Human Fertilisation & Embryology Authority

Authority meeting

Date: 18 May 2022 – 1.30pm to 4.30pm

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

Agenda item	Time
1. Welcome, apologies and declarations of interest	1.30pm
2. Minutes of the meeting held on 23 March 2022 and matters arising For decision	1.35pm
3. Chair's and Chief Executive's Report – to note (circulated prior by email) For information	1.40pm
4. Committee Chairs' Reports For information	1.55pm
5. Performance Report For information	2.05pm
6. Covid-19 update For decision	2.30pm
Break	3.00pm
7. Gamete and embryo storage update For information	3.15pm
8. Modernising Fertility Regulation – update For decision	3.45pm
9. Any Other Business	4.15pm
10. Close	4.20pm

Minutes of Authority meeting 23 March 2022

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	18 May 2022		
Author	Debbie Okutubo, Governance Manager		
Output:			
For information or decision?	For decision		
Recommendation	Members are asked to confirm the minutes of the Authority meeting held on 23 March 2022 as a true record of the meeting		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes			

Minutes of the Authority meeting on 23 March 2022 held via teleconference

Members present	Julia Chain Margaret Gilmore Anne Lampe Catharine Seddon Jason Kasraie	Jonathan Herring Gudrun Moore Alison Marsden Tim Child
Apologies	Ermal Kirby Ruth Wilde	
Observers	Graham James Zeynep Gurtin Alison McTavish Frances Flinter Alex Kafetz Maria Nyberg (Department of Health and Social Care - DHSC) Amy Parsons (DHSC)	
Staff in attendance	Peter Thompson Richard Sydee Clare Ettinghausen Rachel Cutting Catherine Drennan Sonia Macleod	Paula Robinson Debbie Okutubo Shabbir Qureshi

Members

There were 9 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, observers and staff.

1.2. The Chair informed everyone present that the Secretary of State had announced the appointment of seven new Authority members and was pleased to welcome five of the seven members to the meeting as observers.

1.3. The Chair stated that the meeting would be audio recorded in line with previous meetings and the recording would be made available on our website to allow members of the public who wanted to listen to our deliberations to hear it afterwards.

1.4. Declarations of interest were made by:

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

2. Minutes of the last meeting

2.1. Members agreed that the minutes of the meeting held on 9 February 2022 were a true record of the meeting and could be signed by the Chair.

2.2. The status of all matters arising was noted.

3. Chair and Chief Executive's report

3.1. The Chair gave an overview of her engagement with key stakeholders and advisory committees of the Authority. She commented that we had recently advertised for new members of the Scientific and Clinical Advances Advisory Committee (SCAAC) and that interviews will take place with her in the chair, supported by Tim Child (SCAAC Chair) and Andy Greenfield (previous Authority member and current SCAAC external adviser).

3.2. Members were also advised that Authority meetings will now be held in person. Committee meetings will mainly be held online as this would enable members to participate fully in their respective committees to fit in with their other commitments.

3.3. On the work the Authority had set up to consider how the Act should be modernised, members were advised that the aim was for proposals to go to the Department of Health and Social Care (DHSC) by the end of the year. To inform the Authority's work an Advisory Panel had been set up with a range of stakeholders representing different interests in the sector.

3.4. Members were informed that all papers from the Advisory Panel will be shared on our website. Members welcomed the work that had started on this.

3.5. Members also welcomed the progression of the Government proposal to extend the storage limits for gametes and embryos, which was part of the Health and Care Bill due to go through the final parliamentary stages later in March.

3.6. The Chief Executive provided an update on the key activities that he was involved in since the last Authority meeting. He reflected on a meeting on the Women's Health Agenda: redressing the balance, and commented that meetings like these gave the HFEA the opportunity to look at fertility treatment in the context of women's health generally.

3.7. On the business plan for 2022/23, members had previously commented on equality and diversity and how we need to ensure that it was embedded in everything we do. Members were assured that work was underway and that there was now a wider government agenda committed to tackling health inequalities, some of which had been identified in HFEA reports. A member commented that she had heard of an apprenticeship scheme aimed at encouraging diversity on boards which was worth pursuing.

3.8. Members asked how the war in Ukraine was affecting UK patients who imported and or exported gametes from and to the country. The Chief Executive commented that some British patients do go to Ukraine particularly for surrogacy. Change in visa requirements now mean that surrogates from Ukraine are now eligible to come to the UK. Although there had been some importing of gametes and embryos from Ukraine, this was a very small percentage of overall use of donated gametes and embryos and would not impact on fertility treatment in the UK.

3.9. Members commented that in terms of cyber-attacks we need to be mindful that as a small organisation we could be targeted as a gateway to cause embarrassment to the government.

3.10. The Chief Executive responded that we now have heightened internet security and that we were contacted recently by NHS England and have met all their requirements. This does not mean that we are complacent, but we feel well placed as our cyber security currently stands. It was noted that cyber security penetration testing was also carried out on a regular basis.

3.11. The Chair commented that members have been asked to do the civil service learning module on information security and data protection online training and that it was mandatory.

Decision

3.12. 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 reports.

4.2. The Licence Committee Chair (Alison Marsden) gave an update on the meeting held in March 2022. She thanked Ermal Kirby and Ruth Wilde who had now stepped down from the committee as they were both finishing their terms of office as Authority members.

4.3. The Statutory Approvals Committee (SAC) Chair (Jonathan Herring) reported that in addition to items approved, there were some complex issues that were discussed in detail at the meeting. He thanked Margaret Gilmore for her dedication and professionalism whilst she was chair of the committee.

4.4. Margaret paid tribute to all the staff who administered the SAC meetings. She extended her thanks to member colleagues and in particular to Anne Lampe and Ruth Wilde for their invaluable contribution to making her tenure on the committee a successful one.

4.5. The AGC Chair (Catharine Seddon) gave an update on items discussed at the meeting and thanked Margaret for her time on the committee, for many years as the deputy chair. The AGC Chair also extended her gratitude to Ermal Kirby, Gudrun Moore and Anne Lampe who joined the National Audit Office session on cyber risk.

4.6. The Scientific and Clinical Advances Advisory Committee (SCAAC) Chair (Tim Child) informed members that the terms of office of some members on the committee was coming to an end which meant that there were four vacancies. Interviews were scheduled to be held in March 2022 with the positions being advertised widely.

4.7. The Authority Chair thanked everyone who had contributed thus far on all committees and to new members who would also be sitting on committees in due course.

Decision

4.8. Members noted Committee Chairs' updates.

5. Effective governance

5.1. The Governance Manager presented this item. It was noted that on an annual basis all committees reviewed their own effectiveness using a standard framework. The summary of positives and areas to note and for improvement was presented to the Authority.

5.2. Members were assured that areas for improvement highlighted would be put into an action plan and committee officers would work with the committee chairs to see how these can be implemented.

5.3. Members also noted that some aspects of the standing orders had been revised and as stated in the notice of motion circulated to members, a formal vote will be required to pass the amendments.

Appointments committee

5.4. Members were advised that the appointments process for external members was now formalised, with the full involvement of the Chair and Deputy Chair at interview and selection stages. This meant that two of the three members were already involved from the beginning of the recruitment process. As a consequence when Appointments Committee meetings were convened, they were only to ratify what had already been agreed by a majority of those who sit on the committee since it is made up of three members.

5.5. It was therefore recommended that the current Section 5 in Standing Orders (the terms of reference for an Appointments Committee) be deleted and the Chair formally signed off all external member appointments as part of her delegated powers from the Authority, following a formal recruitment process.

5.6. Members were advised that the main required change (other than the deletion of the terms of reference) was shown in 3.3.1(i) under particular responsibilities of the Chair of the Authority, but in addition several other paragraphs are also required to be edited, as follows:

- 3.3.1(i) The appointment of external members and advisers to committees or working groups, and the oversight of associated selection processes.
- 7.2.3 The Chair of the HFEA shall only appoint persons who are not Authority members to a committee or working group where it has been agreed during the recruitment and interview process that such persons are suitable for appointment.
- 7.3.3 (c) where appropriate, sign the minutes of any previous meetings with any agreed amendments that may be necessary; except in the case of the Remuneration Committee, whose minutes should be signed off by the Chair as soon as they have been agreed by members following the most recent meeting.

Statutory Approvals Committee (SAC)

5.7. The SAC currently operates from a pool of up to seven members with no more than five members attending each meeting. Members were advised that the proposed change was in section 3.4:

- The Statutory Approvals Committee shall operate from a pool of up to 10 members, with no more than five members attending each meeting.

5.8. In the section immediately below that to read ‘the membership shall include’:

- c) up to eight other Authority members.

5.9. A further minor change was proposed to the list of persons who would usually attend the meetings 3.11(c), to include the correct up to date job title of the Licensing Manager (formerly called the Senior Governance Manager).

5.10. A member commented that over the last seven years there had never been an instance where the committee was not quorate and for continuity reasons it was best if members remained as consistent as possible, as this was helpful on the rare occasions that items were adjourned.

5.11. The SAC Chair commented that this was a new way of working and would be subject to review.

Remuneration Committee

5.12. It was recommended that in the event that the Deputy Chair of the Authority and the Chair of the AGC are one and the same person, the Authority Chair should appoint another Authority member to take the third place on the committee.

5.13. This required the addition of a new section 4.5:

- In the event that the Deputy Chair of the Authority and the Chair of the Audit and Governance Committee are the same person, the Chair of the Authority shall appoint another Authority member to the third place on the Committee.

Scientific and Clinical Advances Advisory committee

5.14. Members were advised that to ensure a good skill mix it was proposed that expert advisers of SCAAC be appointed for a maximum of two terms, with a term lasting for one, two or three years.

Licence Committee

5.15. The current terms of reference of the Licence Committee, set out in Annex D of Standing Orders, prevented most staff from observing a Licence Committee meeting.

5.16. It was proposed that paragraph 5.3 of annex D be eased slightly to allow new inspectors and those with other relevant roles to observe a meeting of the committee as part of their induction into the organisation.

Equality and diversity

5.17. A member commented that in addition to the above that in Standing Orders where equality and diversity was mentioned that the word ‘inclusion’ should be added. This was agreed.

Board effectiveness

5.18. The Chair commented that in around a year’s time a full board effectiveness review should be considered as new members would have been in their roles for a few months by then and that it was good practice.

Decision

5.19. Members noted the feedback from the annual reviews of committee effectiveness and the action points for each committee.

5.20. Members unanimously approved the revised Standing Orders which would come into effect from 1 April 2022.

6. Performance report

6.1. The Chief Executive commented that a new 'Working from Home' policy had been launched and it offered permanent work from home contracts to all staff. Staff would also have the option of a new more flexible office-based contract.

6.2. Members were informed that it was an offer to staff subject to the agreement of the line manager and that both of these contracts were planned to be in place from the start of the new financial year.

6.3. Members asked if this would extend to the opening the register (OTR) team, because at the start of the pandemic when everyone was working from home, the team suspended operations for register security reasons.

6.4. The Chief Executive responded that the OTR service was suspended because clinics were closed. In deciding whether HFEA staff could work from home we needed to be satisfied that they have an appropriate place to work and that information can be stored securely. It is an offer of working from home, not a guarantee, but as long as staff met the security standards their request would in most cases be granted.

6.5. Members asked if there was a tipping point for staff working from home. The Director of Finance and Resources responded that desk to officer ratio was 1:3 and that from a policy perspective the new contract better enables us to recruit from outside of London and means we are in line with the government's wider agenda of levelling up. There were staff who would be more likely to opt to work from home due to the distance to the office.

6.6. The Chief Executive commented that in line with the new business plan we would review the key performance indicators to ensure we measured the things that were the most meaningful and useful in terms of understanding our performance.

6.7. On C1: Efficiency of the end-to-end inspection and licensing process, members commented that it had remained red for a very long time and that this should be one of the key performance indicators that are revisited. It was confirmed that this measure is under review.

Strategy and Corporate Affairs

6.8. The Director of Strategy and Corporate Affairs presented this item. She briefly outlined some of the major pieces of work happening in her directorate which included:

- The national fertility patient survey, the report on which would soon be published in April
- Analysis of fertility treatment numbers in 2020 to be published in May
- Many HFEA staff were working to ensure changes to the law on gamete and embryo storage would be implemented smoothly and particular thanks was given to Catherine Drennan, Rachel Cutting, Joanne Anton and other members of the compliance and policy teams.
- A working group of clinic staff had met to discuss aspects of the Ethnic Diversity in fertility treatment report. This was chaired by Jason Kasraie and had usefully discussed issues relating to donor use and recruitment and multiple births.

6.9. The Chair commented that as part of the work on equality, diversity and inclusion, some patients had raised the issue of requiring translation and it was noted that in some conversations with patients, translation was being given by a partner or another person and, on some occasions, there was uncertainty as to whether risks relating to treatment, such as those from multiple births, were being fully discussed.

Compliance and Information

6.10. The Director of Compliance and Information provided an update on the number of inspections. It was noted that by the end of March, 120 inspections would have taken place in the 2021/22 business year.

6.11. Members were reminded that during the Covid pandemic we stopped unannounced interim inspections to clinics but that the Inspectorate wanted to re-start interim inspections on this basis for those clinics having their SAQ released from April 2022

6.12. Members were informed that the OTR service had turned a positive corner with respect to the number of OTR applications being closed. In February 72 were closed and in March, 105 responses have been sent out so far with 57 ready for second checking.

6.13. The Director of Compliance and Information outlined the challenges of 2023 when the first donor conceived people reach 18 following the change in legislation whereby donors became identifiable from 2005 onwards. Members were advised that the demand for the service had increased over the last two years and that there had also been a rise in the complexity of applications. The Legal and Policy teams were building a framework to deal with these complexities and a project is underway to improve the service in terms of processing and efficiency.

6.14. In response to a question, it was noted that it takes some months to train up staff in the OTR team but we were now building resilience in the Register team to provide cover for the OTR team should the need arise.

6.15. Members asked about the counselling service for donors conceived individuals. The Director of Compliance and Information responded that the current contract with The Hewitt is being extended for a 4th year under terms of the contract. This will give more time to work on projecting future demand and undertaking a review of the service. An options paper would be brought to the Authority in the autumn.

6.16. The Chief Executive commented that counselling was part of the service we currently provide but we need to evaluate the service to determine what the future demands and associated costs may be.

6.17. Members commented that the current fees structure could disadvantage non-traditional families who relied on donors, for instance same sex families. The Chief Executive responded that we would have to reflect on the cost of regulation when conducting our forthcoming fee structure review. The board was clear that the information we send out needs to be accurate and being the information provider has an attached cost which we needed to recover.

6.18. The Chair commented that the issues around counselling would need to be revisited.

6.19. The Chair acknowledged the amount of work that was being done on storage of gametes, particularly work done by the Head of Legal and Director of Compliance and Information.

Finance and Resources

6.20. The Director of Finance and Resources informed members that as at the end of January we were migrating our data into PRISM, leading to some uncertainty about income while bills had to be estimated. Invoicing was estimated according to historic data with income projections based on previous activities of clinics.

6.21. It was also noted that a number of clinics might not have submitted their data by the end of this financial year, and therefore until we reconciled with the real data we would not know the actual costs and income which could mean that final figures vary significantly.

Decision

6.22. Members noted the performance report.

7. 2022/23 Budget proposal

7.1. The Director of Finance and Resources presented this item. Members were advised that at the November meeting the Authority agreed the proposal to increase the clinic fee for IVF cycles from £80 to £85 and that the increase will take effect from 1 April 2022. We now had HMT approval for that increase.

7.2. It was noted that the increased licence fee would allow the HFEA to increase its headcount to accommodate a growth in workload and invest further to support our use of data.

7.3. The expenditure budgets contained a number of assumptions around inflationary and demand pressures, as well as providing for some difficult to predict areas of spend.

7.4. A detailed breakdown of the income and expenditure budgets was discussed with the Authority.

7.5. It was noted that data relating to the 2020/21 and 2021/22 business years varied significantly from historic activity data in both volume and distribution. As such our budget for 2022/23 was based on activity from the 2019/20 business year. Members were advised that a 1% variance against this estimate would result in a change to our income forecast of £55,000.

7.6. Members asked about grant in aid. The Director of Finance and Resources responded that it had remained the same amount for a long period now which give inflation was a reduction in real terms. However, this payment was for work carried out on behalf of the government, which is not covered by the licence fee or treatment fees.

7.7. The Chair commented that recruiting IT capacity for PRISM and to other pertinent business areas was essential, since the extra resources were required.

Decision

7.8. Members:

- Noted the approval and announcement of the HFEA licence fee increase for 2022/23
- Approved the HFEA operating budget proposed by the Executive for 2022/23
- Noted the assumptions that underpinned the 2022/23 budget, and that further work would be undertaken with the AGC to review the HFEA's financial performance for 2021/22 at its meeting in June 2022.

8. Next steps in relation to HFEA response to Covid-19

8.1. The Director of Compliance and Information presented this item. Members were reminded that in March 2020 the Authority made the decision to suspend all licensed fertility treatment in the UK,

in response to the Covid-19 pandemic, professional body guidance and government restrictions. Treatment was halted from 15th April by means of General Direction 0014.

8.2. The framework governing the resumption of treatment was set out in the revised General Direction 0014 v2 which was issued on 11 May 2020 and remains in place. It was noted that it was introduced to ensure the safe resumption of treatment.

8.3. It was noted that the British Fertility Society (BFS)/Association of Reproductive and Clinical Scientists (ARCS) issued updated guidance on 28 February 2022.

8.4. Members were advised that it was good regulatory practice to remove unnecessary rules and if the pandemic developed a serious further wave in future that required new restrictions, we could always reintroduce the measure in the same form or an amended form to suit the new circumstances.

8.5. A discussion ensued and majority of members felt that it was too soon to revoke GD 0014v2 as there are some restrictions which still remain a legal requirement across some of the four nations.

Decision

8.6. It was agreed to retain GD 0014v2 until the next Authority meeting in May.

9. Strategic risk register 2020-2024

9.1. The Head of Planning and Governance presented this item. Members were advised that the planned risk policy review was overdue and that an internal audit of our operational risk system was currently underway, which would further inform the policy review. It was noted that at a future meeting there would be a discussion with the Authority about risk appetite.

9.2. Members noted that the new Choose a Fertility Clinic (CaFC) data would not be published until after November 2022, once the data had been validated.

9.3. The Authority noted the update on all risks, controls and scores and made the following points in discussion:

- C2: Leadership capability - members commented that the inherent and residual risk were quite high considering the calibre of the senior management team and the Authority Chair, and the recent appointments of new Authority members.
- CS1: cyber security – Members confirmed that this should be considered a high risk at present, considering current world events.
- I1: Information provision - members commented that they agreed with the rating but that the risk needed to be reviewed once the findings of the patient survey were known and that this should also feed into the new communication strategy.

9.4. The Chair commented that the risk register would be brought back to the board one more time this year.

Decision

9.5. Members noted the strategic risk register.

9.6. Members agreed that CV1: Coronavirus should be discontinued from June 2022 onwards and any residual elements should be integrated into C1: Capability.

10. Add-ons rating system and survey options

10.1. The Chair explained the treatment add-ons rating system and commented that we were currently working with SCAAC members and other relevant stakeholders on further improving the rating system. The Chair invited the Scientific Policy Manager to present this item.

10.2. Members were reminded that at the September 2021 Authority meeting it was agreed that more work would be done to make the presentation of the treatment add-ons rating as useful as possible for patients and ensure that patients remained the primary audience for any future system.

10.3. Members made a number of comments including:

- For people who were colour blind, some of the colours looked too similar
- For option 2 with the additional grey rating, members felt that the two meanings of no evidence, 'We cannot rate the effectiveness of this add-on as so few studies have been done' and 'This add-on has no impact on the chance of having a baby' should not be conflated. It would be clinically incorrect for an add-on to be used if there was no evidence for its efficacy, and so this should be red rated.
- The concept of financial harm was raised where some members felt patients were being encouraged to spend money on add-ons where there was no evidence that it would help them have a baby.

10.4. Members asked if grey could become amber in time when enough RCTs had been done.

10.5. Members commented on whether aromatherapy should be classified as an add-on.I It was noted that holistic therapies were not rated in the HFEA system and a previous Authority discussion had agreed that there should be information on the HFEA website on alternative and holistic therapies but not given a 'traffic light' rating.

10.6. Members commented that the different outcomes remained important but the main add-on ratings need to be based on live birth rates. Also, that where there was no evidence of benefit to live births, the add-on should be rated red under the current system.

10.7. Clarification was sought on what 'on balance' meant. Members were informed that it meant patients needed to interpret the rating with some caution, since there was not absolute certainty.

10.8. It was suggested that the National Institute for Health and Care Excellence (NICE) were using a system of having broad statements which were layered with information when clicked on and suggested that staff could look into this approach of laying out the information.

10.9. The Chair commented that we should not go out to consultation with any option that was not viewed as clinically correct. Staff should liaise with the professionals on the Authority to agree wording before it goes out to consultation.

Decision

10.10. Members agreed that the wording on options one and three would be reviewed by professionals on the Authority prior to consultation.

11. Any other business

11.1. The Chair commented that there were a number of members standing down and this meeting would serve as their last Authority meeting.

11.2. The Chair thanked Ermal Kirby in his absence for his contribution and support whilst on the Authority. It was noted that he first joined the Authority in 2009 and left in 2012 and then returned in 2019.

11.3. Ruth Wilde joined the Authority in 2016. In her absence, Ruth had sent in a message that the Chair read to the meeting. Ruth was thanked for her commitment and dedication as a member of the Authority.

11.4. Anne Lampe first worked with the HFEA as a peer reviewer before becoming a member in 2016. The Chair thanked Anne and commented that she hoped that Anne would be willing to offer training in clinical genetics to new members.

11.5. Margaret Gilmore was thanked for her contribution and dedication during her tenure on the Board. She became a member in 2015, and had served as the Chair of SAC, the Deputy Chair of the Authority and from 2018 the Deputy Chair of the AGC.

11.6. Anne and Margaret thanked everyone who had contributed to their time at the HFEA including the HFEA Chair, Chief Executive, Senior Management Team, staff and other Authority members.

11.7. Margaret thanked all member colleagues.

Chair's signature

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

Signature

Chair: Julia Chain

Date: 18 May 2022

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:	18 May 2022
Author:	Julia Chain, Chair and Peter Thompson, Chief Executive
Annexes	N/a

Output from this paper

For information or decision?	For information
Recommendation:	The Authority is asked to note the activities undertaken since the last meeting.
Resource implications:	N/a
Implementation date:	N/a
Communication(s):	N/a
Organisational risk:	N/a

1. Introduction

1.1. The paper sets out the range of meetings and activities undertaken since the last Authority meeting in March 2022.

1.2. Although the paper is primarily intended to be a public record, members are of course welcome to ask questions.

2. Activities

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

- 28 March – interviews (with Tim Child and Andy Greenfield) for new members to join SCAAC
- 29 March – chaired first meeting of the Legislative Reform Advisory Group
- 29 March – Peter and I met representatives of Fertilis
- 30 March – meeting for the Public Chairs Forum on Diversity in public appointments
- 6 May – chaired second meeting of the Legislative Reform Advisory Group
- April and May - conducted appraisal meetings with members of the board.

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

- 24 March – participation in UK/ Chinese dialogue on assisted reproduction technologies
- 29 March – Legislative Reform Advisory Group
- 29 March – Julia and I met representatives of Fertilis
- 19 April – interview to ITV on the launch of our National Patient Survey
- 26 April – interview to BBC Radio 4's Money Box
- 27 April – meeting with Advertising Standards Authority
- 6 May – Legislative Reform Advisory Group

Changes to Standing Orders

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
Agenda item:	3a
Meeting date:	18 May 2022
Author:	Debbie Okutubo, Governance Manager
Annex:	None

Output from this paper

For information or decision:	For decision
Recommendation:	• Agree the proposed changes to Standing Orders, effective immediately (vote required).
Resource implications:	In budget
Implementation date:	19 May 2022
Communication(s):	The Standing Orders are published on our website and on the staff Hub. They are also included in the standard licensing pack, which will be updated.
Organisational risk:	Low

1. Introduction

1.1. This report is to update Standing Orders relating to the Scientific and Clinical Advances Advisory committee to allow for more Authority members to sit on the committee as members.

2. Review of Standing Orders for the Scientific and Clinical Advances Advisory committee (SCAAC)

2.1. The Chair of the Authority appoints members to SCAAC.

2.2. In accordance with current standing orders, SCAAC consists of up to five Authority members: the Committee Chair, Deputy Chair and up to three other Authority members, of which three are required for a meeting to be quorate, with the quorum including either the Committee Chair or the Deputy Committee Chair.

2.3. The change proposed is that the committee should expand to include an additional Authority member, which will bring the number of Authority members on the committee to six. This will be reflected in paragraph 5.3 (c) in Standing Orders

(5.3) c) up to four other Authority members.

2.4. The Authority is asked to review and approve the proposed change to Standing Orders, as set out above and if approved, the new Standing Orders would come into effect on 19 May 2022.

2.5. Since this is a minor change, the Standing Orders are not appended to this paper, but can be viewed on our website at https://www.hfea.gov.uk/media/3362/1-april-2021-standing-orders.pdf

3. Recommendation

3.1. The Authority is asked to:

- Approve by a majority vote, revised Standing Orders paragraph 5.3 (see section 1.3 in Standing Orders), to come into effect from 19 May 2022.

Committee Chairs' reports

Details about this paper

Area(s) of strategy this paper relates to:	The best care/The right information/Shaping the future
Meeting:	Authority
Item number:	4
Meeting date:	18 May 2022
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:		
5 May 2022	1 Initial Research Licence (resumed) 1 Renewal Treatment Licence 1 Special Direction (continuation of licence)	The minutes from this meeting have not yet been finalised.
Other comments:	Legal training for most new members was held on 27 April and 10 May.	
Executive Licensing Panel:		
22 March 2022	3 Interims 1 Variation of activities 1 Extension of Licence 4 Change of Person Responsible 2 Change of Licence Holder	All granted/approved
5 April 2022	1 Initial 1 Renewal 1 Interim 1 Extension of Licence 1 Change of Person Responsible	All granted/approved
19 April 2022	1 Renewal 3 Interims	All granted/approved
3 May 2022	2 Renewals 1 Executive Update	All approved/granted
Other comments:	The volume of items continues to be high at most meetings.	
Licensing Officer decisions:		
	ITE Certificates - 25 Change of Centre Name - 3 Change of Licence Holder –1 Voluntary Revocations – 3 Amendment to Centre Address - 1	All granted/approved
Other comments:	None.	

Meetings held	Items considered	Outcomes
Statutory Approvals Committee:		
24 February 2022	1 Mitochondrial Donation application 5 PGT-M applications 2 Special Direction applications	All granted/approved
31 March 2022	3 PGT-M applications 4 Special Direction applications	All granted/approved
28 April 2022	2 Mitochondrial Donation applications 2 PGT-M applications 2 Special Direction applications	The minutes from this meeting have not yet been finalised.
Other comments:	Legal training for new members was held on 26 April.	

Audit and Governance Committee:	
The next AGC meeting will be held on 28 June 2022.	
Other comments:	None.

Scientific and Clinical Advances Advisory Committee:
The next SCAAC meeting will be held on 6 June 2022.

3. Recommendation

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

Performance report

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	5
Meeting date:	18 May 2022
Author:	Shabbir Qureshi, Risk and Business Planning Manager
Annexes	Annex 1: Performance scorecard Annex 2: Financial management information Annex 3: High level KPIs

Output from this paper

For information or decision?	For information
Recommendation:	The Authority is asked to note and comment on the latest performance report.
Resource implications:	In budget
Implementation date:	Ongoing
Communication(s):	The Senior Management Team (SMT) reviews performance in advance of each Authority meeting, and their comments are incorporated into this Authority paper. The Authority receives this summary paper at each meeting, enhanced by additional reporting from Directors. Authority's views are discussed in the subsequent SMT meeting. The Department of Health and Social Care reviews our performance at each DHSC quarterly accountability meeting (based on the SMT paper).
Organisational risk:	Medium

1. Latest review

1.1. The attached report is for performance up to and including March 2022.

1.2. Performance was reviewed by SMT in April 2022.

1.3. The financial information is from February data as March data was not available in time due to year end.

2. Key trends

2.1. Performance was generally good in March.

Red indicators in March (4)

- HR1: Sickness
- HR2: Turnover
- C1: Efficiency of the end-to-end inspection and licensing process
- C3 PGT-M average processing

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

3. Follow up from previous Authority performance discussion

3.1. Guidance on public sector pay rises for 2022 has been released and we are working with the department for implementation.

4. IT and Register performance reporting

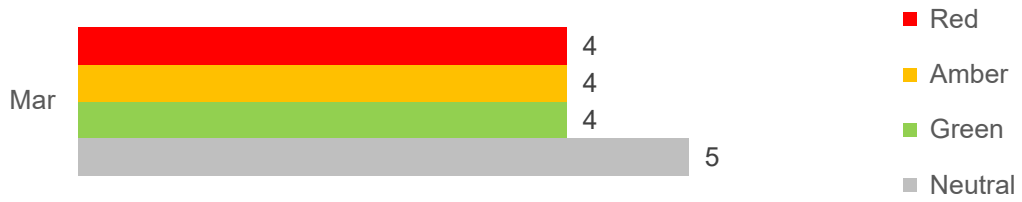
4.1. All clinics that used the old EDI system are now submitting data via PRISM. As of 11 May, 5 clinics are still due to be deployed. The target is for all clinics to have caught up by 1 July.

4.2. Performance is good. The current error rate is 0.8% for direct clinics and 6.6% for API, however, one API clinics is at 0.5%.

4.3. We are continuing to actively engage with clinics to support them in the transfer to PRISM.

Annex 1 HFEA Performance scorecard and management commentary – March data

Breakdown of total Red, Amber, Green and Neutral Indicators



RAG	Area	Trend and key data
Red – not at target	**People –** Employee sickness Target: between 2.5%	4.28% 4 employees with 2 on long term sickness; one COVID related
Red – not at target	**People -** Employee turnover Target: between 5%-15%	20.1% Turnover 1 leaver just before end of short term contract
Red – not at target	**Regulatory efficiency -** Time for end-to-end inspection and licensing process Target: 100% in 70 working days or less	67% within target. Average of 75 wds (items beginning with an inspection)
Red – not at target	**PGT-M –** average processing time Target: 75 working days or less	20% within target 86 average days taken
No target	**Engagement -** HFEA website sessions	82,033 sessions (86,920 in same month last year)

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

Type	Actual in YTD £'000s	Budget YTD £'000s	Variance Actual vs Budget £'000s	Forecast for 2021/2022 £'000s	Budget for 2021/22 £'000s	Variance Budget vs Forecast £'000s
Income	6,949	6,288	(661)	7,431	7,049	382
Expenditure	(5,852)	(6,384)	532	(7,049)	(7,044)	(5)
Total Surplus/(Deficit)	1,097	(96)	1,193	382	5	377

Commentary on financial performance to 28 February 2022

Year to date we have a surplus against budget of £1,193k. The continued increase in income coupled with the various underspends across the business has contributed to this.
Our forecast position at 31 March 2022 is currently showing a surplus against budget of £377k which includes surpluses against our non-cash items. We are forecasting a gross surplus overall of £382k, removing non-cash items reduces this to £110k. We are also reviewing the period over which PRISM should be amortised which may see increase in the surplus of non-cash income versus costs.

Management commentary

During March, staff turnover has remained high. We had one leaver in March and no new starters. Sickness has remained red for the past two months, with 2 staff members on long term sick.

The end-to-end inspection and licensing process has remained in red in March and throughout the previous quarter with several inspections above the 70 working day target. A review of this KPI has been completed and we are dividing the existing 70-day KPI between the compliance and licencing teams to better identify where the shortfalls in performance are occurring. We expect to have this data available from April performance.

With the OTR backlog, we have additional resource in place and with these changes, double the number of OTRs were completed compared to February.

We are in the process of updating the KPIs used within the Comms team, with updated reports for our social media channels. These will be in place for April performance data.

Red indicators in January:

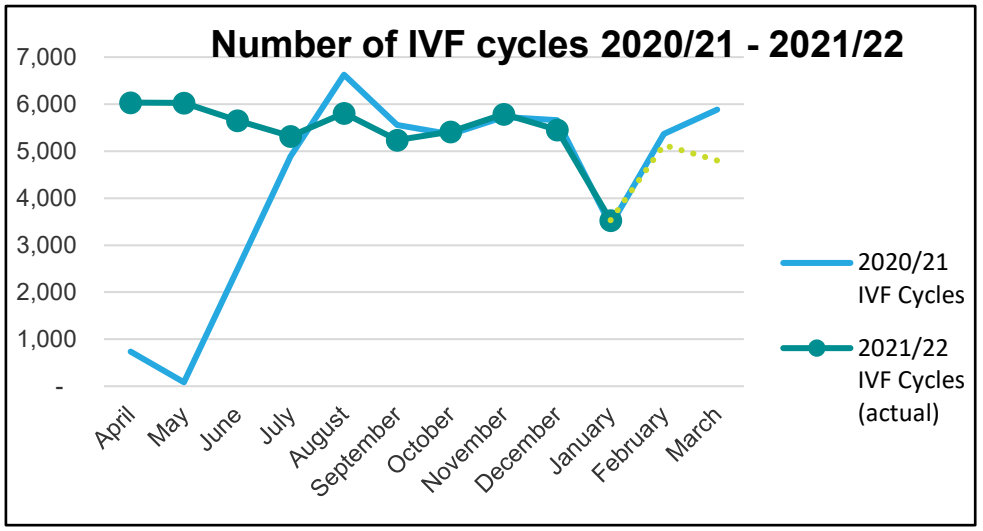
HR:

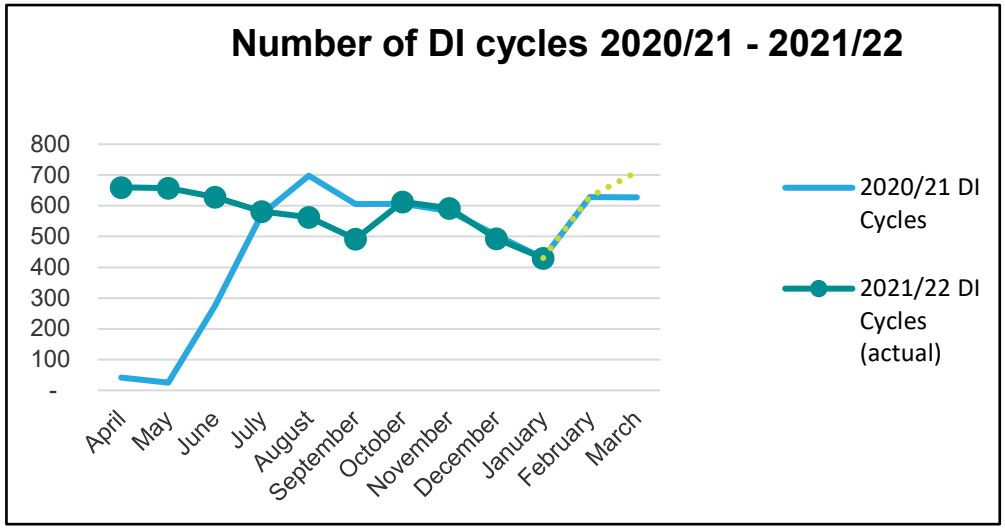
- **HR1 Sickness:** sickness absence has remained high for the last two months due to long terms absence from 2 staff, one of which is COVID related.
- **HR2 Turnover:** turnover is slightly higher this month, we have one leaver and no new starters.

Compliance & licensing:

- **C1 Efficiency of the end-to-end inspection and licensing process:** as stated above, from next month, this KPI will be reported differently to identify and address the pinch points in the process from next month. For the three inspections that were over the KPI (70 working days), one was delayed due to inspector workload and re-prioritisation; another due to inspector sickness and the last one due to additional DBA following change of premises and amendments made to LC minutes.
- **C3 PGT-M average processing time:** 4 out of 5 applications were above the 75 working day target. Due to high numbers of applications and pressure on SAC agendas. The average was 86 days.

Annex 2 Financial management information





IVF Cycles	YTD		YE Position	
	Volume	£	Volume	£
2020/21 IVF Cycles	45,913	3,673,040	51,795	4,143,600
2021/22 IVF Cycles (actual)	59,384	4,750,693	64,184	5,134,693
Variance	13,471	1,077,653	12,389	991,093

DI Cycles	YTD		YE / Forecast	
	Volume	£	Volume	£
2020/21 DI Cycles	4,971	186,413	5,598	209,925
2021/22 DI Cycles	6,341	237,788	7,051	264,413
Variance	1,370	51,375	1,453	54,488

YTD IVF volumes are up 29% on the same period in 2020/21 and 3% over budget. For the month of February, we have seen a 4.4% drop compared to 2020/21.

Similarly, DI volumes are 7% higher than budget and 28% higher than the same period last year. This is a small increase (0.2%) for the month of February compared to same in 2020/21.

We continue to raise estimated invoices whilst clinics strive to submit a backlog of treatment forms. The deadline was March 2022 (with clinics catching up by July 2022), which will enable reconciliations to be conducted and any under recoveries to be collected via additional invoices.

HFEA Income & Expenditure

Feb-22

	Year to Date				Full Year		
	Actual £'000	Budget £'000	Variance £'000	Variance YTD %	Forecast £'000	Budget £'000	Variance £'000
Income							
Grant-in-aid	1,256	825	(431)	(1)	1,256	1,098	158
Non-cash (Ring-fenced RDEL)	473	473	-	-	516	516	-
Grant-in-aid - PCSPS contribution	92	92	-	-	100	100	-
Licence Fees	5,036	4,787	(249)	-5%	5,448	5,188	260
Interest received	1	2	2	1	1	2	(1)
Seconded and other income	92	109	17	15	110	145	(35)
Total Income	6,949	6,288	(661)	**(11)**	**7,431**	**7,049**	**382**
Revenue Costs							
Salaries (excluding Authority)	4,223	4,090	(133)	(3)	4,747	4,447	(300)
Staff Travel & Subsistence	46	54	8	14	64	73	9
Other Staff Costs	80	88	8	9	99	111	12
Authority & Other Committees costs	195	213	18	8	244	234	(11)
Facilities Costs incl non-cash	438	858	419	49	666	954	288
IT Costs	410	586	176	30	536	642	106
Legal / Professional Fees	238	296	59	20	344	339	(5)
Other Costs	143	199	56	28	246	244	(2)
Other Project Costs	79	-	(79)	-	102	-	(102)
Total Revenue Costs	**5,852**	**6,384**	**531**	**8**	**7,049**	**7,044**	**(5)**
TOTAL Surplus / (Deficit)	**1,097**	**(96)**	**1,193**		**382**	**5**	**377**
Adjusted for non-cash income/costs	**835**	**(111)**	**945**		**109**	**4**	**106**

Management commentary

Income.
As at end of February our total income is over budget by 10.% (£661k).The billing of clinics based upon 2019/20,2020/21 is having an impact. Until a full reconciliation is conducted in April, we will not know whether we are under or over-stating our income. Included within this is our grant in aid which we have fully drawn down but currently shows a variance of £431k against budget. This will be rectified at year end.

Expenditure by exception (over £10k variance).
Year to date we are under budget by £532k.
Salary costs - excluding contract staff are under budget by £206k, an decrease of £4k from January. This is offset by the overspend in contract staff of £311k. Contract staff costs are mainly related to PRISM.

Authority & Other Committee costs - £18k under budget which relates mainly to underspends within Members and Non-Committee Travel and Subsistence (£23k and £6k),Members Training (£23k). These are offset by overspend within Venue costs (£23k), Advisor Fees (9k), Non-\Member Training (£4k) and overspends within Appeals costs (£2k).

Facilities costs - underspent by £419K, (an increase of £70k from January. We are underspending on accommodation costs by £158k which include accruals from 2020/21 for 2 Redman place. In addition we have an underspend (£249k) within our non-cash costs, the majority of which relates an asset that has come to the end of its useful life. The balance is made up of small underspends within Office Administration costs.

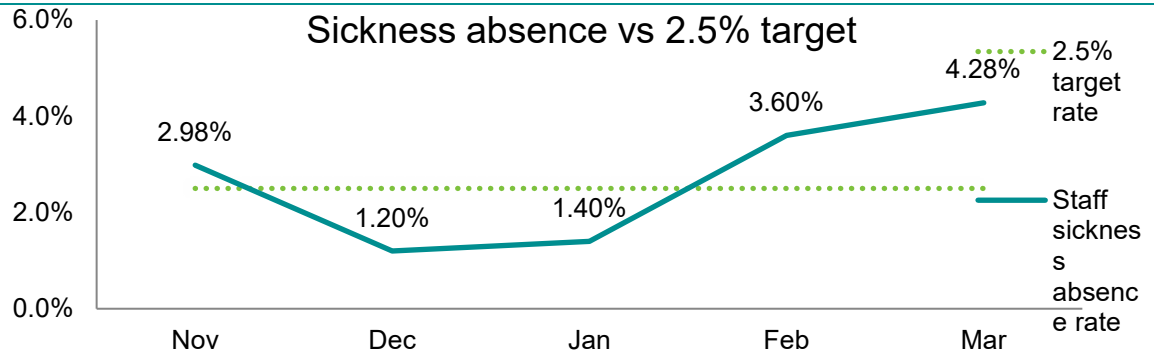
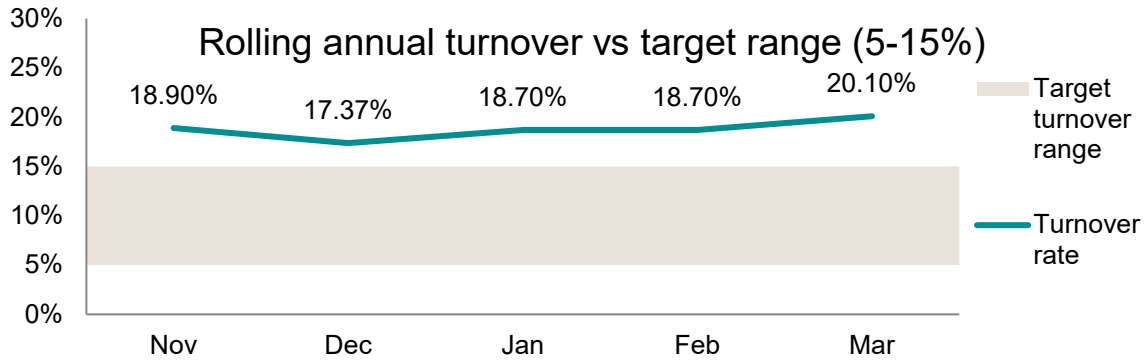
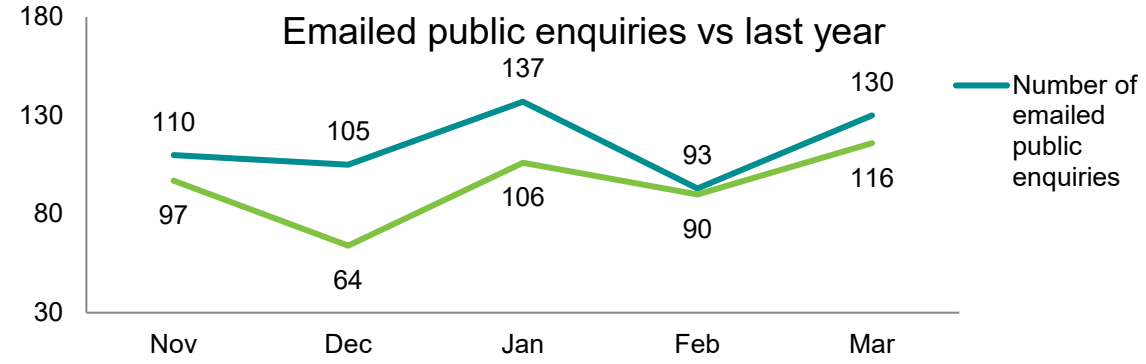
IT Costs - underspent by £176k. The main underspends are within our Support costs £103k, IT Subscriptions of £66k and Low value fixed assets of £10k. The reduction in both support and subscription costs is due to reduced usage of Alscient (Support contract) and within the contract renegotiated for Microsoft Office subscriptions. Offsetting the above are small under and overspends within Photocopying, IT Low value software, Internet and Consumables.

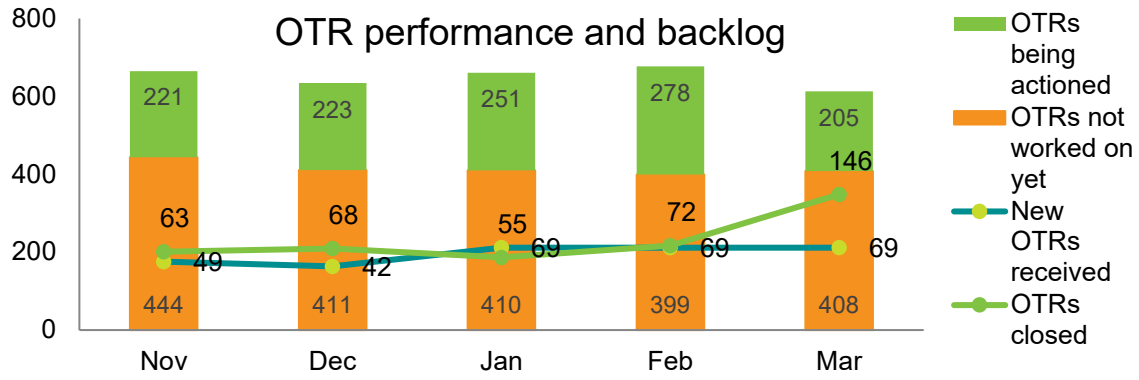
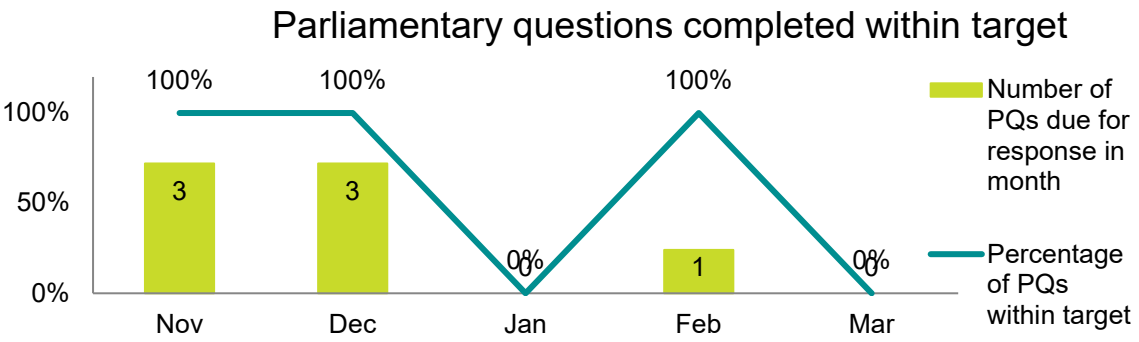
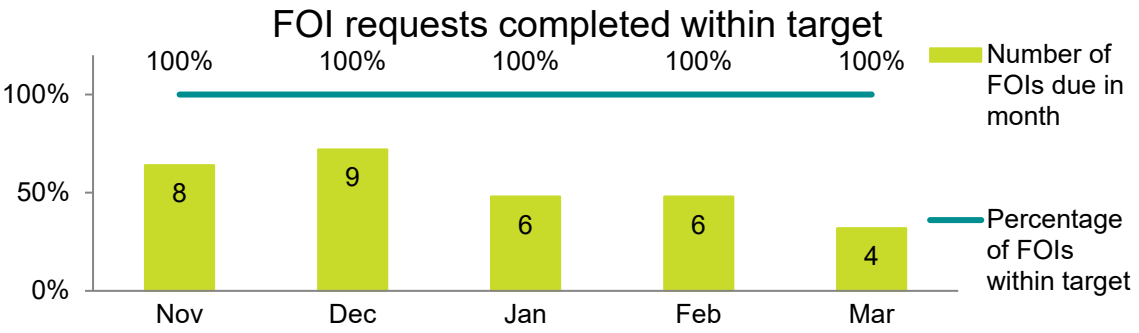
Legal/Professional fee - are under budget by £59k. This is represented by an underspend within the legal budget of £62k which includes a contingency of £30k. Offsetting the above are under spends within our Internal (£2k) and overspend against budget within our External Audit fees of £5k.

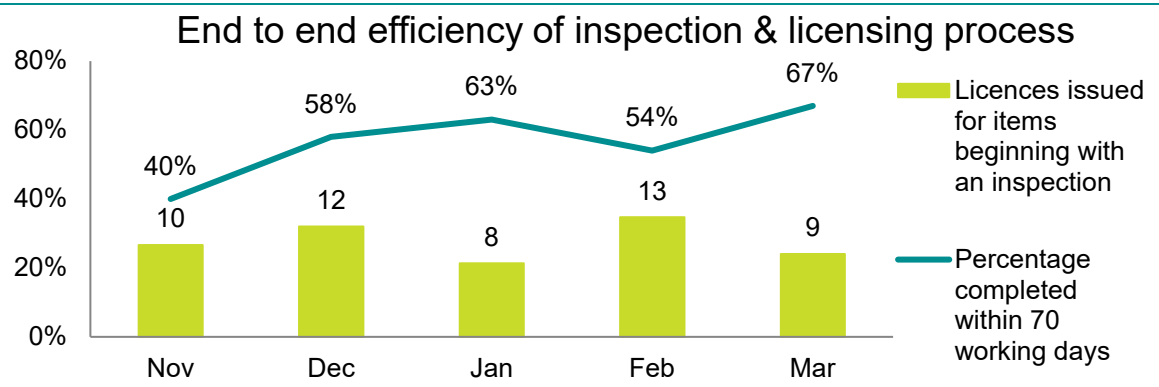
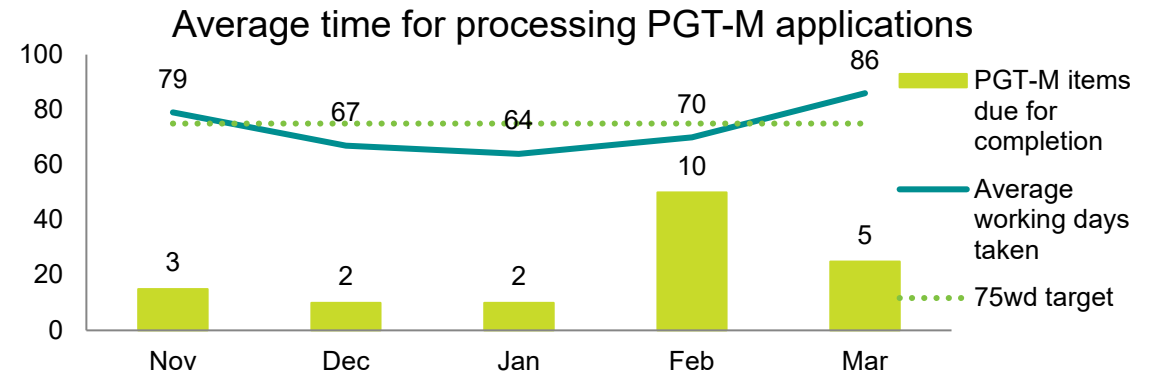
Other costs/Project Costs - are underspent by £56k and overspent of £79k respectively. The most significant variances are within Compliance Other (£12k), Stakeholder Events (£37k), Discretionary training (£6k). There are smaller underspends sub £5k across areas the Compliance and Information directorate totalling £13k. We are overspending against Donor Information costs of £9k. These costs relate to the Donor Conceived Register and includes costs relating to prior year. The overspend of £79k relates to the EU Transition work which is funded by grant in aid of £140k which has been drawn down.

Forecast.
We are forecasting a surplus of £382k at year end. This includes a surplus within our non-cash costs of £272k which reduces our surplus to £110k. This also incudes a surplus against the EU Transition project of £39k and assumes there are no unexpected costs incurred during March.

Annex 3 – Key performance indicators – Authority summary

Key performance indicator name and description	Graph showing performance trend for last 5 months	Commentary (if any)	RAG rating
HR1 – Sickness **Target**: less than or equal to 2.5%. Target is based upon ONS 2018 data (2.7% for the public sector)		Sickness has been high for the last 2 months. 2 staff on long term sick with one COVID related	Red
HR2 – Turnover **Target**: between 5 and 15% turnover for the rolling year.		70 – Headcount 68 – Establishment (posts) Turnover remains high with 1 leaver and no joiners.	Red
Supplementary data - Public enquiries No target.		19 complaints, 15 complex and 84 straight forward enquiries. 5 enquiries were specific to egg freezing/ fertility preservation	No target

Key performance indicator name and description	Graph showing performance trend for last 5 months	Commentary (if any)	RAG rating
R1 – Percentage of Opening the Register requests completed within 30 working day target. (excludes counselling time) **Target:** changed from 100% in 20wd to 95% in 30wd from April 2020. **Note: target not currently active.**		A steady number of OTRs received in the last 3 months. Over double the number of OTRs sent out in March in comparison to February.	Neutral
RI1 – PQs responded to within deadline set (Based on deadlines agreed with DHSC) **Target:** 100% within deadlines set.		None.	Neutral
RI2 - FOIs responded to within deadline **Target:** 100% within statutory deadlines.		There were also 11 enquires received in March. 4/11 were about egg/embryo freezing, which seems to be of increasing interest since COVID-19.	Green

Key performance indicator name and description	Graph showing performance trend for last 5 months	Commentary (if any)	RAG rating
C1 - Efficiency of end-to-end inspection and licensing process. **Target:** 100% within 70 working days (wds). % processed in 70 working days, for items where minutes were sent in month. Measured from inspection date to date minutes sent.		Average working days taken – 75. Most days taken: 164 working days Least days taken: 35 working days.	Red
C3 – Average PGD processing **Target:** average processing time of 75 working days. Average number of working days taken for those due in month. Note: Target changed from 66 to 75 in April 2020.		Average working days taken – 86 Most working days taken: 95 Least working days taken: 68	Red

Covid-19 update

Details about this paper

Area(s) of strategy this paper relates to:	The best care/The right information
Meeting:	Authority
Agenda item:	6
Meeting date:	18 May 2022
Author:	Clare Ettinghausen, Director of Strategy and Corporate Affairs Rachel Cutting, Director of Compliance and Information
Annexes	

Output from this paper

For information or decision?	For decision
Recommendation:	That the Authority notes the actions taken by the HFEA in relation to Covid-19 and makes decisions in relation to: • GD 0014v2 • Patient and professional information • Covid-19 and impact on treatment • Preparation for the Covid-19 Public Inquiry
Resource implications:	Dependent on decision
Implementation date:	May 2022
Communication(s):	Dependent on decisions
Organisational risk:	Low

1. Introduction

1.1. The Covid-19 pandemic has been front and centre in our work over the past two years. The Authority took the unprecedented step of requiring all HFEA licensed centres to close in April 2020 (via General Direction 0014v1) and then putting in place rules that allowed centres to apply to reopen in May (via GD0014v2) – the fastest resumption of any elective service. Since the pandemic began, the Authority have been updated through an agenda item at each meeting. Updates included actions taken by the HFEA, changes to professional and other guidance, patient, clinic and other enquiries and concerns, the regular monitoring of treatment numbers across the UK, reviews of inspection suspensions and commencements, and a range of other issues.

1.2. This paper covers a range of actions that have been carried out including: section 2 on how Covid-19 impacted on treatment numbers in 2020; section 3 patient and professional information; section 4 on General Direction 0014v2; section 5 on the Covid-19 Public Inquiry; and section 6 on next steps.

1.3. The Authority are then asked to consider a number of decisions in section 7 of the paper.

2. Covid-19 and impact on treatment

2.1. To help our understanding of the impact of Covid-19 on fertility treatment, we published a report in May 2022 looking at this in detail.

2.2. The main points found in data show:

- Private fertility clinics reopened faster than NHS clinics, with 83% of private and 34% of NHS clinics approved to resume service by 15 May, although it should be noted that many private clinics also treat NHS patients. By November 2020, nearly all private and NHS clinics had approvals to reopen.
- NHS-funded IVF treatments decreased across the UK from 35% in 2019 to 28% in 2020.
- Privately funded IVF cycles exceeded 2019 levels in July 2020, whereas NHS-funded IVF cycles had yet to reach 2019 levels by June 2021.
- IVF treatments using fresh embryos decreased by 28% from 2019 to 2020, compared to an 11% decrease in frozen embryo transfer IVF.
- Embryo storage increased by 6% from 2019 to 2020 and was the only activity to increase from 2019 to 2020. This may reflect the recommendation to take a more cautious approach to OHSS to lessen the risk of patients requiring emergency care.
- IVF cycles decreased by 25% among patients aged 18-34 from 2019 to 2020, compared to a 15% decrease among patients aged 40-50. This shows that clinics followed professional body guidance on prioritising particular patient groups.
- Patients in heterosexual relationships had a 22% decrease in IVF cycles from 2019 to 2020 compared to a 6% decrease among patients in female same-sex relationships.
- Registrations for new egg donors decreased by 23% from 2019 to 2020, compared to an 14% decrease in new sperm donor registrations.
- The decreases in IVF cycles varied across the four nations, with a 39% decrease in IVF cycles in Wales from 2019 to 2020 compared to a 19% decrease in England.

- In our recent national patient survey, 10% of patients having treatment from 2020-2021 said that Covid-19 caused a delay in speaking with a GP, and 28% said that Covid-19 caused a delay to starting treatment.
- Black, Asian, Mixed or Other ethnicity patients were more likely to have reported a delay in speaking with a GP due to COVID-19 (20%) compared to White patients (9%).
- Survey respondents were twice as likely to report a delay to starting treatment due to COVID-19 if they were NHS-funded (41%) compared to privately funded (21%).
- Patients mentioned concerns over restrictions in partner attendance to clinic appointments due to COVID-19, NHS waiting lists and the use of online/phone appointments in open-text responses to our survey.

3. Patient and Professional information

3.1. From March 2020 until April 2022 key information for **patients** and **clinic staff** was prioritised on our website. This involved regularly updating Frequently Asked Questions and liaising with professional and patient groups, as well as national and devolved governments to provide accurate and up-to-date information.

3.2. As of April 2022, these pages are no longer being updated but the information has been retained on our website and clinic portal.

3.3. The Scientific and Clinic Advances Advisory Committee continues to monitor any impact of Covid-19 on fertility, assisted conception and early pregnancy and we have published information on the latest scientific literature in this area on the **clinic portal**.

4. General Direction 0014v2

4.1. At the **March Authority meeting** members considered whether it was the right time to revoke GD0014v2. The General Direction was issued as a necessary measure to ensure treatment resumed safely after 11 May 2020 when centres were able to apply to reopen. It was decided in March, in view of some restrictions remaining at this time, the decision should be deferred until the May Authority meeting.

4.2. GD0014v2 sets out the conditions a centre is required to have in place before treatment resumed. Apart from paragraph 6(d), it does not impose any ongoing obligations on clinics. Paragraph 6(d) requires clinics to record “all new or revised standard operating procedures or protocols whilst maintaining compliance with the Government’s current requirements relating to freedom of movement and social distancing”. The aim of this paragraph was to ensure that centres were able to continue to deliver services safely as Government requirements changed.

4.3. Government legal restrictions have now eased across the UK, only some guidance remains, for example, Scottish government recommends wearing a mask in indoor public spaces and on public transport, and face masks are required in healthcare settings in Wales, England and Northern Ireland.

4.4. Whilst GD 0014vs2 could stay active indefinitely, if restrictions are no longer in place, then it follows good regulatory practice to remove unnecessary rules. The flexibility remains that if in the future a further significant wave occurs and restrictions are reintroduced, GD0014v2 could again be reviewed and brought into force.

5. Covid-19 Public Inquiry

5.1. The Government have set up a **public inquiry** into Covid-19 to 'examine the UK's preparedness and response to the Covid-19 pandemic, and to learn lessons for the future'. A similar inquiry has also been set up in **Scotland.**

5.2. In common with all other health Arm's Length Bodies (ALBs) the HFEA has been asked to take various actions in preparation for a public inquiry, including retention of all records and review of documentation and timelines in relations to any actions taken in response to the pandemic.

5.3. The HFEA has complied with these formal requests as well as taking an active part in cross-ALB groups established by the DHSC to consider any cross cutting practical matters in advance of the inquiry. (NB these groups do not consider any issues of policy or other substantive matters that may arise in the inquiry).

5.4. The inquiry draft terms of reference are broad, and it will take several years to complete. We do not know what, if any, information the HFEA will be required to submit, but we are confident that we have the relevant records available, should we be asked to provide evidence in due course.

6. Next steps

6.1. The HFEA workforce adapted swiftly to the changing conditions of the pandemic, from moving to home-based working, inspections changing to a hybrid in person/virtual model, and priorities re-assessed to ensure Covid-related work came first. Our workforce has been impacted by the effects of Covid-19 in their personal lives including suffering from Long Covid and close bereavements.

6.2. As the UK moves into a 'living with Covid' mode, it seems appropriate for the HFEA to take action to step down our activity in relation to Covid-19 including updating our website information. We have now analysed the data from 2020 and will further consider this with our professional and patient stakeholder groups and the impact on both patients and staff of the pandemic.

7. Decision

7.1. The Authority is asked to make a decision whether to:

- Retain GD 0014v2 indefinitely; or
- Revoke GD 0014v2 now most all legal restrictions have been lifted.

7.2. The Authority is asked to note the Covid-19 and fertility treatment report published in May 2022

7.3. The Authority is asked to note that patient and professional information will no longer be updated on our website unless the situation with the pandemic changes again
The Authority is asked to note the preparation that has taken place for the Covid-19 Public Inquiry and the next steps outlined in section 6 above.

Human Fertilisation & Embryology Authority

Gamete and embryo storage

Item 7
Update to Authority

Joanne Anton
Head of Policy (job-share)

Current legal regime

- HFE Act 1990 set out the storage limit at a maximum of 10 years

- Since 1991, it has been possible for certain patients to extend storage beyond 10 years, however this was only possible if they could meet the requirements of the relevant regulations on **premature infertility**

- In 2020 Coronavirus regulations enabled patients whose treatment was impacted by the pandemic to extend storage for a further 2 years provided certain requirements were met

- Following a Government consultation on gamete and embryo storage, the Government introduced changes to the HFE Act 1990 in the Health and Care Act 2022 which has recently received Royal Assent.

Human Fertilisation & Embryology Authority

Key storage changes

- **Patients wishing to store gametes or embryos for their own treatment will be able to store for up to a maximum of 55 years,** provided they renew their consent every 10 years.
- **Donors will be able to store for up to 55 years** and do not need to renew their consent
- **Transitional provisions will enable patients who already have gametes or embryos in storage to benefit** from the extended storage period provided certain steps are taken within prescribed timeframes.
- **2009 regs are being revoked**. All patients will need to move to the new regime. Patients in extended storage for premature infertility will need to be contacted when the MS expire
- **Patients can consent to the use and storage of their gametes or embryos in the event of their death for 10 years** from their date of death, or 10 years from when they have been certified as having lost capacity

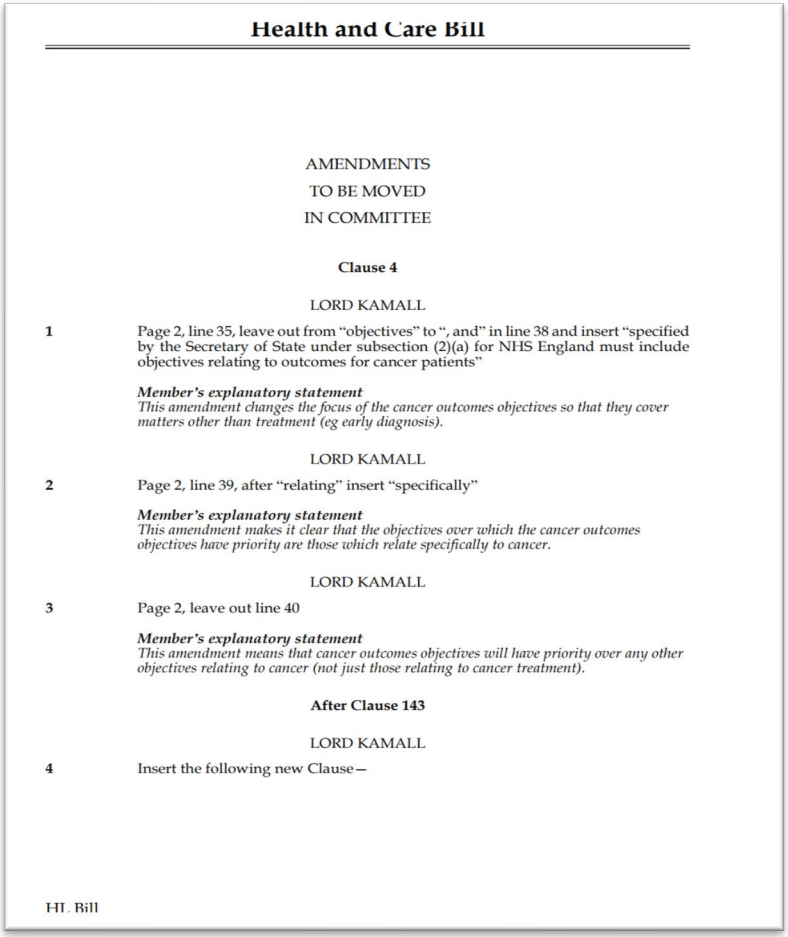
Human Fertilisation & Embryology Authority

Timeframe for storage changes

- The commencement date for the new law **is 1st July 2022.**

- The transitional period (during which all material already in storage must brought under the new regime) will begin on the **1st July 2022 and end on 30 June 2024.**

- Full amendment can be read at: https://bills.parliament.uk/publications/44657/documents/1241



Health and Care Bill

AMENDMENTS
TO BE MOVED
IN COMMITTEE

Clause 4

LORD KAMALL

1 Page 2, line 35, leave out from "objectives" to ", and" in line 38 and insert "specified by the Secretary of State under subsection (2)(a) for NHS England must include objectives relating to outcomes for cancer patients"

Member's explanatory statement
This amendment changes the focus of the cancer outcomes objectives so that they cover matters other than treatment (eg early diagnosis).

LORD KAMALL

2 Page 2, line 39, after "relating" insert "specifically"

Member's explanatory statement
This amendment makes it clear that the objectives over which the cancer outcomes objectives have priority are those which relate specifically to cancer.

LORD KAMALL

3 Page 2, leave out line 40

Member's explanatory statement
This amendment means that cancer outcomes objectives will have priority over any other objectives relating to cancer (not just those relating to cancer treatment).

After Clause 143

LORD KAMALL

4 Insert the following new Clause—

HL Bill

Human Fertilisation & Embryology Authority

HFEA preparatory work

- These changes will significantly impact clinics and will require considerable change to clinic practice.
- The HFEA is developing new guidance and gathering stakeholder feedback (eg, from SING nurses, BFS, clinicians, LCP, Authority members) on a number of new consent forms and a new clinic guide on the storage changes
- By the end of May/beginning of June 2022, we aim to be in the position to:
  - Issue new guidance in the form of a Clinic Guide which will assist clinics with understanding and implementing the changes
  - Publish new and amended consent forms for use from 1 July 2022
  - Issue communications regarding revised Licence Conditions. Clinics will be issued with licences that include the revised LCs either at the interim point or on renewal
  - Publish new and updated General Directions mandating, amongst other things, the use of the new consent forms
  - Following 1 July we will work with clinics to continue to develop further guidance and training material, including hosting a number of training events, to help clinics understand and implement the new changes.

Human Fertilisation & Embryology Authority

Risks

- **New rules are very complex** setting out different storage periods depending on who is storing, the purpose of storage or whether gametes or embryos are being stored posthumously or in the case of mental incapacity. It sets out a renewal of consent processes that clinics must follow at prescribed times.
- **Provisions on posthumous use will negatively impact some patients**. Currently if a person consents to posthumous use, the surviving patient will have up to 10 years to store/use their gametes and in many cases, as much as a further 10 years to use any embryos created with their gametes. Under the new scheme, patients will only have 10 years from the date of the gamete providers death to use gametes and create and use any embryos
- **Significant changes required for clinic staff to understand which will take time** and they will need to update all their SOPS, patients information and conduct training for staff. This will increase the risk on non-compliance (especially in the early days)
- **Short time frame for implementation** - interpreting the new rules has been a complicated process and we have had very little time to do it. As a result we are unable to give clinics the usual 6 weeks notice of the new guidance and consent forms

Human Fertilisation & Embryology Authority

Next steps

- Publish new Clinic Guide, along with new and revised consent forms, (including renewal of consent forms) and revised General Directions on Clinic Portal by end of May/early June
- New Licence Conditions and General Directions will come into force 1 July 2022 (Authority has delegated Chair to sign off)
- Strikethrough out of date Code of Practice guidance on storage and direct clinics to Clinic Portal storage information. Update Code of Practice in due course.
- Use the transitional period to continue to work with clinics to develop further guidance and training material, including hosting a number of training events, and webinars to help clinics understand and implement the new changes.

Human Fertilisation & Embryology Authority

Questions?

Human Fertilisation & Embryology Authority

www.hfea.gov.uk

Human Fertilisation & Embryology Authority

Modernising Fertility Regulation - update

Details about this paper

Area(s) of strategy this paper relates to:	Shaping the future
Meeting:	Authority
Agenda item:	8
Meeting date:	18 May 2022
Author:	Clare Ettinghausen, Director of Strategy and Corporate Affairs Laura Riley, Head of Policy (Scientific)
Annexes	Annex 1: Paper discussed at the Legislative Reform Advisory Group on 29 March 2022

Output from this paper

For information or decision?	For decision
Recommendation:	The Authority is asked to: • Consider the issues raised in section 3 and add to them as needed • Note the next steps in relation to this work outlined in section 4 • Note the risks outlined in section 5
Resource implications:	Staff resources required to ensure this work is kept on track
Implementation date:	Ongoing
Communication(s):	As outlined in the paper – through regular public and stakeholder updates
Organisational risk:	Medium

1. Introduction

1.1. At the February 2022 Authority meeting, members noted our **plans** for developing the HFEA view on legislative change. The aim is to deliver an outline proposal to the Department for Health and Social Care (DHSC) at the end of the year. Any decision on the future reform of the HFE Act (the Act) is for the Government.

1.2. It was noted that a number of activities took place during 2021 to start this work and more detailed plans would be developed during 2022 including establishing a **Legislative Reform Advisory Group** (LRAG) to discuss key topics.

1.3. The Authority noted the outline of activities that took place during 2021 and approved plans for developing proposals during 2022 for reform of the Act.

1.4. This paper provides an update for Authority including an outline of the key topics that will be looked at as part of this work (section 2); a summary of the issues raised by the LRAG in relation to questions on regulatory and licensing changes (section 3); next steps (section 4); and key risks (section 5).

2. Key topics

2.1. The key topics that Authority has previously agreed to look at in more detail are:

Patient protection

- The Act is silent on patient centred care
- There is a limited range of enforcement mechanisms or sanctions to drive improvement and current sanctions are blunt or slow
- There are no economic sanctions which have been shown to be an effective driver of improvement in other competitive markets
- The Act assumes a clinician ownership model which increasingly no longer exists – where does that leave the 'person responsible'
- Work of the CMA is welcome but raises questions of what should be within our remit and extent to which patients would be better protected if all aspects of the fertility sector were subject 'end to end' regulation by the HFEA
- The Act is overly prescriptive - e.g., requires inspections every two years – which limits the scope to reward good compliance with more streamlined regulation

Scientific developments

- The Act is at risk of being overtaken by research advances
- 14-day rule has proved effective and any replacement would need to offer the same degree of certainty and regulatory clarity
- Process is overly prescriptive e.g. in relation to mitochondrial donation
- There are no means to encourage new technology or other innovation through trials or regulatory experimentation

Consent, data sharing, anonymity

- Consent is overly complicated which creates costs for clinics and increases risk of errors
- Patient and donor confidentiality and disclosure of register data maybe out of step with other areas of healthcare and with new challenges such as DNA testing websites. Is the idea of data confidentiality out of date? Where will this go in another 10 years or more?

3. Key questions and actions on licensing and regulation

3.1. The first meeting of the multidisciplinary LRAG looked at issues relating to patient protection and regulation under the umbrella of 'licensing and regulatory reform'. The discussion paper considered by this Group is on our website but is attached at Annex 1 for convenience.

3.2. The LRAG discussed the issues raised in the paper on patient protection and licensing and made the following points:

Patient protection

3.3. LRAG agreed that a principle explicitly stating a duty to protect the patient should be added to the Act.

3.4. LRAG members raised that:

- While they agreed strongly with the important need to add in 'patient' protection, this should be drawn more widely than individuals in treatment, to include their existing children, or whole family as needed. Their partners, donors and other people whose interests are at stake should also be protected.
- In thinking about how 'patient' protection might be best achieved, the 2005 Mental Capacity Act and new Mental Health White Paper might provide a suitable model, involving some overarching principles, that then guide the rest of it. An updated HFE Act could provide such principles (for example around patient protection) and then state that the regulator should decide on how these principles should be applied in practice.

Compliance and enforcement

3.5. LRAG agreed on the need for the HFEA to have a wider range of sanctions, both in the event of serious non-compliance and in general, to shape clinic conduct. An updated regulatory scheme, broadly in line with the Regulators' Code, should include powers to impose licence conditions, suspend all or part of a service for a defined period, issue fixed penalty warning notices, and impose financial penalties on clinics.

3.6. LRAG members raised that:

- HFEA could consider seeking new legislation for more appropriate powers to regulate and sanction, rather than seeking to add more detail on the face of the legislation.
- Fines will be felt differently by clinics depending on their ability to pay.
- Some clinics may push back on the proposal to introduce financial penalties. HFEA will need to give clear reassurance of checks and balances involved in any new financial powers.
- It was suggested that 'straightforward' IVF could be entirely removed from regulation in future. However, other members disagreed, replying that while medically some IVF may be

straightforward, from the perspective of patients, their embryos are precious, valuable and significant. Anecdotally, one of the reasons that patients have said that they stayed in the UK for their IVF treatment, is that UK regulation involves an appropriately high standard of regulation.

Length of the clinic licence

3.7. Most members of the LRAG agreed on the need for the HFEA to move to a more risk-based model where the HFEA regulates performance. This would see licensed clinics keeping their licence unless their performance suggests otherwise. Currently, fixed-term licensing periods are mandated regardless of performance. Removing periodic licensing would not remove periodic inspection.

3.8. LRAG members raised that:

- an indefinite license system should specify that the licensed clinic remains subject to the rules that are in force at that particular time, but if the HFE Act or HFEA Code of Practice changed and re-licensing was required, the process for this would need to be made clear.

The role of the clinic PR

3.9. LRAG agreed on the need for a deputy PR role to be permitted by the Act. Job sharing jointly in the PR role and similar inclusive, flexible working arrangements should also be permitted. LRAG also agreed that the HFEA should require Persons Responsible to be revalidated when requirements on PRs change. The 'suitability' test for the PR should also be defined in the Act.

3.10. LRAG members raised that:

- This approach would allow HFEA to give more focused support to PRs. It would help to maintain communication and contact when there is a change of PR.
- The Act should permit one PR to be appointed for a group of linked clinics, especially if HFEA begins to license groups of clinics together in future, and a number of deputies at each clinic.
- PR role currently has a lot of responsibility but little explicit power in the Act to affect change. In practice, the influence of the PR depended on the circumstances of particular clinics.
- In some clinic models the PR role is peripheral to the running of the clinic. But even where the role is central, HFEA must maintain the current clinic licensing regime alongside requirements focusing just on the PR, in order to support patient safety and well-run clinics.
- Junior staff must always be able to raise concerns about PRs. The regulator needs to be able to see the clinics in the round, not just hear the PR's account of it. Virtual inspections must build in ways for inspectors to make informal, free and private approaches to other staff, in the way that in-person inspections do.

Role of the Clinic Licence Holder

3.11. LRAG agreed that the HFEA should propose that the clinic licence holder role should be made mandatory and more clearly defined in the Act, as distinct to the PR, including to determine who

is “suitable” to be a LH and how this is assessed. Alternatively, the LH role should be removed and the deputy PR role introduced instead.

3.12. LRAG members raised that:

- in an updated Act, the LH could be the business or NHS Trust who was providing the service not the individual.
- Some clinics have a corporate entity and an individual as licence holder, but the role does not work well without a real personal sense of responsibility so this needs to be brought into the role.
- Some LH are currently uninvolved, so could not deputise for the PR because they don’t know much about the working of the clinic.
- By contrast, HFEA research licence holders, tend to be very directly involved in their project. This could be because in research, the project itself is licenced, rather than the institution it is based in.

4. Next steps

4.1. The LRAG will be meeting regularly with the work programme agreed in March 2022.

4.2. The topics to be covered will include consent; data sharing; anonymity and the challenges of the DNA testing websites to this; and scientific developments.

4.3. A targeted consultation is planned for late July and August to get further input from licensed clinics, patients and key stakeholders on our ideas.

4.4. The Authority will be updated at each meeting on this work and time will be set aside to enable full discussions on these issues.

5. Risks

Short time to complete work

5.1. This work is planned to be completed within 12 months. The aim is a high-level overview of a range of key issues together with a set of possible solutions involving changes to the Act, rather than detailed drafting proposals.

5.2. However, given other time dependent and high-risk activity, such as the work on storage regulations or Opening the Register, and the overlap of key staff, there is a risk that there are limited key individuals who can take on this work.

5.3. This has been mitigated to some extent by re-prioritising work from key staff and recruiting some external help for this and other key projects. However, the risk cannot be removed completely as the work on the modernisation of the Act is highly dependent on a small number of people.

Criticism of the issues/focus

5.4. The high-level focus and relatively short time frame do create a risk that some stakeholders and/or patients will be unsatisfied with the outcome as it may not cover all the issues that might be raised with us in the consultation.

5.5. There are mitigations against this in how we frame this discussion in public and particularly, in the language used in the consultative exercise later in this year. We need to ensure that it is clear that there is no Government commitment to legislative change, but an agreement with the DHSC to look at proposals from the HFEA. If the Government decide to review the Act in future, then they may run a full government consultation. We should make it clear that this is merely the first stage in a potentially longer project of reform.

Lack of consensus

5.6. When presenting this work externally, we have said that we will make it clear in our final report where our proposals enjoy a broad consensus of support and where there is divergence. Given the contested nature of elements of the Act, we should not be surprised if there is a divergence of views on some issues. That may require us to make difficult choices.

5.7. The Legislative Reform Advisory Group meet regularly to discuss key issues and the papers are on our website and published in Clinic Focus.

5.8. The planned consultation in the summer should expose where differences lie, and Authority can then consider at that point key issues of concern or where there is lack of consensus.

Challenge

5.9. Our broad view is that much of the 'Warnock settlement' remains fit for purpose, but that elements of the Act could be usefully modernised to better meet the regulatory challenges of today and in the future. However, in raising issues relating to the Act, there is a risk that it gives rise to wider challenges for or against the idea of regulation itself – some may want a more restrictive or more permissive regulatory regime, limiting the powers of the HFEA, blocking modernisation, or proposing changes (reductions) to some existing norms, such as the 14-day rule.

5.10. In talking about these reforms, we will need to ensure the case for regulatory oversight of care and research and to hold treatment data is always made clearly. By ensuring key stakeholders are involved in the work, we hope to build a body of collegiate discussion and to establish some areas of consensus. This will help to mitigate against future challenges seeking to reduce existing norms, where these challenges might (in our view) be harmful to UK patients, to their care in licensed clinics, or to licensed research. It is possible that these issues become more relevant should government decide to move forward on changes to the Act.

6. Recommendations

6.1. Authority is asked to note the issues outlined above and:

- Consider the issues raised in section 3 and add to them as needed
- Note the next steps in relation to this work outlined in section 4

- Note the risks outlined in section 5

Annex A: Legislative Reform Advisory Group – paper discussed on 29 March 2022

Regulatory reform: Licensing

Introduction

1. The HFEA's regulatory framework is set out in the Human Fertilisation and Embryology Act 1990 (as amended) (the Act). The Act sets out the conditions that govern the procurement, creation, distribution, storage and use of gametes and embryos. With limited exception, such activities can only take place under a licence granted by the HFEA and undertaking these activities without a licence is a criminal offence.
2. The regulatory framework was largely left intact when the Act was last updated in 2008 which means the HFEA is regulating with a set of powers which are over 30 years old. Yet the fertility sector has changed markedly over that time in terms of its size, ownership structure, services offered and much else. Moreover, policy thinking on regulation more generally has developed significantly over that time too. All of this suggests that a review of the regulatory framework governing fertility treatment in the UK is long overdue.
3. This paper sets out several areas of the existing licensing framework that might benefit from reform. The focus is only on the arrangements for clinics providing fertility treatments (the term is used here to cover both treatment and storage). Research licensing will be considered separately.
4. In thinking about the licensing framework set out in the Act, it is helpful to break it down to its key elements:
   - Compliance and enforcement;
   - The length of the licence;
   - The protection of the patient;
   - The licensed entity and the role of the Person Responsible.
5. The remainder of this paper considers each element in turn. Each section begins with a short summary of the current situation, followed by an identification of the issues where the Act is showing its age and concludes with a set of potential options for change. The aim is to provoke debate on the merits of those options.

Compliance and enforcement

The current situation

6. There is currently a tension between the Regulators' Code and the Act. This is most apparent in the idea that good regulation involves an expectation that regulators should act proportionately, which is usually taken to mean the least necessary action to address regulatory risks and non-compliance.

7. Leaving aside the informal steps that can be taken to promote compliance (recommendations, management meetings with the PR etc) the Licensing Committee of the HFEA have limited options for responding to the most serious non-compliances. In such circumstances the committee can suspend with immediate effect, revoke a licence, or vary a licence to impose additional conditions. Yet the Act is drafted in such a way that it can only consider varying or suspending a licence if it has the power to revoke, or if it suspects that there are grounds to revoke.

6.2.

8. There are no other formal sanctions available and, to date, the HFEA hasn't resorted to the kind of informal sanctions that some other regulators have used, e.g. 'naming and shaming' or publicising when regulatory action is being considered.

Issues

9. **The options available to the HFEA in the event of serious non-compliance are limited** – the requirement that the test for revocation is met before other sanctions are available, makes it hard for Licencing Committees to take proportionate action. What is lacking is a wider range of licensing options which would allow the sanction to better match the seriousness of the non-compliance.
10. **There are no financial penalties available to the HFEA to shape clinic behaviour or to address serious non-compliance** – financial penalties are commonly available as sanctions against providers of other healthcare services and in many other regulated activities, e.g. charities, political parties, financial conduct.

Options for change

11. **The options available to the HFEA in the event of serious non-compliance are limited** – the Act requires a 'ladder of escalation' which would provide a broader suite of sanctions in addition to the current powers. Regardless of the level of sanction, enforcement action would always be subject to formal decision making against appropriate thresholds. While the power to revoke a licence should remain as an appropriate sanction for the most serious non-compliances, references to having to have "grounds to revoke" should be removed from the sections on variation and suspension. Instead, there should be a power to impose conditions, suspend all or part of a service (for a defined period) and to fine (see below), where there have been critical or major non-compliances with the Code of Practice. In effect, this would re-order the sanctions in a logical and more proportionate order and enable an approach more in line with the Regulators' Code.
12. **There are no financial penalties available to the HFEA to shape clinic behaviour or to address serious non-compliance** – a power to fine could be added to the Act though it will require detailed work on what kinds of non-compliances might warrant a fine and the appropriate level of any fine. In thinking about these issues the Health and Care Act (Regulations 2014) is perhaps instructive. This allows the CQC to fine a service provider where it fails to provide safe care or provides treatment that results in avoidable harm to a service user or exposes them to a significant risk of exposure to harm. The CQC also has the power to issue Fixed Penalty Notices and warning notices, with powers which flow from a breach of a warning notice.

The length of the licence

The current situation

13. Treatment and storage licences can be issued under the Act for up to five years but are typically issued for a maximum of four because of the requirement to inspect at least every two years.

Issue

14. **The existing rules are rigid and are arguably out of step with modern risk-based regulation** – the requirement to inspect at least every two years, means there is no scope to exempt clinics from an inspection as a reward for good performance. A more risk-based inspection cycle – and we have recent experience of elements of such a model with the introduction of a number or changes to the current inspection regime during Covid - would vary the frequency of inspection according to risk. Such an approach would also be more closely aligned with the Regulators' Code principle that regulators should base their regulatory activities on risk. The growth of groups of clinics, some of which have common operating procedures is also relevant here.

Option for change

15. **The existing rules are rigid and are arguably out of step with modern risk-based regulation** – the Authority could be given greater freedom as to how often inspections are to be conducted. Such freedom could either sit within the existing idea of periodic licences (whether five years as now or longer) or, a more radical option would involve the move to granting all, or the best performing, clinics an indefinite licence, subject to periodic inspection and annual fees. The latter approach would take away the artificial 'cliff edge' of a licence renewal and send a signal that once licensed the clinic met the standards required until performance suggested otherwise. If the latter option was pursued an additional statutory power to be able to grant licenses for a specified duration in certain circumstances would allow the length of licence to be used as an improvement tool in itself.

The protection of the patient

The current situation

16. The Act is focused on the special status of the embryo, not the patient. As such it reflects the concerns of the time that Warnock was drafted and pre-dates the move toward more patient-centred health care. In response the HFEA's enforcement documents do refer to actual or potential risks to the safety of patients, gametes or embryos, but there is no statutory reference to the "patient". And there is nothing in the Act that puts the patient or patient centred care as a focus – as is evident from the periodic calls for a "welfare of women" test to match the existing "welfare of the child" – to inform the work of the HFEA.

Issue

17. **A lack of focus on the needs and protections of patients is out of step with modern healthcare** – evident most recently in the Cumberlege Report, 'First Do No Harm' (2020). Regulations for example allow the CQC to focus its inspections around five themes: are services Safe? Effective? Caring? Responsive to people's need? and Well-led? And the GMC has an overarching objective to protect, promote and maintain the health and safety of the public.

Option for change

18. **A lack of focus on the needs and protections of patients is out of step with modern healthcare** – an over-arching objective regarding patient care could be inserted into the Act with a requirement that HFEA decision-making and compliance by its LH/PRs should have reference to it. There is then

an open question of the nature of that reference, which could range from a flexible but ill-defined "have regard", to something more concrete and capable of evidencing, e.g. included as one of the statutory responsibilities of the PR.

The licensed entity and the role of the Person Responsible

The current situation

19. Under the Act licences are granted to "Licence Holders" (which may or may not be the same as the "Person Responsible"). The LH can be a corporate entity such as a health trust, a private business or an individual.

20. Every clinic must also have a PR (and they must be an individual). As the name suggests the PR is the person whom the regulatory regime holds accountable for the conduct of all licensed activities in the clinic. The PR is required to have certain academic and professional qualifications, work experience and registrations. The LH and the PR must both be considered 'suitable' and the Authority must be satisfied as to the character of the PR.

21. The Act also sets out the powers and duties of the PR, though these fall short of a formal job description. The HFEA has issued a key behaviours and role description which sets out what is expected of a PR in their role as clinic leaders and has developed the PR Entry Programme to support PRs. There is no formal provision for deputy PRs or for the role to be shared. And the law does not permit a PR to delegate their responsibilities.

Issues

22. **The Act does not define what sort of person or entity can be a "Licence Holder"** – and therefore it is not clear who is "suitable" to be a LH or how this is assessed. The holders currently vary from private business entities to hospital trusts to individuals who are also PRs. There are no requirements for private providers to be financially viable or any formal restrictions on who can be involved in the ownership or governance of a fertility business and, as a consequence there is no scrutiny of the owners/shareholders of a private clinic or its financial viability, unlike in the school or care sectors.

23. **The current 'suitability' test for the PR does not provide an adequate regulatory tool** – experience to date in both the fertility sector, and arguably the wider health and care sector, suggest that 'suitability' is too vague a test to be always effective in deciding whether to approve a PR. Given the vital role the PR plays in clinic leadership this is in some cases a real weakness.

24. **The Act places onerous responsibilities on the PR but provides her/him with no formal powers/influence to facilitate change** – it is widely accepted that it is the PR who sets the culture for most clinics. In the clinician/owner model that used to dominate the private sector that was rarely an issue, as the owner and the PR were one and the same. Increasingly, private sector clinics are part of group structures and/or financed by private equity and some individual PRs may find it hard to facilitate change. Experience suggests that PRs in clinics that are part of a larger NHS Trusts face similar problems.

25. **In some settings the responsibilities of the PR role may be too much for one person or too inflexibly defined to accommodate group structures** – in a modern workforce it may be appropriate to allow for job sharing and/or a deputy PR role.

Options for change

26. **The Act does not define what sort of person or entity can be a "Licence Holder" –** the LH could be made mandatory and distinct from the PR, and the expectation might be set that the LH was the business/NHS Trust who was providing the service. At a level below the Act, the HFEA could set out what matters it needed to be satisfied about in relation to a LH. There are several possible models here, including the requirements that exists for CQC providers or schools and children's services. The HFEA could require limited information about the owners and managers (directors) of a business – for example, for the purposes of assessing suitability, to enforce debts, to consider whether the new LH might have an adverse impact on the quality of services offered.
27. **The current suitability test for the PR does not provide an adequate regulatory tool** – a more structured set of criteria might provide a more rigorous test, particularly where a PR moves from one licensed clinic to another. Elements of the 'duty of candour' test might be a useful starting point here.

28. **The Act places onerous responsibilities on the PR but provides her/him with no formal powers/influence to facilitate change** – there are several existing models which may be relevant: for example, the CQC registration process designates a "Registered Manager" who is legally responsible and accountable for meeting the CQC's fundamental standards for quality and safety; and there is a similar role in pharmacy registration. While the Act could be amended to ensure that PR has the authority to make decisions (and whether there should be any exemptions for NHS providers), it is an open question as to whether that change alone will be sufficient.
29. In some settings the responsibilities of the PR role may be too much for one person or too inflexibly defined to accommodate group structures - provision could be made for more than one PR to be appointed, along the lines allowed by the CQC. If this element of the Act were amended it would also be worth looking at the risks and benefits of allowing PRs to act for more than one clinic in a group structure.

Discussion

30. The Advisory Group are invited to consider the issues identified and potential options for change as set out above. In summary:

Compliance and enforcement

- Issue: The options available to the HFEA in the event of serious non-compliance are limited
  - Option for change: re-order sanctions in more logical and proportionate manner
- Issue: There are no financial penalties available to the HFEA to shape clinic behaviour or to address serious non-compliance
  - Option for change: a power to issue a fine could be added to the Act

The length of the licence

- Issue: The existing rules are rigid and are arguably out of step with modern risk-based regulation

  - Options for change: greater freedom over timing of inspections; EITHER within existing framework of periodic licences OR grant clinics an indefinite licence, subject to periodic inspection and annual fees

The protection of the patient

- Issue: A lack of focus on the needs and protections of patients is out of step with modern healthcare
  - Option for change: an over-arching statutory objective regarding patient care

The licenced entity and the role of the Person Responsible

- Issue: The Act does not define what sort of person or entity can be a “Licence Holder”
  - Option for change: LH could be defined in the Act and supported by guidance on requirements

- Issue: current suitability test for the PR does not provide an adequate regulatory tool
  - Option for change: a more structured set of criteria to provide a more rigorous test, particularly where a PR moves from one licensed clinic to another
- Issue: The Act places onerous responsibilities on the PR but provides her/him with no formal powers/influence to facilitate change
  - Options for change: several existing models e.g. CQC “Registered Manager”; similar role in pharmacy registration; Act could be amended to ensure that PR has the authority to make decisions
- Issue: In some settings the responsibilities of the PR role may be too much for one person or too inflexibly defined to accommodate group structures
  - Option for change: more than one PR to be appointed