.

4.5. In the meantime, the HFEA will continue to be an effective regulator within the statutory framework that currently exists.

5. For decision

5.1. Authority is asked to:

- Discuss and approve the proposals set out in Annexes B, C and D on:
  - Consent
  - Release of donor information
  - Scientific developments

Annex A: Draft proposals

The proposals below use the text from the public consultation. This text maybe revised in the coming weeks.

Patient safety and promoting good practice:

1. The HFEA should have greater freedom to decide the regularity and form of inspections.
2. There should be more flexibility in the appointment of clinic leaders, for example introducing the option of a deputy PR, and broadening the criteria for the qualifications and experience required to be a PR.
3. The HFEA should have a broader, more effective range of powers to tackle non-compliance.
4. The HFEA should have a broader range of powers to impose financial penalties across the sector.
5. There should be an explicit duty on the HFEA and clinics to act to promote patient care and protection.
6. The Act should be revised to accommodate developments in the provision of related fertility services in order to have a broader range of powers to tackle related fertility services not taking place in licensed clinics.
7. The Act should be amended to allow the HFEA to determine and set a more proportionate appeals process.
8. The HFEA should have the ability to make rules governing how standard licence conditions are made and revised, there should be more flexibility for the HFEA to make rules governing the setting of standard licence conditions.

Access to donor information:

9. Clinics should be required by law to inform donors and recipients of the potential for donor identity to be discovered through DNA testing websites. (This may fall away in future years if donor anonymity is removed).
10. The Act should require all donors and recipients to have access to information about the implications of their decision before starting treatment.
11. Further proposal following Authority discussion on September 13th.

Consent:

12. The sharing of fertility patient data in a non-fertility medical setting should be brought in line with the current regulations for the sharing of other patient/medical data between healthcare providers.
13. Consent for donating embryos should be extended to allow patients who wish to, to give consent to research embryo banking.
14. Further proposal following Authority discussion on September 13th.

Scientific developments:

15. The Act should explicitly give the HFEA greater discretion to support innovation in treatment.
16. Further proposal following Authority discussion on September 13th.

Annex B

Consent – updated proposal

1. Introduction

1.1. The Authority agreed at the meeting on 17 July 2023 that further consideration of the recommendation in relation to consent should be undertaken before the September Authority meeting.

1.2. Members recommended that the following option should be developed and proposed:

- A thorough overhaul of the statutory consent regime should be undertaken, possibly identifying areas where opt-out might be appropriate for some patients. The HFEA should work closely with the DHSC, professional and patient bodies and other stakeholders to continue to review the current consent regime and make detailed recommendations at a later stage.
- This work should consider recent academic arguments regarding changes to legal parenthood.[1]

2. Background

2.1. Members have long recognised that the law to which fertility patients and donors are consenting under is complex - especially in terms of consenting to the use of gametes and embryos in the more difficult scenarios of posthumous use and donation. A variety of discreet improvements to consent have been identified via discussions over several years with Authority members, sector representatives and in **LRAG discussions**. Yet simplifying the consent regime is not straight forward as it is part of a process which enables patients and donors to express their wishes in an informed manner. Members also noted that having a more flexible consent regime would allow for future changes to be incorporated more easily over time.

2.2. Members acknowledged that while the opt-out proposal set out in the consultation drew some support it did not attract widespread consensus. Given the impact that the current consent regime has on patients and clinics, members recommended an overhaul of the consent regime, in collaboration with the sector and other stakeholders, would be the most appropriate proposal, while recognising the complexities of the issues involved.

2.3. For clarity, the consents that the HFEA are concerned with are solely those that are required by the HFE Act - such as the use of data held by the HFEA, use of gametes and embryos and legal parenthood. Any consent taken by NHS or private clinics relating to medical consent to treatment are entirely separate.

[1] See for example Horsey, Kirsty, Jackson, Emily. The Human Fertilisation and Embryology Act 1990 and non-traditional families. *The Modern Law Review*. 2023; 00-00. **https://doi.org/10.1111/1468-2230.12818**

3. Principles of any new system

3.1. If the Authority are to recommend a thorough overhaul of the consent regime, to be developed over time in collaboration with the sector and other stakeholders, it would be appropriate to agree overarching principles that any revised system should reflect as the basis for any future reform. During the process of drafting the proposals for submission to the DHSC, many different options for proposals for changing the consent regime have been considered.

3.2. There are a number of well-established principles of medical consent (notably, for example, those agreed by the GMC in 2020) which should be reflected in any changes to the consent regime. In addition, the following principles (in no particular order) should be central:

- **Importance of freely agreeing to consent without undue influence**

  Consent must be able to be freely given without any undue influence from anyone else involved. and.

- **Dynamic consent**

  Any future system should enable anyone involved to change their mind at any point about what happens to their gametes and any resulting embryos.

- **Simplification**

  The current system is complex, and this complexity can lead to costly errors, uncertainties about legal parenthood, and difficulties for patients and clinic staff. Any future system should respect that the record of consent must reflect the true and free wishes of those involved. It must also be as straightforward as possible and ensure there is no ambiguity about a person's wishes for what happens with their gametes or embryos in future and in different scenarios, for example, after their death.

- **Modern families**

  The current system does not appropriately reflect the range of modern family types that exist, and any revised consent regime should focus on the intention to be the legal parent.

- **Special status of embryos created**

  Any consent system within fertility treatment or human embryo research is concerned with making decisions about any embryos created and their potential use. Unlike in other areas of medicine, decisions made through consent from patients and donors impact on future children and their families. This area is therefore different from any other area of medical treatment and often involves the express consent of multiple parties. Consent should continue to reflect the potential of the human embryo and the lifelong consequences of any decisions made.

4. Proposal

4.1. The Authority is asked to approve the following proposal in relation to consent and reform of the HFE Act.

4.2. The HFEA recommend a thorough overhaul of the consent regime. We strongly encourage that this should be carried out together with interested parties among professional bodies, patient groups and licensed centres within the fertility sector.

4.3. Any revised consent regime, should uphold the following principles (in no particular order):

- Reflect current best practice and guidance, for example, the GMC principles of consent
- The importance of free consent
- Dynamic consent
- Simplification
- Recognition of modern families
- The special status of the embryo

Annex C

Access to donor information – updated proposal

1. Introduction

1.1. The Authority agreed at the meeting on 17 July 2023 that further consideration of the recommendation in relation to access to donor information should be undertaken before the September Authority meeting.

1.2. Members recommended that the following option should be developed and proposed:

- Removal of anonymity with consideration of how this could be best implemented over time.

2. Background

2.1. Members noted that changing access to donor information would have a range of potential consequences which will raise complicated policy questions.

2.2. Members recommended that, given the increasingly widespread availability of DNA data, the complete removal of anonymity so that donors are identifiable to recipients would best 'future-proof' the Act. Further consideration would be needed on the point at which identification could take place; for example, from the time of selecting a donor so donor details are always identifiable, or after selecting a specific donor, or when treatment commences, or upon pregnancy, or birth.

2.3. It is not known what the public appetite would be for the complete removal of anonymity as this option did not form part of our recent consultation, nor what any unintended consequences of this option would be at this stage.

2.4. Members agreed that the immediate removal of anonymity would be a significant departure from current practice. It was also noted that not all donors are UK-based, and that those in the UK may have a different view to overseas donors. Members therefore agreed that a gradual approach to the removal of anonymity, over time, may be appropriate.

2.5. Members agreed that before any firm legislative change is before Parliament, further work must be done to obtain the views of the public, donors and donor-conceived individuals on this and consider any unintended consequences.

2.6. It was acknowledged that extra work would be needed as a result of this recommendation and any change in the law in this direction would require close working with our stakeholders and the provision of clear information for clinics and support for donors.

3. Principles of any new system

3.1. In the recent public consultation, it was recommended that any new system should uphold the following principles:

- That there remains a need for an official 'record of truth' and the HFEA should continue to collect data about children born from a donor.
- That consent is properly obtained, and donors and recipients are fully informed about the potential challenges to anonymity from DNA testing and matching services.
- That parents should not be legally required to disclose to their children that they are donor-conceived, but patients should continue to be encouraged by clinics to be open with their children about how they were conceived.

4. Further consideration

4.1. Previous changes in the law have come about after hearing the experiences of donor-conceived people and their voices, together with those of donors and potential donors and recipients of donation, must remain central to the development of new approaches. As the first cohort of donor-conceived 18-year-olds will be able to access their identifiable donor details in 2023, research would help to establish their experiences of identifiable donors.

4.2. The following should be considered in relation to the proposal to remove anonymity. It should be noted that none of these changes would impact on the current ability to have a 'known donor' which would be maintained under any new system:

- **The timing of the removal of anonymity**

  Any change to the law is likely to be some years ahead. The proposal could be that donor anonymity should be removed from that time – i.e., when the new law comes into effect, going forward. This would likely give time to work with stakeholders and others to prepare for a new system, albeit all subject to parliamentary approval. This assumes a change in anonymity in less than five years which could be set out in legislation through an implementation timescale. Alternatively, a future date could be recommended suggesting working towards removal of donor anonymity, say over 10 years. However, this may be too long a timescale given the access to information already available through DNA testing websites.

- **The timing of when donor information can be requested**

  The Authority should consider whether the removal of anonymity should be from the time of choosing a donor or from after a donor is used, for example, following a pregnancy of the birth of a child. The options will carry consequences which have not yet been fully explored. When considering the previous proposal of a dual-track approach, the recommendation was for identification from the time of birth. This would be in line with the current approach, that parents can apply to the HFEA for non-identifiable information from the time of birth of a child. However, Authority will want to consider if that is the system they support, or whether they want a fully identifiable system where recipients choose from donors at the time of selection, which already occurs in some other countries.

- **Access to the donor sibling registry for non-donor conceived offspring of donors**

  The Authority should consider if they want to recommend widening access in this way. Although this was not considered in the recent consultation, it was raised by several respondents in feedback. LRAG members were also supportive that further consideration should be given to information rights to donor's children regarding their half or full genetic siblings.

- **Continued respect of donor anonymity for pre-2005 donors and no retrospective *early* removal of anonymity for post-2005 donors**

The Authority should consider whether it maintains the position that there is continued respect for anonymity for those who donated pre-2005 and that there is no call for retrospective removal of anonymity before the age of 18 to post 2005 donors. To date, we have taken the view that the consent that donors provided at the time of donation should be respected.

5. Proposal

5.1. The Authority is asked to agree the following proposal in relation to access to donor information and reform of the HFE Act:

- The HFEA recommend removal of donor anonymity from the birth of any child born from donation. Before any change to the law is implemented there would need to be in-depth discussions with interested parties among professional bodies, patient and donor groups, donors and donor conceived individuals and licensed centres within the fertility sector.

5.2. Any revised system for releasing donor information, should uphold the following principles:

- That there remains a need for an official 'record of truth' and the law should continue to require the HFEA to collect data about children born from a donor
- That consent should be properly obtained, and donors and recipients are fully informed about the potential challenges to anonymity from DNA testing and matching services.
- That parents should not be legally required to disclose to their children that they are donor-conceived. But patients should continue to be encouraged by clinics to be open with their children about how they were conceived.

5.3. That the Authority's initial proposals on the removal of anonymity are as follows - subject to any further development - when future consideration of consequences has been undertaken:

- Removal of anonymity should take place following legislative change with an implementation date to be agreed
- Donor is known from time of birth if information is requested by parents but that a wholly 'open' system of donor selection is not recommended at this stage, while recognising that it does occur in other countries
- Access to the donor sibling registry for non-donor conceived offspring of donors is considered as part of any further work on consequences of the changes above and views of all parties are looked into
- Continued respect of donor anonymity for pre-2005 donors and no retrospective early removal of anonymity for post-2005 donors.

Annex D

Scientific developments – updated proposal

1. Introduction

1.1. The Authority agreed at the meeting on 17 July 2023 that further consideration of the recommendation(s) relating to scientific developments should be undertaken before the September Authority meeting.

1.2. The following were considered key issues:

- The regulation of certain scientific advances/new technologies in the Act means that the rules can be slow to adapt to the detriment of patients.
- Scientific advances are creating new 'categories' of cells such as in vitro-derived gametes, embryo-like entities, and stem-cell-based embryo models which are outside the regulatory categories of the Act. It should be noted that such models are not yet considered sufficient substitutes for human embryo research.
- The Act places limits on the use of human or admixed embryos in research which are now being challenged by scientific developments.
- Whether the Act should continue to not permit interventions in the nuclear DNA of gametes or embryos for use in reproduction.

1.3. Members agreed that:

- The HFEA needed the ability to regulate more flexibly given that we operate in a fast-moving area of science. Such advances occur frequently and would be very difficult for Parliament to respond to in a timely way. This could be better addressed by the HFEA having more discretion within an agreed governance framework, which might allow the licensing of certain activities for specified purposes under conditions set by the regulator. Such a regime might model the traditional clinical trials pathway and/or encompass the kind of 'regulatory 'sandbox' model being adopted in other sectors.
- Some scientific advances are likely to be controversial, for example any extension to the 14-day rule and might be reserved to Parliament itself, whether through primary or secondary legislation.
- Members noted that further work would be needed to resolve whether any of the new categories of cells (which are currently not regulated at all, and do not fall under the definition of a 'permitted' embryo under the HFE Act) would merit some form of statutory oversight, and if so, what form that should take. It was also noted that such research is likely to take place alongside human embryos.
- No changes should be made, at this time, to the restrictions surrounding heritable nuclear germline genome editing. However, further work may be required on this at some stage, and therefore any agreed principles made to the DHSC ought to be applicable to this technology too.

1.4. Members noted the importance of ensuring that the legislative framework continues to strike a balance between allowing scientific and clinical innovation alongside the consideration of ethical, social, and philosophical issues.

2. Principles of any new framework

2.1. The Authority is asked to consider overarching principles that any revised framework should reflect.

2.2. Any changes to the Act to adapt to scientific developments should reflect the following principles:

- **Public engagement and discussion before authorisation.** Consideration of significant scientific advances and any changes in the regulation of those advances should be preceded by broad and meaningful public debate and engagement, as appropriate to the issues raised.It should be recognised that the views of scientific researchers are not the only important ones, and that the examination of ethical issues should form part of any additional future work.
- **The ability to set bespoke regulatory rules.** Without a flexible regime, whether based on clinical trials and/or 'regulatory sandboxes', the potential future use of novel scientific developments for patient benefit (including, for example, disease modelling and drug testing) could be limited, even when the advances in the field establish that their use is ethical and safe. Any new system should therefore consider the benefits of licensing in a specific and conditional manner so that, for example, particular research establishments and/or clinics could be licensed to undertake novel procedures in a manner similarly to the way mitochondrial donation is currently licensed.
- **Continuous monitoring.** Evidence will accumulate through use and any new regulatory framework needs to be better able to monitor, respond and to set rules that adapt to that evidence. For example, where scientific advances establish safety concerns or absence of benefit with the use of a novel/pilot process, a future framework should consider the need to include a pathway for deauthorisation of its use.
- **Ongoing scrutiny of regulatory decisions.** It is essential that any changes to the regulation of scientific developments is open to public scrutiny. For example, if it was considered appropriate for the HFEA to permit developments and use of novel technologies, ongoing parliamentary scrutiny would be beneficial, so that the HFEA is not seen to be 'writing its own rules' on a range of matters. This could, for example, be through an amendment to the Act that requires regular updates by the HFEA to a relevant parliamentary select committee.
- **Balance of different interests.** Considering the balance of scientific and clinical innovation alongside the ethical, social, and philosophical issues in any new regime.

3. Proposal

3.1. Authority is asked to approve the following proposal in relation to scientific developments and reform of the HFE Act:

  – The HFEA recommend that the Act should be amended to 'future proof' it, so that it is better able to accommodate future scientific development/new technologies. Ongoing policy work should take place with relevant interested parties among professional bodies, scientific researchers, patient groups and licensed centres within the fertility sector to

agree a set regulatory changes to address the challenge posed by novel scientific developments.

3.2. Any revised regime, should uphold the following principles:

- The need for public engagement and discussion coupled with appropriate consideration of any ethical and social concerns
- Ability to set bespoke regulatory rules
- Continuous monitoring
- Ongoing scrutiny
- Balance of different interests

Draft Business Plan 2024-25

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy: The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society
Meeting:	Authority
Agenda item:	8
Meeting date:	13 September 2023
Author:	Shabbir Qureshi, Risk and Business Planning Manager
Annexes	-

Output from this paper

For information or decision?	For decision
Recommendation:	The Authority is asked to note and comment on the business plan priorities for 2024/25, for further development over the next two to three months.
Resource implications:	In budget
Implementation date:	1 April 2024 – 31 March 2025
Communication(s):	HFEA website
Organisational risk:	Low

1. Introduction

1.1. This paper forms part of our annual business planning process and outlines the proposed activities to be included in the next business plan. Comments from members are invited. It is important to be clear about our priorities so that we can plan our resource allocation appropriately as we develop the business plan itself. This will also be helpful to us if, in the next few months, we then need to review our prioritisation again in light of new information – for example from our Public Bodies Review or the upcoming changes to the EU Tissues and Cells Directive.

1.2. The business plan will be drafted in the coming months and submitted to the Department for approval in February-March 2024 (on request). Therefore, the Authority will receive a draft business plan at its January 2024 meeting.

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

2. Strategic priorities for 2024/25

2.1. Our ongoing statutory work accounts for almost all our resources, whether in the form of running costs or in terms of system improvements. We also have several current pieces of work that will continue into next year in some form.

2.2. The three workstreams on OTR will conclude in this year. However, the impact from the implementation of the new OTR system and the expected increase in applications will frame our resource allocation for the next business year. We will also need to plan for whatever follows the existing OTR support services project.

2.3. Our inspection and licensing database (Epicentre) needs to be replaced, owing to risks relating to the platform that hosts it, which is no longer supported. This work will be a major project in the next year.

2.4. Implementation of the recommendations from our Public Bodies Review may need to be addressed in 2024/25, and we will know more once the review has concluded this year.

2.5. Other priorities for 2024/25, in addition to our statutory duties, include the following, noting that this is not an exhaustive list, and we will not have the capacity to do all of these:

- Further work on our proposals for law reform, if agreed, following on from this year's work.
- Work following the Women's Health Strategy to improve primary care health information about fertility.
- Our planned work on regulatory transparency, which is likely to be a multi-year process with several pieces of work prioritised over time, based on capacity.
- A fees review.
- Increasing our focus on genetics and Artificial Intelligence (AI)
- Completion of the review of the list of conditions approved for PGT-M
- Development of our new strategy for 2025-2028, following initial conversations this business year.

2.6. Our normal range of statutory work will also be incorporated into the business plan, as usual, including:

- Inspection and licensing
- Information provision
- Maintaining the Register
- Information for researchers
- Horizon scanning and maintaining the Code of Practice
- Handling DHSC or wider government requests
- PRISM and Choose a Fertility Clinic
- Core IT system maintenance

2.7. The above priorities will be impacted by a variety of current 'unknowns' such as if the updates to the EUTCD results in any appreciable changes to legislation work for the HFEA. Similarly, if we have a large number of recommendations to address after our Public Bodies Review, this may also require work in the next business year. As and when more information is available, we will consult the Authority on any reprioritisation that is necessary.

3. Recommendation

3.1. Authority members are asked to note this report and comment on business plan priorities.

3.2. Further development work of the business plan will follow, and an update will be provided at the January 2024 Authority.