Human Fertilisation & Embryology Authority

Authority meeting - agenda

13 March 2019, Church House, Deans Yard Westminster, London SW1P 3NZ

Agenda item	Time
1. Welcome, apologies and declaration of interests	12.45pm
2. Minutes of 30 January 2019 Authority meeting **HFEA (13/03/19) 907** For decision	12.50pm
3. Chair's report (verbal)	12.55pm
4. Chief Executive's report (verbal)	1.05pm
5. Committee chairs' reports (verbal)	1.15pm
6. Performance report **HFEA (13/03/19) 908** For information	1.25pm
7. Effective governance **HFEA (13/03/2019) 909** For information	1:40pm
8. Finance and business plan update 2019/20 **HFEA (13/03/2019) 910** For decision	1:55pm
9. EU exit **Presentation** For information	2.15pm
Break	2.30pm
10. Strategy development **HFEA (13/03/19) 911** For decision	2:40pm
11. The use of electronic consent **HFEA (13/03/19) 912** For decision	3:15pm
12. Any other business	3:45pm
13. Close	3.50pm

Minutes of Authority meeting 30 January 2019

Strategic delivery:	☐ Safe, ethical effective treatment	☐ Consistent outcomes and support	☐ Improving standards through intelligence

Details:	
Meeting	Authority
Agenda item	2
Paper number	HFEA (13/03/19) 907
Meeting date	13 March 2019
Author	Helen Crutcher, Risk and Business Planning Manager
Output:	
For information or decision?	For decision
Recommendation	Members are asked to confirm the minutes as a true and accurate record of the meeting.
Resource implications	
Implementation date	
Communication(s)	
Organisational risk	☒ Low ☐ Medium ☐ High
Annexes	

Minutes of the Authority meeting on 30 January 2019 held at Church House, Deans Yard, Westminster, London SW1P 3NZ

Members present	Sally Cheshire Margaret Gilmore Anthony Rutherford Emma Cave Anita Bharucha Gudrun Moore	Kate Brian Rachel Cutting Ruth Wilde Yacoub Khalaf Anne Lampe
Apologies	Jonathan Herring Bobbie Farsides	
Observers	Dafni Moschidou (Department of Health and Social Care)	
Staff in attendance	Peter Thompson Clare Ettinghausen Nick Jones Richard Sydee Catherine Drennan	Paula Robinson Caylin Joski-Jethi Joanne Triggs Helen Crutcher (minutes)
Other attendees		

Members

There were 11 members at the meeting; six lay members and five professional members.

1. Welcome, apologies and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members and members of the public to the first meeting of 2019. As with previous meetings, it was audio-recorded, and the recording would be made available on our website to enable interested members of the public who could not attend the meeting to listen to our deliberations.

1.2. Apologies were received from Bobbie Farsides and Jonathan Herring.

1.3. Declarations of interest were made by:

- Anthony Rutherford (Clinician at a licensed centre)
- Rachel Cutting (Clinician at a licensed centre)
- Yacoub Khalaf (Clinician at a licensed centre)

2. Minutes of Authority meeting held on 14 November 2018

2.1. Members agreed the minutes of the meeting held on 14 November 2018 for signature by the Chair of the meeting.

3. Chair's report

3.1. On 22 November 2018 the Chair attended the second HFEA leadership event for PRs, held in Manchester. This event, along with one earlier that month in London, was a success and marked a step change in the way in which we engage with the senior leadership of the sector. Members heard that we would be looking to hold further events on leadership, including a workshop at our annual conference.

3.2. On 28 November the Chair and Chief Executive attended the Huxley Summit, which brings together leaders from business, policy making and science.

3.3. On 5 December the Chair spoke at the Progress Educational Trust conference on whether the HFE Act should be updated.

3.4. On 7 December the Chair chaired a Remuneration Committee.

3.5. On 10 December the Chair attended our all staff awayday.

3.6. On 24 January 2019 the Chair and Chief Executive visited Scotland and met the Minister for Public Health in Scotland, Jim Fitzpatrick MSP. They also attended the National Fertility Group Meeting and met some of the PR's and other staff that work in Scottish clinics. In the evening, the Chair took part in a debate organised by the Progress Educational Trust to mark 40 years in IVF. The Chair acknowledged the positive work being done in Scotland to provide full IVF provision according to the NICE guidelines.

4. Chief Executive's report

4.1. The Chief Executive and Senior Management Team joined the Chair for the second HFEA event for PRs in Manchester on 22 November.

4.2. On 28 November the Chief Executive attended the Huxley Summit.

4.3. On 4 December the Chief Executive attended the HFEA Audit & Governance Committee meeting.

4.4. On 5 December the Chief Executive attended the Progress Educational Trust event on whether the HFE Act should be updated.

4.5. On 7 December the Chief Executive attended the HFEA Remuneration Committee meeting.

4.6. The Chief Executive advised members that the staff awayday, held on 10 December, provided the opportunity to agree how best to improve communication between teams, manage workload pressures better and give more time for learning and development. The discussion felt very open, acknowledged the pressures staff were under, and produced a set of actions which he believed would make a difference.

4.7. On 14 December the Chief Executive attended a meeting hosted by Sir Mark Sedwill, Cabinet Secretary and Head of the Civil Service. Following this, he participated in the annual general meeting of the Association of Chief Executives.

4.8. On 3 January the Chief Executive attended the annual British Fertility Society conference in Birmingham. The Director of Compliance and Information and other staff represented the HFEA on other days.

4.9. On 9 January the Chief Executive attended the first of a regular series of meetings on EU exit planning between Department of Health and Social Care (DHSC) arm's length body (ALB) Chief Executives and the Minister of State. An item on EU exit would follow later in the agenda.

4.10. On 10 January the Chief Executive and Senior Management Team attended the DHSC and HFEA quarterly accountability meeting, which focussed on EU exit preparedness.

4.11. On 23 January the Chief Executive attended the latest Health and Care Leaders Scheme senior talent board meeting.

4.12. On 24 January, the Chief Executive accompanied the Chair to Scotland as above.

5. Committee Chairs' reports

Licence Committee

5.1. The Chair of the Licence Committee reported that the committee had met on 8 November 2018 and 10 January 2019.

5.2. The Chair of the Licence Committee provided the members with an update on the 8 November 2018 meeting, the minutes for which had not been published at the time of the last Authority meeting. At this meeting the committee approved six research renewal applications. The committee considered one treatment and storage renewal, including a variation to change premises and refused this, with a proposal to revoke the licence. The committee also received one executive update with variations to change the Person Responsible and Licence Holder and it noted the update and approved the two variations.

5.3. At its 10 January 2019 meeting the committee considered one revocation of licence, following the earlier proposal to revoke in November, and revoked the licence.

5.4. The following items were also considered: one research renewal, one treatment and storage renewal, one serious untoward incident investigation report from an NHS Trust, following an earlier consideration of a grade A incident, and one executive update following an interim inspection. The minutes for these items were not yet signed, so the Chair of the committee could not provide details of the decisions made.

Statutory Approvals Committee

5.5. The Chair of the Statutory Approvals Committee (SAC) reported that the committee met on 25 October, 29 November and 13 December 2018.

5.6. The Chair of the Statutory Approvals Committee updated members on the outcomes of the 25 October meeting, the minutes of which had not been signed off by the last

Authority meeting. The Committee considered three mitochondrial donation applications, one of which it adjourned and two it approved. It also considered five PGD applications all of which it approved, though one for a single type only.

5.7. In November, the committee considered eight items: four PGD applications all of which it approved, though one for a single type only, and four special directions applications three of which it approved and one it refused.

5.8. In December the committee considered six items: five PGD applications which were all approved and one HLA tissue typing application which was adjourned.

5.9. The committee chair noted that the trend in special directions was unusual but the reason was not yet known. Busy was now the new normal. A new pool system for SAC members would help the committee to manage this workload.

Executive Licensing Panel

5.10. The Chair of the Executive Licensing Panel (ELP) advised members that the Panel had met four times since the last Authority meeting, on: 20 November, 12 December 2018, 2 January and 15 January 2019.

5.11. The panel considered twelve items in total: two initial applications which were both approved, three renewals one of which was deferred and two approved, three interims all of which were approved, four variations which were all approved and it noted one executive update.

5.12. The Chair of ELP reported that the Licensing Officer had considered 13 importing tissue establishment (ITE) certificate applications.

Audit and Governance Committee

5.13. The Deputy Chair of the Audit and Governance Committee (AGC) reported that the committee had met on 4 December 2018.

5.14. Aside from the usual standing items and updates from internal and external audit, the committee received reports on:

- An update on the Strategy and Corporate Affairs directorate
- Digital Programme Update
- Brexit
- Estates Update
- Reserves Policy
- Review of AGC activities & effectiveness, terms of reference

Remuneration Committee

5.15. The Chair reported that the Remuneration Committee had met on 7 December 2018 to discuss senior managers' pay awards.

6. Performance report

6.1. The Director of Compliance and Information provided an update about the data submission system (PRISM) and data migration to support this. Members heard that a careful, risk-based approach was being taken. Regular updates had been provided to AGC to assure the Authority of effective governance and these would continue, until the programme was complete. The Director assured members that there was no risk in the continued use of the existing submission system, although it was sub-optimal. Clinics were being updated regularly.

6.2. The Director of Compliance and Information advised members of progress with appointing a provider for the donor conceived voluntary contact register. Following an item to the Authority in November the executive and Chair had arrived at a model that would ensure provision of support and an effective, well managed service. Members had provided comments and agreed this approach. All organisations that had previously expressed an interest had been invited to respond to a tender, to demonstrate how they would work with the HFEA to provide the service.

6.3. Having a new supplier in place by April was a priority. The possibility of bridging any end of contract gap would be explored with the current providers, the National Gamete Donation Trust. A paper would be provided to the Authority to assure members that the design of the service was effective in practice. Members confirmed their satisfaction with the progress that had been made.

6.4. The Director of Strategy and Corporate Affairs provided an update on key activities. She noted that the new 9th edition of the Code of Practice had come into force on 2 January 2019 and thanked staff for their hard work on this. The treatment add-ons consensus statement had also been launched and received positive coverage in the press.

6.5. The Director of Strategy and Corporate affairs noted some upcoming parliamentary activity relevant to the HFEA.

6.6. The HFEA had worked with various professional bodies to produce commissioning guidance and this was now being tested with Clinical Commissioning Groups.

6.7. A Women's Health Taskforce had been set up and the Director of Strategy and Corporate Affairs would be attending on behalf of the HFEA. This would be a good opportunity for the HFEA to engage with stakeholders on key issues, such as fertility education.

6.8. The Chair noted that the coverage on add-ons was positive and this collaborative approach would be a tactic we would take on other issues.

6.9. Members heard that work was ongoing on the next Fertility Trends report and key trends were being identified. Meanwhile, the impacts of the National Fertility Patient Survey results were being considered.

6.10. The Director of Finance and Resources provided members with information on the financial forecast.

6.11. The Director noted that DHSC had asked all ALBs about the extent to which non-essential expenditure could be deferred until the following financial year, so that funds

could be returned to the centre. We had proposed an amount and the department had taken us up on this. This sum was made up of additional income from IVF activity which was higher than forecast and a reserve for litigation which would not be spent this year.

6.12. Members heard that this agreement not to spend would have no material impact on organisational plans before the end of the financial year.

6.13. Work would be underway in the following weeks to look at the financial forecast for 2019/2020. The details of this review would follow to the Authority in March.

6.14. The Chair thanked staff for their ongoing hard work across the organisation during a very busy time.

Decision

6.15. The members noted the latest performance report.

7. Standing Orders

7.1. The Head of Planning and Governance presented a report on three small proposed revisions to the HFEA's standing orders.

7.2. The Head of Planning and Governance reminded members that revisions to standing orders require a notice of motion to be sent to members in advance and that in this instance this was circulated on 15 January 2019.

7.3. Accepting revised standing orders also requires:

- Two thirds of members to be present at the meeting.
- At least half of members present to vote in favour.

7.4. If approved, the changes would have effect from 31 January 2019.

7.5. The Head of Planning and Governance provided members with details about each of the proposed revisions.

SAC terms of reference

7.6. In order to include new Authority members in decision making, and in recognition of the workload of the Committee, it was proposed that SAC would operate from a rotating pool of seven members. In accordance with current standing orders, the committee would continue to sit with a maximum of six members at each meeting.

7.7. It was proposed that the authorisation of mitochondrial donation treatment would also be added to the list of decision types in the SAC terms of reference.

SCAAC terms of reference

7.8. The membership of SCAAC had been revised to reflect recent turnover in Authority membership (this requires no changes to standing orders). The members heard that the Chair took this opportunity to review the current expert adviser appointments on the committee, in light of upcoming areas of work.

7.9. As a result, it was proposed that paragraph 6.4 be amended to increase the number of external expert advisers appointed to the committee from eight to eleven.

7.10. This reflects an identified need for further expertise to complement the existing SCAAC membership, in developmental biology genetics and embryo research, clinical 'big data' and andrology.

Register Research Panel terms of reference

7.11. The proposal for Register Research Panel (RRP) was to extend its role and function to include making decisions for access to 'safeguarded' data requests. This additional scope has been introduced through a Data Research Project which aims to provide more useful and timely data to researchers, where this can deliver public benefit.

7.12. The membership of RRP also needed to be revised to reflect recent turnover in HFEA staff, and to recognise the new expertise we have in the organisation, following the organisational restructure (including the Head of Research and Intelligence and Research Managers).

7.13. To ensure that appropriate independence is retained when making decisions, while recognising that the risk and impact of decisions taken at RRP can vary significantly, it was proposed to amend the membership considerations to include 'due consideration to the balance of membership to ensure a fair and robust appraisal of any research applications and decisions.'

7.14. It was also proposed to make explicit the requirement for the Chair of the panel to sign off all decisions and minutes.

7.15. Members discussed the change to a pool system for SAC and the need for continuity of decision-making for all committees. For items returning to committees, minutes could be provided from the previous discussion and the same members selected to hear the item, to ensure consistency. A member noted that the wording of the changes to the SAC could be clearer and suggested it be reworded to 'The SAC shall operate from a pool of members, with no more than six members attending each meeting'.

7.16. Members discussed the SCAAC changes and stressed the importance of identifying gaps in SCAAC expertise and ensuring that the committee had the required capabilities.

7.17. The Chief Executive noted that the RRP changes were appropriate and consistent with the way this committee would operate in the future.

Decision

7.18. Members unanimously voted to approve the revised Standing Orders, subject to the suggested wording change.

8. EU exit preparations

8.1. The Chief Executive and Director of Compliance and Information presented a paper setting out the arrangements relating to the Authority's preparedness for EU Exit.

8.2. The Director of Compliance and Information explained that the Department of Health and Social Care (DHSC) is leading and co-ordinating planning across the health and social care sector and all its 15 ALBs have been asked to play their part.

8.3. Members heard how the UK's membership of the EU affects the provision of assisted reproduction and research involving human embryos in two principal ways: legally and operationally. The Director of Compliance and Information provided information about the HFEA's readiness in both respects.

8.4. Regarding legal readiness, the Director of Compliance and Information highlighted the five pieces of EU law that are relevant to the responsibilities of the HFEA and explained that all five Directives were transposed into domestic UK law.

8.5. Members heard that there was one outstanding legal issue, concerning the draft Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019 which were laid in Parliament in November 2018.

8.6. Regarding operational readiness across the fertility sector, members heard that the role of the HFEA differed from some other regulators since it was not a delivery body, but we had a role in ensuring the sector provided patients with continuity of care. Members heard that the HFEA had surveyed licensed clinics in May 2018, this feedback indicated that the sector was not facing serious problems in relation to staffing levels and any consequences to those levels resulting from EU exit.

8.7. The Director of Compliance and Information provided information about communications that had been made to the sector directly from the HFEA and information passed on from DHSC. He also set out the ongoing communication and supporting role the HFEA would play. A clear position would need to be reached about how the Authority would respond if EU exit caused regulatory issues for clinics.

8.8. Members heard how the actions that clinics will need to take to prepare for EU Exit will in part depend upon whether they are within the NHS or independent sector.

8.9. Members also heard how the HFEA had been asked to implement 'no deal' plans of which this paper was a part. The Director of Compliance and Information had been appointed as SRO (senior responsible officer) and was participating in various regular official meetings. The main concern was to ensure that the HFEA maintained the delivery of its statutory duties and continuity of care for patients.

Decision

8.10. The members discussed the paper. Members who work in clinics described their own experiences and organisational readiness for EU exit. Members suggested that some parts of the sector (particularly those clinics not in an NHS Trust or a large independent healthcare group) may not have the same degree of knowledge and resources available to consider implications and prepare effectively. Members agreed that it was important for the Authority to enable clinics to share their experiences and plans with others in the sector.

8.11. Members discussed the important role of the Authority in ensuring clinics could respond to any concerns from patients about how EU exit might affect their treatment.

8.12. Members discussed the administrative consequences of EU exit for the Authority's inspection and licensing functions. The Head of Legal confirmed that the power of the SAC to agree Special Directions would not change and regulatory standards would be consistent at the point of EU exit. Inspectors would be contacting clinics. The extent of

the impact on clinics may vary depending on the type of EU exit and this was a challenge for preparations. The timeliness of advice was important and although this might change over time, the Authority would continue to provide guidance.

9. Communications strategy

9.1. The Head of Engagement presented a paper on the delivery of the 2017-2020 communications strategy, which runs alongside the main organisational strategy.

9.2. Members heard that the key aims of the communications strategy were to:

- raise awareness of the HFEA
- equip patients with reliable/impartial information
- raise the quality of care
- use the media to maintain our public reputation as a robust regulator
- get better engagement with clinic staff
- promote better engagement with HFEA staff.

9.3. The Head of Engagement provided an overview of communications work that had been delivered with different HFEA audiences and stakeholders. Key successes included: the launch of the new HFEA website, increased social media presence, a redesign of the Clinic Focus newsletter for clinic staff and development of the knowledge base section of the clinic portal.

9.4. Members heard that future work could include:

- Ongoing development of the campaigning and social and digital media work
- The consideration of a new, more proactive approach to media management
- Bolder approaches on key issues. Ongoing work on treatment add-ons.
- More work with key partners to identify spokespeople in the sector.
- More work on how to communicate with clinic staff

9.5. Members were asked for their thoughts on how HFEA moved forward on key areas during the final year of the communications strategy, including the approach to:

- Social/digital media
- Print/broadcast media
- Clinic communications

9.6. The Director of Strategy and Corporate Affairs noted that the capacity of the organisation both in terms of staffing and resource was limited. However, the opportunity to take advantage of collective activity and low-cost initiatives was great and this was an underused and cost-effective area for HFEA to consider further work in.

9.7. Members discussed the paper and identified some key areas for future focus, providing the following comments:

Print and broadcast media

9.8. Members discussed how taking full advantage of communications capabilities would enable us to benefit more from partnerships and connections. Members stressed that taking a proactive approach was important for addressing issues raised in the press and by clinics, we should take advantage of connections in the sector and continue the good work to raise the profile of the organisation on key issues. They highlighted a need to do more to identify 'go-to' spokespeople, to make sure that our voice was heard in the media.

Social/digital media

9.9. Members made comments on the channels and approaches available to the organisation, particularly for approaching patients. It was not clear exactly which channels patients used to access information about the HFEA and fertility treatment and it was important to establish this first to ensure that the use of resources was worthwhile and effective.

9.10. Members discussed the need to be involved in communication before patients reached a clinic. GPs provided this initial information to many patients and we should consider how we could begin to engage with them. Members also discussed the importance of fertility education and heard that efforts were being made by other bodies such as the British Fertility Society in this area. A member noted that male fertility should be part of our communication with patients.

Clinic communications

9.11. On communications with clinics, members noted that the removal of the clinic element on the HFEA website meant that it was now hard to find key information for clinicians and professionals and that it could be made quicker for clinics to find information on the Clinic Portal. This was also an area of the website that other professionals such as journalists and researchers used to use, and they may not be able to find the right information now though the HFEA. Members asked the executive to reconsider the way this information was provided on the website.

Decision

9.12. Members complimented staff on the progress made, particularly towards working with professional organisations and other partners. They were conscious of the importance of providing information in the right way without simply telling patients what to do. Members noted that communications should be derived from the strategy and aligned with the key organisational objectives. This included the approach to building relationships with political and other stakeholders and developing a wider public affairs strategy.

9.13. The executive agreed to reflect on the points raised and consider implementation methods. Merely providing information would not guarantee the desired behavioural changes. The public affairs element would be key in this and offered a significant opportunity to achieve bigger effects.

9.14. The Chair noted that this was a strong base to build on and getting communications right would set the organisation up well for delivering the final year of this strategy and the next one.

10. The register research panel (RRP) and data research

10.1. The Head of Research and Intelligence presented a paper on the Register Research Panel (RRP) and data research, which had three main aims:

- To provide an overview of the work conducted in 2018 which falls under the RRP's delegated functions.
- To provide an update on the steps we have taken so far towards improving data research.
- To provide a summary of the data access process in the future.

10.2. The Head of Research and Intelligence provided members with some background information, including how in its 2017-2020 strategy the HFEA committed to 'improve the quality of treatment, by encouraging world class research and clinical trials'. Data research was key to understanding and improving the safety and efficacy of fertility treatment.

10.3. Members also heard that the HFEA held the largest register of fertility treatment data in the world, with experience of world class research being carried out using our data, either alone or, since 2010, by linking to other datasets.

10.4. The Head of Research and Intelligence explained that since October 2009, patients who registered for fertility treatment were asked to consent to their information being included in studies where patient 'identifiers' were needed. However, the overall consent rate for some years (2009-2012) was quite low at around 50%. By working with clinics, the HFEA had improved the status of data research and members heard how consent rates were now around 70%.

10.5. The Head of Research and Intelligence highlighted the benefits of large-scale linkage studies which use identifiable data. She provided an overview of the new data access process, to make it easier for high quality research which will benefit the public to take place.

10.6. The remit of the RRP, under the 2010 regulations, is to consider and, where appropriate, authorise access for research studies which require identifiable data. Such identifiable data can only be released through an RRP determination (with due regard to the regulations) and for patients who have consented to the use of their data being used.

10.7. The Authority, in its role as the 'Oversight Committee', considers an annual report submitted by the RRP.

10.8. The Authority was asked to note the activity conducted by the RRP, the steps taken to improve data research and the process in place for accessing data.

Decision

10.9. Members discussed the paper and stressed the importance of the renewed energy and focus on data research. Members highlighted possible links the Authority could make with other organisations in the field of data research, to increase stakeholder engagement in this area. Further information would be provided to the Authority in future.

10.10. Members noted the progress made in the last year and the plans to improve things further in future.

10.11. The Chair noted this was the last meeting of the Head of Research and Intelligence and thanked her and the whole Intelligence team for the progress they had made.

11. Estates update

11.1. The Director of Finance and Resources presented a paper setting out the circumstances around the relocation of the HFEA away from Spring Gardens in 2020. The move was being managed as part of a wider DHSC programme to coordinate the movement of several of its ALBs to outer London hubs.

11.2. The Director of Finance and Resources provided an update to members on the DHSC programme and the recommendation that Stratford was the preferred future location.

11.3. Members noted the proposed governance timeline, although they also noted that a meeting that day had suggested this could be delayed from the original DHSC plans. The most recent steering committee meeting had also agreed that the Stratford project would now be managed as a two-stage approach, which may mitigate some possible delays for the HFEA. However, the required sign-off process may mean further delays.

11.4. Members heard that the formal business case decision would be brought to a later Authority meeting.

Decision

11.5. The members noted the above points, and positively acknowledged the progress that had been made to date.

12. Any other business

12.1. The Chair noted that this was Director of Compliance and Information, Nick Jones' last Authority meeting before he departed to become CEO of the General Chiropractic Council. The Chair thanked Nick on behalf of the Authority and the Chief Executive also expressed his thanks on behalf of staff.

12.2. Members added their thanks on behalf of the sector, particularly noting his positive outlook and problem-solving abilities, which had been appreciated greatly.

13. Chair's signature

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

Signature

Chair

Date

Performance report

Strategic delivery:	☒ Safe, ethical, effective treatment	☒ Consistent outcomes and support	☒ Improving standards through intelligence
Details:			
Meeting	Authority		
Agenda item	6		
Paper number	HFEA (13/03/2019) 908		
Meeting date	13 March 2019		
Author	Helen Crutcher, Risk and Business Planning Manager		
Output:			
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	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: HFEA performance scorecard		

1. Introduction

1.1. The attached paper summarises our performance up to the end of January 2019.

1.2. Further updates on performance and trends since this point will be provided verbally in the meeting.

2. Reviewing performance

2.1. SMT reviewed the December and January performance data at its 25 February 2019 meeting.

2.2. Overall performance is good. Three indicators are currently classified as red. There is a full discussion of these in the performance report, provided in the annex to this paper.

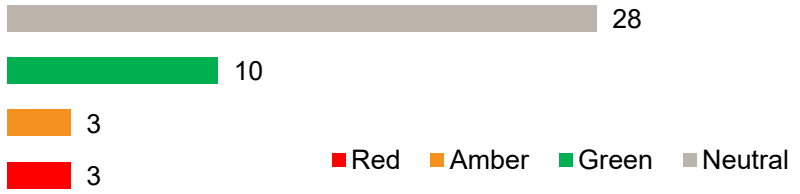
3. Recommendation

3.1. The Authority is asked to note the latest performance report.

HFEA performance scorecard

Dashboard – January data

Overall performance – RAG status (all indicators)



People – capacity

Establishment leavers per month
(% turnover for the year).
KPI: 5 - 15% establishment turnover

⇩
Leavers: 1
(23.6%)

Engagement – Website traffic

Website sessions this month
Arrow tracks performance since last month

⇧
62,744

Licensing end-to-end

Length of the whole inspection and licensing process
KPI: ≤ 70 working days

★
51 working days

Money – budget

Summary Financial Position - 31 January 2019

	Year to Date			Full Year		
	Actual	Budget	Variance	Forecast	Budget	Variance
	£'000	£'000	£'000	£'000	£'000	£'000
Income	**5,321**	**5,261**	**(60)**	**6,933**	**6,490**	**(442)**
Expenditure	**5,294**	**5,181**	**(113)**	**6,624**	**6,270**	**(332)**
TOTAL Surplus / (Deficit)	**27**	**80**	**(53)**	**309**	**221**	**88**

Commentary

We are reporting a small surplus of £27k as at the end of January. This is a drop from that reported in December of £219k due to the increase in expenditure relating to IT and Contingent Labour.
The full year forecast is a surplus of £309k which is £88k higher than budgeted. This position takes into account final plans from Directorates and provisions for work relating to our telecoms and non-capitalisable IT systems.

Overall performance – January 2019

SMT reviewed the overall performance picture on 25 February. There were three red indicators. Overall, January performance was generally good.

January saw the highest number of visits to the new website since it launched. January is usually the month with the most traffic, but this increase was also driven by the launch of the joint statement on treatment add-ons. January also saw a significant increase in visits to social media channels.

Red indicators

The three red key performance indicators (KPIs) shown in the 'overall status - performance indicators' bar chart on the dashboard are as follows:

People

- Establishment ('unplanned') leavers per month. Our target is to remain within 5 - 15% headcount turnover for the year. Performance in January was 23.6%. The overall planned and unplanned leavers for the year is 25.2%.

Licensing decisions approved and finalised

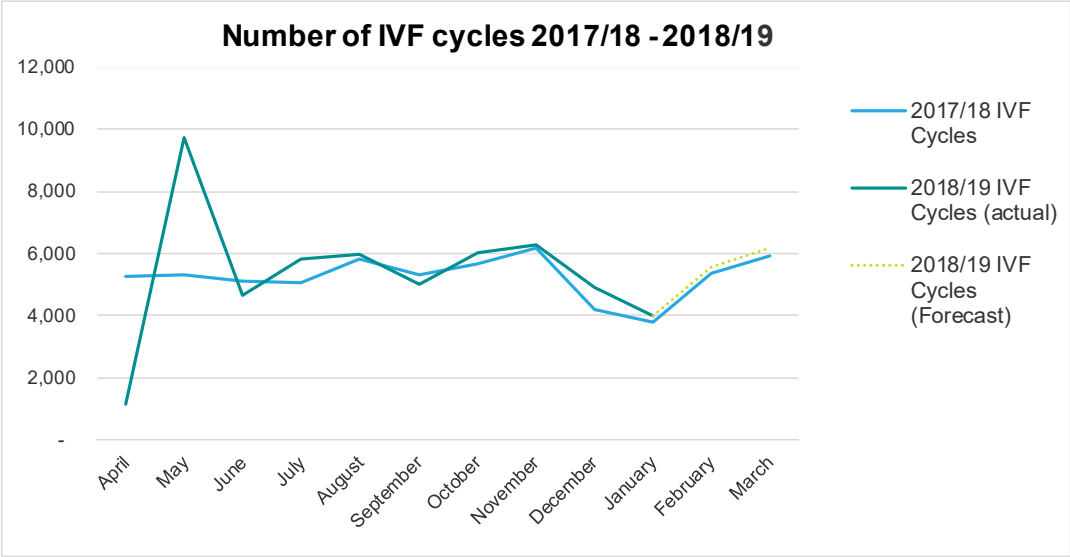
- Average number of working days between SAC date and minutes being finalised (signed by the Chair). The target for SAC minutes is 100% in 20 working days but in January average performance was just over at 21 working days (only 16% of the items were finalised within the 20 working day target). Increasingly complex SAC items are adding to delays in finalising these minutes

PGD processing

- 3 month rolling average figure – Percentage of all PGD applications processed within 3 months for the three months to date. Our target is 100% within 66 working days, but in the four months to January this has remained at 0% (none of the 12 due for completion in the three months to January were done), with an average processing time for those that had been completed of 83 working days.

Budget status – January data

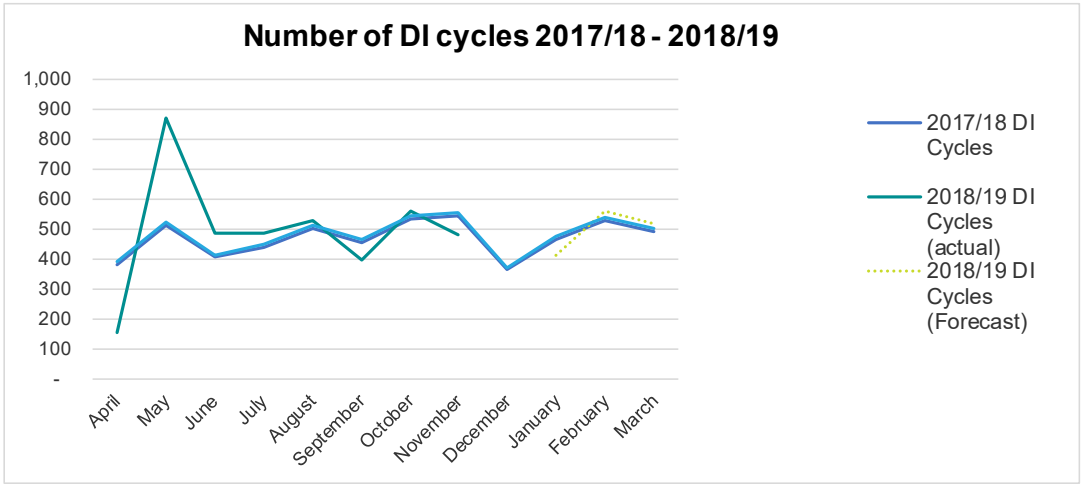
2018/19 Income



IVF Cycles	YTD		YE / Forecast	
	Volume	£	Volume	£
2017/18 IVF Cycles	51,676	4,134,080	62,969	5,037,520
2018/19 IVF Cycles	53,568	4,285,440	65,274	5,221,957
Variance	1,892	151,360	2,305	184,437

The year to date position shows an increase of 3.7% in IVF activity over the same period last year, this has increased since we reported at the end of Q3 due to January 2019 treatment volumes being 5% higher than those from January 2018. As our budget for 2018/19 anticipated a 2% increase on 2017/18 volumes, current volumes would suggest full year income of from IVF fees of £5,221k - £84k higher than budgeted and £184k higher than 2017/18

We will continue to review our income forecast monthly over the last quarter and consider the impact of this level of increased activity as we prepare 2019/20 budgets



DI Cycles	YTD		YE / Forecast	
	Volume	£	Volume	£
2017/18 DI Cycles	4,590	172,125	5,607	210,263
2018/19 DI Cycles	4,836	181,350	5,907	221,513
Variance	246	9,225	300	11,250

Year to date, the volume of DI treatment cycles reported is 5% higher than for the same period in 2017/18. DI activity for January (un-adjusted) is lower than the same period last year.

Our year end position anticipates current activity levels remaining broadly constant and would result in c £11k of additional income this financial year.

HFEA Income & Expenditure — Jan-2019

	Year to Date			Full Year		
	Actual £'000	Budget £'000	Variance £'000	Forecast £'000	Budget £'000	Variance £'000
Income						
Grant-in-aid	700	700	-	934	934	-
Licence Fees	4,493	4,443	(50)	5,510	5,416	(94)
Other Income	12	-	(12)	12	-	(12)
Seconded Salary reimbursed	116	117	1	477	141	(337)
Total Income	5,321	5,261	(60)	**6,933**	**6,490**	**(442)**
Revenue Costs						
Salaries (excluding Authority)	3,456	3,259	(197)	4,121	3,911	(210)
Staff Travel & Subsistence	109	137	27	160	162	2
Other Staff Costs	109	105	(5)	131	126	(5)
Authority & Other Committees costs	199	237	38	255	280	25
Facilities Costs incl non-cash	581	577	(3)	715	710	(5)
IT Costs	336	178	(157)	543	211	(310)
Legal / Professional Fees	286	460	174	396	585	189
Other Costs	218	227	9	303	285	(19)
Total Revenue Costs	**5,294**	**5,181**	**(113)**	**6,624**	**6,270**	**(332)**
TOTAL Surplus / (Deficit)	**27**	**80**	**(53)**	**309**	**221**	**88**

Management commentary

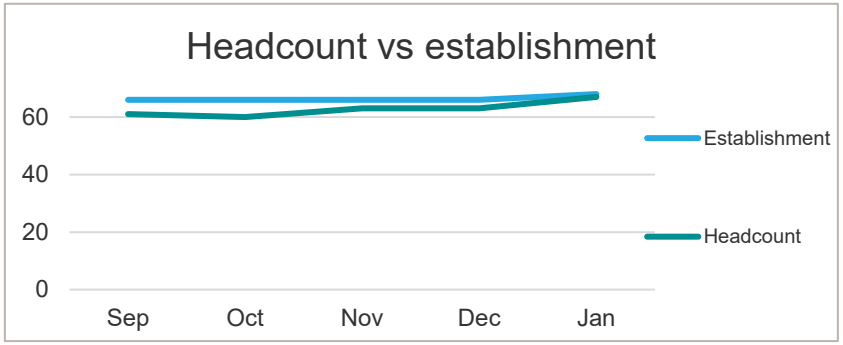
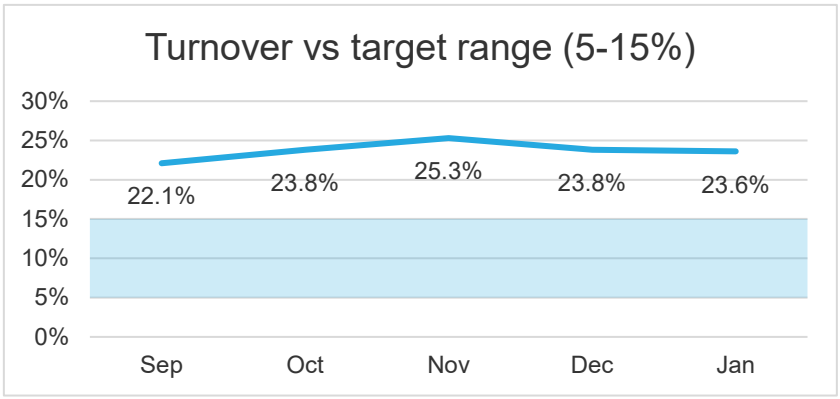
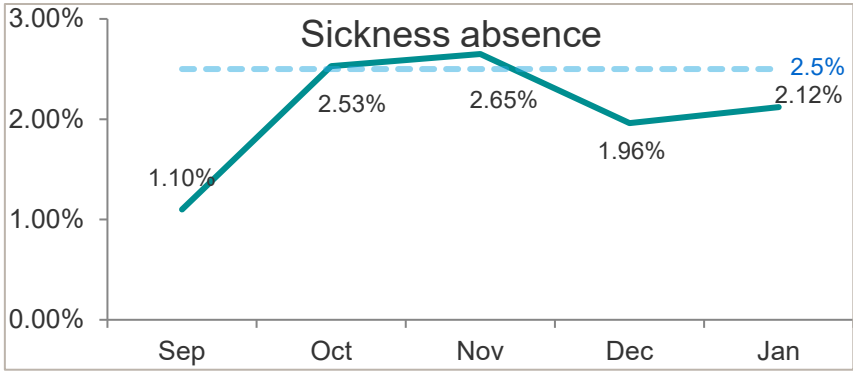
Income.
Year to date income is **£50k** higher than budgeted for due to increased activity in treatment fees and EUTD fees. A small adjustment has been made to the year end forecast reflecting the movement in volumes.

Expenditure.
Year to date expenditure is above our budget by **£113k** (2%). Below are details of our material variances:

Staff costs including Temporary staff - £194k above budget - a result of overspends on agency staff (£423k) offset by underspends in salary and on-costs (national insurance and pension).
Facilities including non-cash - £3k above budget - cost of additional space rented in Q1-6 offset against reduced depreciation charges which relate to the cost of PRISM which have not yet been capitalised.
IT Costs - £157k over budget - due to significant overspends within IT Consultancy/Support costs (£77k), IT subscriptions (£10k) and Consumables (£76k) which is the result of recent necessary pieces of work agreed by SMT.
Legal and Professional fees - **£174k under budget**- The overall underspend in this area relates to the litigation contingency funds that were held to meet a Court of Appeal hearing. This has since not materialised, and the funds have been redeployed.
Authority and Other Costs £38k - underspends relate to costs budgeted for external advisers of £12k, cost of appeals £10k and Venue Hire costs £12k which have not materialised.
Other Costs - £9k - underspends are within the Strategy directorate totalling (£29k) offset by a nil variance within Compliance. The most significant area under budget remains within Stakeholder Engagement (£14k) and Patient Survey (£12k) which is due to timing of billing.

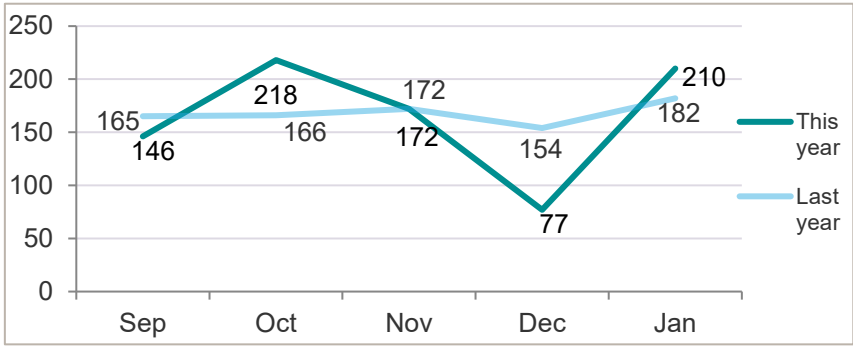
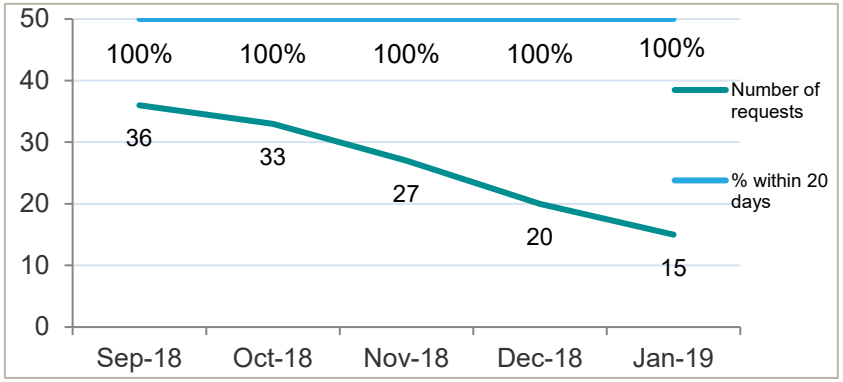
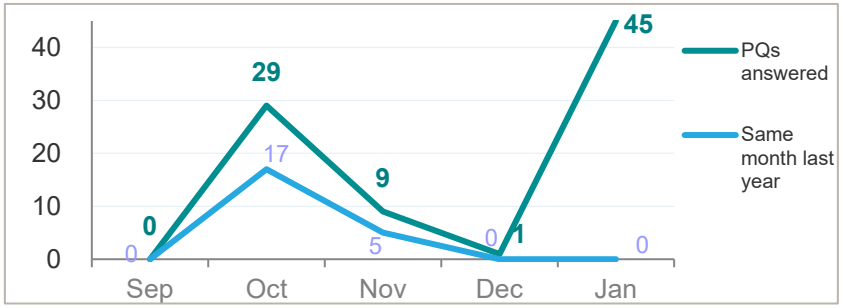
Forecast Outturn.
Overall, we are forecasting a surplus **£309k** against budget of **£221k** - an increase of **£88k**. Currently, our forecast expenditure takes account of all agreed spend on IT, Consultancy and other support costs.

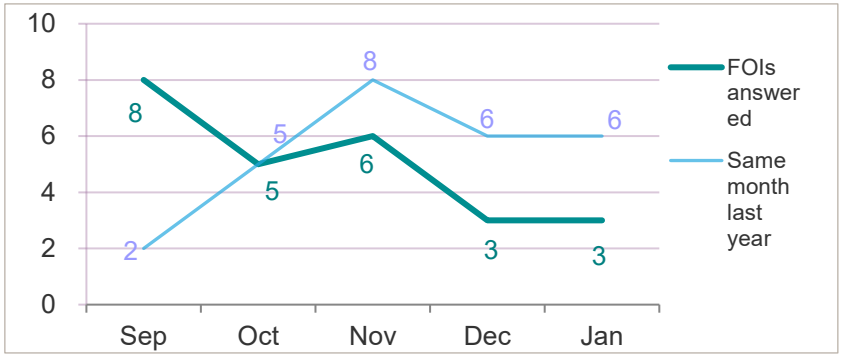
People – key performance and volume indicators

Indicator	Score	RAG	Recent trend[1]	Notes
Current headcount by month Staff in post/headcount	67/68	⇧		Overall volume (capacity) indicator.
Turnover: Establishment ('unplanned') leavers (% establishment turnover for the year). This is done monthly for the rolling year to date.	23.6%	⇩		KPI range: 5-15% turnover for the rolling year The public-sector average is 10.9% (Xpert HR 2017) on which we base our target.
Staff sickness absence rate (%) per month.	2.12%	⇧		KPI: Absence rate of ≤ 2.5%. Average rate of public sector sickness absence is 2.6% versus 1.7% for the private sector. (Source: ONS data 2017)

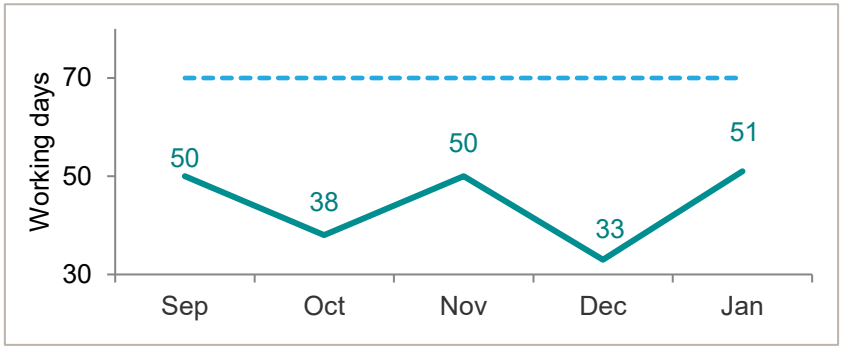
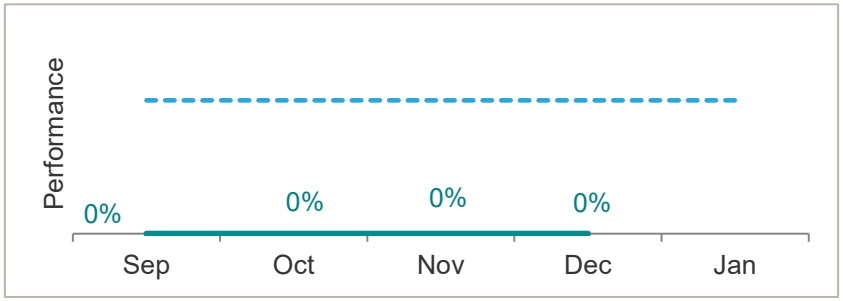
[1] KPIs, where applicable, are shown as a blue dashed line in graphs. This line may be invisible when performance and target are identical (eg, 100%). Our establishment turnover KPI is a range, which is shown as a blue band in the graph.

Information – key performance and volume indicators

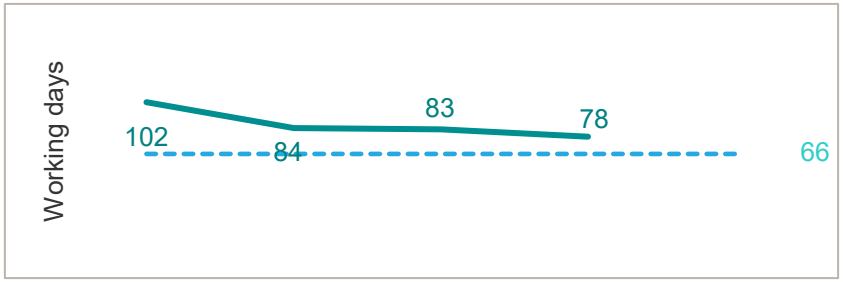
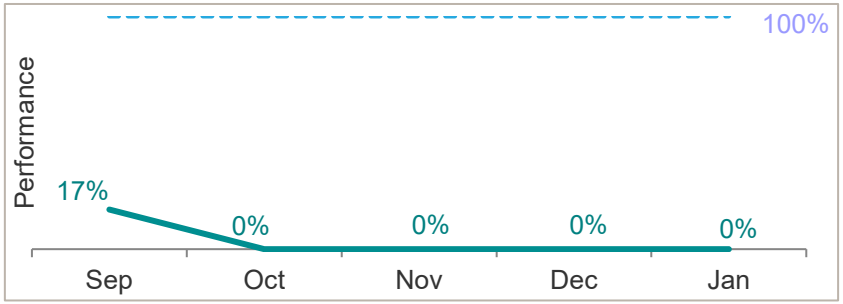
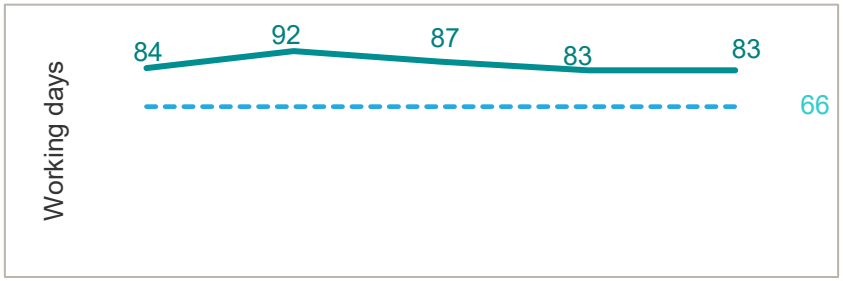
Indicator	Score	RAG	Recent trend	Notes
Number of emailed public enquiries received (compared with same month last year)	210	⇧		Volume indicator.
Percentage of Opening the Register requests responded to within 20 working days	100%	★		KPI: 100% of complete OTR requests to be responded to within 20 working days (excluding counselling time)
Number of requests for contributions to Parliamentary questions	45	⇧		Volume indicator. The number of PQs is large this month because the requestor wanted details of number of eggs collected for multiple categories, fresh and frozen cycles and age bands.

Indicator	Score	RAG	Recent trend	Notes
Number of Freedom of Information (FOI) requests	3	⇔		Volume indicator.

Inspection and licensing process – key performance and volume indicators

Indicator	Score	RAG	Recent trend[2]	Notes
Average number of working days taken for the whole licensing process, from the day of inspection to the decision being finalised (signed off by the chair)	51	★		KPI: Less than or equal to 70 working days.
Monthly percentage of PGD applications processed within three months (66 working days).	-% (0/0)	N/A		KPI: 100% processed (i.e. considered by SAC) within three months (66 working days) of receipt of completed application. No applications were due to be completed in January, so there is no data to report.

[2] KPIs, where applicable, are shown as a blue dashed line in graphs. This line may be invisible when performance and target are identical (eg, 100%). Our establishment turnover KPI is a range, which is shown as a blue band in the graph.

Indicator	Score	RAG	Recent trend[2]	Notes
Average number of working days taken (in the month).	N/A	-		
Cumulative 3 month (rolling average) percentage of PGD applications processed within three month KPI (66 working days)	0% (0/12)	⇔		KPI: As above.
Average number of working days taken (cumulative 3 month picture).	83	⇔		

Effective governance

Strategic delivery:	☒ Safe, ethical, effective treatment	☒ Consistent outcomes and support	☐ Improving standards through intelligence
Details:			
Meeting	Authority		
Agenda item	7		
Paper number	HFEA (13/03/2019) 909		
Meeting date	13 March 2019		
Author	Paula Robinson, Head of Planning and Governance		
Output:			
For information or decision?	For information.		
Recommendation	For comment.		
Resource implications	In budget.		
Implementation date	Ongoing.		
Communication(s)	-		
Organisational risk	☒ Low	☐ Medium	☐ High
Annexes	-		

1. Introduction

1.1. As an effective and trusted regulator, the HFEA needs high quality decision making processes which are clear to clinics, patients and the wider public. To achieve that, we have a number of committees, with clear instructions from the Authority about how they should make decisions. The rules governing decision making are set out in our standing orders.

1.2. The Authority is committed to an annual review of our governance arrangements, consisting of:

- a self-review of each committee's effectiveness; and
- a review of our standing orders.

1.3. This year, we amended Standing Orders at the January 2019 Authority meeting, to make minor changes to several of our committee terms of reference. The changes were implemented on 31 January 2019.

2. Annual review of committee effectiveness

2.1. All committees are required annually to reflect on their own effectiveness. For this we use a standard checklist framework. Between October 2018 and February 2019, this exercise was conducted by the Licence Committee, the Statutory Approvals Committee, the Executive Licensing Panel and the Scientific and Clinical Advances Advisory Committee.

2.2. There is a specific effectiveness tool for Audit Committees, produced by the National Audit Office which was used by the Audit and Governance Committee.

2.3. Generally the feedback from committees has been positive, with some improvement points raised. The reviews are summarised below.

Committee	Positives	Areas for improvement
Audit and Governance Committee	Membership skills and knowledge. Effective regular oversight. Well supported, with constructive and transparent dialogue with staff about areas of risk and governance. Role and scope of Committee well defined and understood. Communication and reporting are of high quality.	Considering succession planning for the future. A member with particular IT skills may be beneficial. For future consideration. The HFEA's resilience to fraud and whistleblowing arrangements for staff both identified as areas of interest for the next meeting. Where relevant, papers should include an assurance map of risks, controls and mitigations, in keeping with our approach to risk assurance mapping.

Committee	Positives	Areas for improvement
Licence Committee	Committee role and scope clear. Membership and skill mix are good, and member turnover has been well managed. Good quality of discussion at meetings, with effective Chairing. Declarations of interest properly made when applicable. Good meeting support and minuting arrangements.	High numbers of research items – consideration to be given to handling. Weighting of agendas is variable (which is unavoidable at times, but staff are looking at whether some improvements in scheduling are possible, to help to balance out agendas). Consider refining the process for considering whether to schedule items directly to Licence Committee rather than ELP, in the event that inspection findings indicate that a longer follow-up process with the clinic may be needed. Videoconferencing capability for meetings would be preferable (staff are working on enhancing our Skype capability – testing is in progress). Suggestions were also made for additional evidence that could be provided to the committee for some of the more uncommon item types, and for returning adjourned items to include a listing of documents that were included for the original consideration. Recommendations to be summarised on agendas, so as to draw them out clearly from the report.
Executive Licensing Panel	Committee role and scope well defined and understood. Membership balance and capacity in place, including new members. Good quality of meeting support and discussions, with effective Chairing.	Consider whether variations to change a PR could be performed by the Licensing Officer. Weighting of agendas is variable (see above). Suggestion of assigning a back-up member to each meeting in case of late apologies or urgent work pressures. Several suggestions were also made regarding the structure and content of inspection reports, which will be fed back to the inspectorate.
Statutory Approvals Committee	Committee role and scope well defined and understood. Good participation and understanding from members. Sufficient flexibility, and experience is	Would ultimately prefer the committee to be smaller if this is possible in the future. But we have arrived at a good working arrangement. For decisions on special directions for import/export, the Committee would appreciate further information on the

Committee	Positives	Areas for improvement
	being maintained and enhanced for the future. Business is large, but manageable. Good balance of members attained at every meeting. Effective learning curve on mitochondrial donation decisions. Effective Chairing and summarising of complex discussion points.	availability of donor eggs, particularly in the UK. Videoconferencing capability for meetings would be preferable (see above). The Committee would prefer to receive the minutes more quickly, but also understand that there are external dependencies involved. Consider submitting a brief annual report to Authority as some other committees do. Work being done to improve quality and consistency in papers is appreciated. Meetings being held in the HFEA's offices is preferred where possible.
Scientific and Clinical Advances Advisory Committee	The Committee engages well with the relevant issues. Scope is clear. High quaity discussions, with the right speakers, tools and advice. Good communication with the Authority; attendance by the Chair and Chief Executive is valued. Excellent secretariat support and paper quality.	Additional expertise is being recruited to assist with growth areas such as big data and developmental biology. Staff were asked to review the frequency and length of meetings, and to consider arrangements in the event that new research becomes available between meetings (eg email communication if new information comes to light about treatment add-ons). The potential for conflicts of interest was noted, since the membership included leading experts in their fields. The potential for a single view to dominate a discussion was also noted.

3. Recommendation

3.1. The Authority is asked to:

- Note the feedback from the annual reviews of committee effectiveness, and the action points for each committee.

Finance and Business Plan update 2019/20

Strategic delivery:	☒ Safe, ethical, effective treatment	☒ Consistent outcomes and support	☒ Improving standards through intelligence
Details:			
Meeting	Authority		
Agenda item	8		
Paper number	HFEA (13/03/2019) 910		
Meeting date	13 March 2019		
Author	Richard Sydee, Director of Resources		
Output:			
For information or decision?	For decision		
Recommendation	To note information about the budget and the business plan, and to agree to the proposed processes for signing off the business plan and budget (see section 5.1).		
Resource implications	In budget		
Implementation date	April 2019		
Communication(s)	The business plan will be published on our website.		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	-		

1. Introduction

1.1. This paper provides an update to the Authority on the current financial and business plans for the 2019/20 business year.

1.2. Income forecasting, and Directorate level budgets, will be refined following the Authority meeting and be subject to the maturation of the planning assumptions and contingencies set out below.

2. Income forecasting

2.1. The 2018/19 financial year has, to date, seen treatment volumes increase in line with the forecast model developed at the start of 2018. IVF treatment volumes to January 2019 are 3.7% higher than for the same period in the 2017/18 financial year and our forecast to the end of the financial year is for this trend will continue, resulting in IVF treatment volumes of 65,274 – 2,305 higher than 2017/18.

2.2. In planning for 2019/20 we must consider whether the underlying assumptions of the forecasting model remain true and whether there is actual or anecdotal evidence that the broader demographic and economic conditions will change during the next financial year.

2.3. There has been no change in the underlying demographic assumptions we presented last financial year and overall the likely demographic based demand for IVF treatment is likely to increase in the medium term. We therefore propose no alteration to the demand profile currently within the model and that over the next 10 years we will likely see continued modest growth in treatment volumes.

2.4. Economic factors are more complex and more likely to impact income receipts in the short term. There are no directly observable economic trends that suggest a fall in demand for private IVF treatments over the next financial year, and although we continue to observe press coverage of Commissioning decisions regarding IVF treatment we have not seen any material change to activity in NHS facilities.

2.5. As with every financial year we must choose between basing our income planning on the recent trend of volume growth in treatment cycles, or to plan more prudently to ensure that should we see a drop in treatment volumes the HFEA will be able to meet it's financial commitments from its annual receipts. Although the model would suggest IVF treatment volumes of 66,579 for 2019/20 for planning purposes we have used an adjusted volume of 64,228 – which represent 2% growth on our 2018/19 budget. This results in a treatment income forecast of £5.35m (which also includes DI treatment income) for 2019/20 and total income, including grant in aid from the Department, of £6.96m

2.6. For planning purposes we have budgeted based on the lower 2018/19 assumption.

3. 2019/20 Budget

3.1. Our 2019/20 expenditure budget is based broadly on our 2018/19 outturn with some changes relating to inflationary pressures and an increase in depreciation and amortisation charges resulting for the conclusion of the Prism programme.

3.2. We have, in line with recent years, retained a reserve against litigation of c£300k, As with this financial year we will develop plans to utilise these funds should they not be required against legal costs.

3.3. Our budget planning still retains some uncertainty relating to staff costs. Recently announced increases in the employer contributions to the Civil Service Pension Scheme could increase staff costs by 6%. This is a wider issue than just HFEA and we await news from the Department on whether these costs will be met in part, or in full, from central funding. As such we have not included the costs in this initial plan.

3.4. Given our prudent income assumptions, and the legal contingency we have maintained, the budget presented below meets all the planned business delivery assumptions for the 2019/20 business year and provides a small buffer should treatment volumes drop.

DRAFT 2019/20 BUDGET

	2018/19 Outturn	2019/20 Budget
Budgeted Income	**£k**	**£k**
Grant in Aid	934	934
Ring-fenced RDEL	337	504
Treatment Fee Income	5,447	5,353
Other income	216	168
	6,933	**6,958**
Budgeted expenditure		
Wages and salaries	3,600	3,968
Authority allowances	154	168
Temporary staff costs	520	103
Other costs	708	610
Info Tech and Telecomms	543	541
Professonal Fees	396	402
Accommodation	372	372
Depreciation	329	503
Legal Contingency	309	291
	6,933	**6,958**

3.5. Subject to the Authority's view on these assumptions we will begin to finalise Directorate level budgets through to the end of March, taking appropriate measures to limit our financial commitments until the pension contribution issue is resolved.

3.6. As with previous years we will develop a number of options to utilise any emerging surplus, with options in direct support of our business plan objectives during the business year.

4. Business Plan 2019/2020

4.1. The Authority agreed a draft of the new business plan for 2019-2020 at its November meeting. Since that time, the content has been developed further and we have added a looking back section, to review what we have achieved in 2018/19. The Corporate Management Group (CMG)

has reviewed the activities in the business plan to make sure that we can deliver within resources and service delivery plans are now being refined.

EU exit content

4.2. As the UK leaves the EU, the new context will require the HFEA to work with DHSC and its arm's length bodies to manage any effects of EU Exit on the health and care system. As the UK regulator, we will play a key role in maintaining the quality and safety of reproductive tissues and cells used in fertility treatments and research, and in supporting licensed clinics to be ready for EU Exit.

4.3. We will be reflecting the activities related to our EU exit role in the business plan, so that it is clear we will be maintaining the same standards and objectives following EU exit. We are in communication with DHSC about the wording to be used and are awaiting a final approved version of this content. We have seen and commented on a draft of this wording which sets out:

- The impact of EU exit on legislation, including the new position of the UK as a third country under the EU Directives
- Our role in ensuring that we and licensed centres are prepared for exit and the activities we will undertake to achieve this
- Our role in providing appropriate guidance to patients and the sector and how we will do this

Year-end content

4.4. In addition to EU exit content, some other content can only be added after year end. This includes performance data, HR benchmarking information, and various other facts and figures that provide a complete picture of the previous business year. We will add this data in April.

Sign-off and publication

4.5. In previous years we have brought the near final business plan along with the budget to the March Authority meeting for sign off. Given wider uncertainties, we have decided not to bring the more developed plan to this meeting.

4.6. We have requested confirmation from DHSC about the process for departmental sign-of the business plan. The draft has not yet been reviewed by DHSC and we still await this timetable. The Department are aware that the plan will need sign-off by the Authority in advance of publication.

4.7. Authority has already agreed the activities section of the business plan, which constitutes the most significant part of the content. This paper also provides the basis for an agreed budget position pending agreement by DHSC.

4.8. If circumstances were to change and EU exit implications proved to impact the business plan more significantly and we needed to make adjustments, we could take an item to the May Authority meeting with a revised plan. Given these circumstances, we propose to await the remaining content, add year-end data, and circulate for Authority sign off via email.

5. Recommendation

5.1. The Authority is asked to:

- note the assumptions behind the 2019/20 income and expenditure forecasts

- note the unusual circumstances around business plan sign-off this year and the imminent addition of further content related to EU exit and year-end
- agree to review and sign off further content via email, though any major revisions to previously agreed content will be brought before the Authority at its May meeting
- agree that DHSC sign-off of the business plan and the associated budget according to their timetable, after which the business plan will be published on our website.

Strategy development - 2020-2023

Strategic delivery:	☒ Safe, ethical, effective treatment	☒ Consistent outcomes and support	☒ Improving standards through intelligence
Details:			
Meeting	Authority		
Agenda item	10		
Paper number	HFEA (13/03/2019) 911		
Meeting date	13 March 2019		
Author	Paula Robinson, Head of Planning and Governance Helen Crutcher, Risk and Business Planning Manager		
Output:			
For information or decision?	For decision		
Recommendation	To comment on the emerging shape of the strategy, and the proposals for consultation and engagement during 2019.		
Resource implications			
Implementation date	1 April 2020		
Communication(s)			
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	None.		

1. Background

1.1. We are about to start the final business year of the current strategy for 2017-2020, where we will build on the progress made and finish work begun in years one and two.

1.2. This paper aims to summarise earlier informal discussions about our next strategy, which we plan to launch in April 2020.

1.3. All good conversations about strategy begin not from an operational premise, but an aspirational one. The central questions are 'how do we want the world to be' and then 'how can we best succeed in moving the world in that direction'.

1.4. With this in mind, our early conversations, summarised in this paper, have focused on our wider operating environment and the ways in which the HFEA can make a positive difference to the quality of care experienced by patients.

2. The strategic context

2.1. We've already had some early conversations to understand the delivery environment for our next strategy, including an initial Authority workshop in January. The following is a summary of the key environmental influences and trends that have shaped our thinking at this early stage, and that will influence our future strategic positioning.

Technological, scientific and social developments

2.2. There have been many developments over the past years in the field of genetic research and we have noted the effects of this in our authorisations of conditions for Preimplantation Genetic Diagnosis (PGD), where we have seen an increase in the number of multi-type and rarer conditions. The public are more aware of the possibilities of genetics, with home genetic testing kits becoming increasingly popular and genetic medicine also coming to the fore in the media, with the promise of 'precision' or 'personalised' medicine becoming available on the NHS for certain conditions. We expect this trend to continue, and have already begun to consider the impact of these developments in various areas of our work, including the need to provide clear guidance to patients and clinics.

2.3. The work we have done to date to provide better information for patients about add-ons has been welcomed, and we want to continue to build on this.

Legal and Political developments

2.4. The HFE Act may well come up for review during the next strategy, which will present a range of opportunities and challenges for us.

2.5. However, regardless of a bigger review, there are some immediate issues which are developing that we will need to be prepared for, including possible changes to surrogacy law which may mean that the HFEA has a wider role to play in surrogacy arrangements.

2.6. In addition, the post EU Exit landscape will become clearer over the coming months.

New work

2.7. In 2020 the first children born after the removal of donor anonymity (in April 2005) will turn 16 and will be able to access non-identifying information about their donors; and in 2023, when they turn 18, identifying information will be available to them. Although we currently have an 'Opening the Register' service that provides available information to donors and donor conceived people, the volumes of requests are likely to increase significantly from 2023 (particularly) onwards, and the needs of these young people and their donors will need to be considered when developing our capability to deliver the future service levels required.

Regulatory remit

2.8. As a regulator, our remit could be narrowly interpreted as issuing licenses and conducting regular inspections. However, given that our area of regulation goes to the heart of a range of personal issues relating to parenthood, family, genetics and research, we have interpreted our role more broadly to enable public discussion of these issues to take place in an informed way.

2.9. In our current strategy, we have been bold in addressing certain issues such as patient support and leadership. While broadly within our remit, the Act does not specify these topics, nor set out how we should address them, and so we have often taken a collaborative approach (with the sector and professional bodies) in order to achieve our strategic vision for the quality of care received by patients, and maximise our overall impact.

2.10. Some of our biggest successes during the current strategic period have come when we worked together with others. Whether it was the work with other organisations on treatment add-ons or bringing clinic Persons Responsible together to talk about leadership, we know we can have more impact and make more targeted interventions when we take a collaborative approach. This will continue to be an important way of working for us, particularly in key strategic areas at the edge of our current regulatory remit. The future regulatory model will be about more than setting standards: we will work with others to achieve cultural and behavioural change. We think that we should shape the next strategy with this in mind.

2.11. We want to continue to demonstrate bold and ambitious leadership, raising the bar for sector performance, and being both collaborative and outward-looking in our approach to regulation.

3. Possible strategic themes

3.1. The following summarises our early thoughts about what our next strategy might focus on. This is not an exhaustive list of everything we might do, but it reflects both recent discussions and the wider trends set out above.

Ethical and effective care

3.2. Following on from our current work with clinics on leadership, and our strategy focus on the evidence for add-ons, we want to focus squarely on ethical leadership and treatment in our new strategy. We want the evidence-base for treatments to be transparent and available to patients, so that their treatment decisions are fully informed. We want to take our existing work further, ensuring consent is properly taken at all stages of treatment, and finding other ways to ensure that the sector fully considers the ethics and evidence for what they offer to patients.

3.3. We also think that male fertility, and the treatment of partners, deserves a stronger focus, and that the information and care afforded to men should be improved.

3.4. Research is another key area that can lead to more effective care. The HFEA holds the oldest and largest database of fertility treatments in the world. We have made some headway on data research under our current strategy, starting to reach out to groups of researchers and reviewing the way we authorise data research using the Register. Part of championing research will be to continue to encourage data research that uses the Register and other information sources, to get the most out of this valuable resource.

3.5. We also know that quality clinical research and safe and ethical innovation will be crucial for improving outcomes of treatment for patients. By encouraging and enabling centres to do more clinical trials and licensed research, and by working to identify and remove barriers to research, we can have a real impact on the development and improvement of treatments for individual patients, and ultimately on their chances of success.

3.6. We can also use our own data and intelligence to positive effect in other ways. For example, to champion consistency of access to fertility treatment, exploring the cost perspective and looking at the cost effectiveness of treatment for the NHS, uncovering the factors that contribute to variations between clinics (eg, in success rates or propensity to refer patients abroad for donor treatment), and to inform inspections, enabling us to challenge poor or ineffective practices while setting out what a 'gold standard' clinic looks like, over and above simply being compliant.

Reaching people before they begin treatment

3.7. Equipping people with the information that they need at the time that they need it is key to helping them to understand their options and make informed choices about their fertility and treatment. We want to make sure that information and intelligence is available throughout treatment, but we recognise that the biggest information deficit is often beforehand, and that new or prospective patients (and their GPs) will not necessarily have insight into the initial choices patients need to make, or the differences between fertility treatment and other areas of medicine. To create new information flows for patients at the pre-treatment stage of their journey, we will need to consider fresh approaches, such as:

- Talking to representative bodies (for instance of GPs, who are otherwise difficult for us to access en masse) and further developing relationships with bodies such as royal colleges to understand how we may provide information and support to GPs, practice nurses and the wider public.
- Using social media and other channels to reach patients at the earliest possible stage.
- Expanding our earlier emotional support work to include support prior to treatment, where previously we have focused mainly on support during and after treatment.

Being future-ready

3.8. As set out earlier, there are several growing technological and social developments with the potential to have significant impacts on the fertility sector, and on people's views on their own fertility and genetics. An important part of the work that we do over the three years from 2020 – 2023 will be to prepare the organisation and the sector for these. Our stance will continue to be proactive, leading and collaborating to promote debate and champion important issues. Key areas will be:

- Genetics becoming a mainstream issue for the general public, encompassing genome research and the possibility of genetic modification of embryos, screening advances, direct to consumer DNA testing, DNA websites etc. The consequences may include a loss of anonymity, an increase in 'testing of the well', and patients who are not infertile entering into treatment at fertility clinics, for specific reasons related to genetics.
- Operational and structural readiness for donor conceived children born after the 2005 removal of donor anonymity contacting the HFEA, especially from 2023 onwards.
- Preparedness for a future legislative review (HFE Act, surrogacy, 10 year storage limit).

4. Strategic approach

4.1. Identifying actions will follow at a later stage of developing the strategy, once we have agreed our focus. Meanwhile, our initial discussions have already identified some of the key tactics we will need to adopt:

- Engagement, collaboration and partnering with other bodies will be key ways of working.
- We will need to find new channels and establish new relationships, to reach and educate new audiences (eg GPs and practice nurses, and patients who have not yet begun treatment).
- As a small public body, we need to magnify our impact through the ways we engage and communicate, including with clinics and clinic staff.
- Our growing intelligence resources will enable us to analyse and publish an expanded range of information, both for patients and the public, and for the sector, giving greater insight into performance variables.

5. Next steps

Further development of themes

5.1. The themes set out in this paper are a starting point. Over the coming weeks, we will need to consider how our aspirations align into structured aims and plans, and this will help us to develop consultation materials.

5.2. It is clear that whatever our areas of focus, we will be faced with hard choices about how far we can go in the next three years, what's achievable and what we think will have the greatest positive impact on quality for patients and the sector. A key step in making the strategy deliverable will also be further conversations with our staff, informed by this Authority discussion.

Consultation channels

5.3. We have several well-established channels already available to us, including our website and social media, and our regular twice-yearly stakeholder meetings with the Licensed Centres Panel, the Professional Stakeholders Group and the Association of Fertility Patient Organisations. In addition, we have recently begun a well-received series of events with PRs, focusing on leadership, and we have regular opportunities to converse with other key professional organisations such as the British Fertility Society.

5.4. As well as talking directly to our stakeholders and engaging through them with their networks about our strategy proposals at upcoming meetings and events (from May through to September this year), we can also consult and communicate about our developing strategy through:

- Our website (and our staff intranet for internal communications)
- social media
- Online surveys
- Our ongoing leadership-themed events with PRs
- Particular engagement with research PRs
- Engagement with relevant senior health leaders and key influencers.

5.5. In order to establish the current public view on key areas, we could also make good use, at a relatively small cost, of the YouGov panel set up during our recent national patient survey.

Indicative timetable

5.6. Our consultation arrangements will be informed by the discussions we have now. The broad timetable for fully developing our new strategy will be:

• March 2019	Discussion of themes
• April 2019	Develop strategy themes and associated activities
• May 2019	Authority agree draft strategy and vision for consultation
• May – September 2019	Consultation - engagement with stakeholders and staff
• September 2019	Report to Authority on consultation findings
• November 2019	Authority review draft strategy
• November – December 2019	Further develop strategy
• January 2020	Authority agree final strategy
• April 2020	Publication

6. Recommendation

6.1. The Authority is asked to:

- Comment on the context and themes set out in this paper, with a view to further shaping our aims and the broad tactics we should adopt to achieve those aims.
- Comment on the broad approach outlined for consulting stakeholders and the general public.

The use of electronic consents

Strategic delivery:	☒ Safe, ethical, effective treatment	☐ Consistent outcomes and support	☒ Improving standards through intelligence

Details:	
Meeting	Authority
Agenda item	11
Paper number	HFEA (13/03/2019) 912
Meeting date	13 March 2019
Author	Dina Halai, Scientific Policy Manager
Output:	
For information or decision?	For decision
Recommendation	The Authority is asked to: 1. consider current practice and use of electronic consent and; 2. the need for the HFEA to mandate and provide guidance on the use of electronic consent (as defined in paragraph 1.3)
Resource implications	Within budget
Implementation date	May 2019
Communication(s)	Code of Practice updates are highlighted in clinic focus articles
Organisational risk	☒ Low ☐ Medium ☐ High
Annexes	Annex A: Description of E-consent providers and their platforms

1. Background

1.1. Consent to fertility treatment is central to the conduct of legal and ethical fertility treatment and respects a person's right to determine what happens to them. Under the HFE Act 1990 (as amended), licensed centres must record any consent of a person whose consent is required under:

(a) Schedule 3 and Section 33B of the Human Fertilisation and Embryology Act 1990 (as amended); and

(b) Sections 37(1) and 44(1) of Part 2 of the Human Fertilisation and Embryology Act 2008

1.2. Centres are mandated to use the official HFEA forms found on the clinic portal and are provided guidance on meeting regulatory requirements via the Code of Practice. However, this guidance only envisaged paper-based consenting using HFEA consent forms, and so is not explicitly applicable to electronic consenting in various ways.

1.3. The term 'electronic consent' may refer to:

- completing and signing a HFEA consent form online in an editable PDF format
- a more sophisticated platform/programme for patients to record and sign the HFEA consent form
- use of videos or other means of electronic information provision to patients or donors about their treatment, donation, or other activities, including where provider platforms may collect information about the extent to which this information provision has been accessed
- consent information entered electronically to other systems for data processing, use or storage i.e. they interface with the clinic's own records system.

1.4. More and more businesses and individuals are using, or are seeking to use, electronic signatures and services. With an increasing number of services available digitally in addition to an increasing number of services going paperless eg banking, insurance etc, there will be continued growth to move towards using electronic systems.

1.5. Electronic consent was first discussed with the sector by the HFEA during the 2018 Code of Practice review workshops. We know that electronic consent methods for seeking, confirming and documenting informed consent have been adopted by three licensed centres in the UK either to supplement the traditional paper-based approach or, where appropriate, as a replacement for it. We know of one clinic who are considering using electronic consent methods in the future. We have established that some clinics are holding back on moving to electronic consent taking in the absence of explicit HFEA guidance. The recent interest amongst centres in electronic consent requires us to consider whether we should provide guidance on the use of new technology.

1.6. The argument in support of the use of electronic consent can be determined from the reasons cited for its use which include more convenience for clinic and patient, more able to facilitate remote completion, reduction in human error, providing more accessible formats for people with limited ability to read and the use of videos allow for a more engaging format for conveying information.

1.7. There have also been a number of legal parenthood cases in which anomalies with paper consent have resulted in dozens of patients having to seek declarations of legal parenthood. Whilst there

are different opinions as to the true cause of the clinic failings that led to these anomalies, certain anomalies are peculiar to a paper-based system of consent. Although not a panacea for all consent failings, electronic consent does present possibilities for avoiding at least some of the failings which have been a feature of these legal cases.

1.8. Moreover, electronic consent service providers based in the UK and the US have proactively approached the HFEA seeking guidance so that they can develop and market 'HFEA compliant' platforms in the UK. The HFEA met with three different providers of electronic consent and electronic signature solution to licensed fertility clinics to investigate the capabilities of the platforms, these were Fertility Consent, EngagedMD and DocuSign (full details of the companies and platforms can be found in Annex A). This showed that there are differences between platforms. HFEA will not endorse use of specific platforms within the proposed guidance.

2. Legal advice

2.1. The HFEA sought legal advice on a range of issues arising in this context, including whether for the purposes of Schedule 3 of the HFE Act 1990 a consent form completed electronically and with an electronic signature would satisfy the requirement for consent to be "in writing". The advice suggests that it can be read in a way that enables the use of electronic consent forms. However, the advice emphasises the importance of appropriate safeguards to secure that person giving consent, and only that person, is able to record and evidence their consent. Similarly, although untested by the Courts, the advice suggests that the legislation can be construed in a way which enables the use of electronic signatures, again with appropriate safeguards in place.

2.2. The HFEA has various powers to mandate compliance with certain requirements which includes a power to issue General Directions. Should the HFEA decide to provide guidance on the use of electronic consent, it could decide to impose certain conditions or require certain minimum criteria to be met through General Directions.

2.3. The HFEA sought further legal advice on the practical and operational issues that our research uncovered. The advice suggested that what is appropriate, reasonable and proportionate for the HFEA to include in guidance would depend in large part on how far it wishes to go in directing the use of electronic consent. To address a number of concerns and to ensure that any electronic system is safe and enables effective consent to be given, consideration would need to be given in relation to, for example:

- Dual factor authorisation ie verifying the identity of the person signing the form by requiring each patient or donor to have their own email address or being sent a personal pin for their own use only.
- Requiring clinics to be able to demonstrate that they have provided relevant information to a patient as part of a discussion and have not relied solely on informational videos on electronic consent platforms. This is due to concerns that videos may be generic and may not be tailored to the specific medical background of patients and systems may not allow patients to ask follow-up questions from clinicians.
- Regular testing and review of conditional logic, which allows parts of a form that are not relevant for a patient to be skipped, to reduce the risk of applicable questions being skipped in error.

- Requiring processes to be in place in clinics to ensure that patients are provided with the correct forms. This is due to concerns that electronic consent platforms assigning consent forms to patients might provide the wrong forms.
- Requiring that where a patient's circumstances have changed since the last time they had treatment, clinics should consider whether their consent is still valid (e.g. if a married couple separate, it would need to be established if they still consent to treatment or legal parenthood). Electronic consent platforms can be set up to supply consent forms at every treatment cycle or a specific timeframe.
- Requiring a documented process to manage withdrawal and change of consent outside the e-consent system until e-consent providers can accommodate this. This is due to doubts as to whether current versions of electronic consent platforms have the capability to facilitate varying or withdrawal of consent.

2.4. This would be the first Code guidance on the use of electronic consent, it is proposed that definitions of technical terms, including 'electronic consent', be included to avoid misinterpretation.

2.5. It is sensible that we consider whether we need to distinguish the different types of consent (ie consent to treatment, storage, donation, training and disclosure of information and legal parenthood) and provide different guidance in relation to each eg some have suggested that consent to legal parenthood should always be given in clinic on a paper consent form.

2.6. Following approval by the Authority of this recommendation to develop Code Guidance, we will bring a draft of wording for the Code of Practice update to the Authority for approval at the May 2019 meeting.

2.7. Looking further ahead we may wish to investigate options for a more robust approach for consenting including considering if paper-based consenting is, from the HFEA's perspective, the preferred default method going forward, particularly as over time the strengths of electronic consent versus paper consent could become so apparent that we may wish to change our guidance.

3. Recommendations

3.1. The Authority is asked to:

- consider current practice and use of electronic consent and;
- the need for the HFEA to explicitly mandate and provide guidance on the use of electronic consent (as defined in paragraph 1.3), using the already mandated official HFEA forms, within the Code of Practice. We would propose that any new guidance on electronic consent will include guidance to ensure that any electronic system is safe and enables effective consent to be given (as summarised in paragraphs 2.3-2.5). Depending on the decision made by the Authority, guidance will be drafted around using HFEA consent forms in an electronic format and will be incorporated into the next Code of Practice update and General Directions.

Annex A

Models of Electronic Consent

The HFEA has been in contact with companies that provide electronic consent platforms to licensed fertility clinics and had demonstrations of how each of the relevant platforms works in practice.

There are currently three platform providers that we are aware of and have spoken to: Fertility Consent, EngagedMD and DocuSign.

Below we set out in some detail how each of the respective models works in practice, based on our meetings with the above providers as well as information on their websites.

Fertility Consent

Fertility Consent is a UK based company who set up clinics with their own portal to carry out the consent process, this portal has a clinic facing interface and a patient facing interface. The patient and their partner (if they have one) is provided each with a separate login to the portal via email, or clinics can provide this on paper. The patient is emailed a Patient ID and a unique phrase which they need to use to access the portal, they then need to use both in order to create a unique password. Going forward, the patient can then access their secure area of the portal by logging in with their patient ID and their unique password.

Before the patient can access any consent forms, they need to watch several information videos which we understand have been produced by Fertility Consent with input from James Lawford Davies, and the system only lets the patient access the forms once they have ticked a box to say they watched and understood the material[1]. The video is what we would describe as a generic, high-level explanation of what is involved in fertility treatment but would not on its own, satisfy the statutory requirement to provide the patient with 'such relevant information as is proper'.

The patient is then required to fill in a registration document or questionnaire asking for their personal details such as their name, address and marital status etc. and this information is then used to pre-populate the relevant HFEA consent forms in the "About you" section[2,3] of the platform, although the provider explained that the platform could be tailored to source the relevant patient details from the clinic's electronic medical records system (a system such as IDEAS for example). The provider however prefers clinics to let patients provide this initial registration information as patients are in their view, less likely to make errors in the spelling of their name etc., whereas if the source of the information comes from the clinic, mistakes are perhaps more likely to have been made by clinic staff who have to key in patient information for dozens of patients. If the patient was to fill any of the information incorrectly on the questionnaire, or indeed if the information were taken from the clinic's own records where an error had been made, then it can be assumed that the error will be repeated if pre-population of forms is enabled. This could be a basis on which to require clinics to disable this function, requiring patients to type in their details manually every time.

[1] note: when we tested this, we could tick the box without watching the video

[2] note: if the patient says that they are single, they can't fill in any sections of the consent forms that ask for partner details, and there are also various other ways certain fields are inactivated via conditional logic

[3] The HFEA's current guidance on consent requires that clinics do not pre-populate consent forms

Once the registration questionnaire as described above is filled in, the patient then proceeds to complete HFEA consent forms. The system contains a library of HFEA consent forms.[4,5] The relevant forms, are by way of an algorithm, automatically assigned to the patients according to their demographics and fertility treatment type. The providers have however explained that at this point in their company development, the algorithm is programmed only to generate the relevant forms for 'basic' forms of treatment e.g. regular IVF. But where the patient's treatment pathway involves treatment options which are more complex, for example surrogacy or donor gametes, the necessary consent forms that the patient(s) and partner must complete need to be selected by the clinic and added to the patient's portal.

The patient fills in the consent forms on the portal providing answers to each section as they would do using a paper form. When the patient fills in the consent form, the system might require the patient to sign straightaway or the signature box may be disabled to require the patient to visit the clinic to sign the form. We were told that the system can be tailored to permit the completion and signing of all or some consent forms by the patient at home, or to enable completion of the form at home but signature at the clinic or both completion and signature of the forms in the clinic. This might be an area on which the HFEA should mandate particular practice. Once the patient has completed the consent forms, they can sign and save the form and after that it is with the clinic for processing and cannot be edited (i.e. is now read only). If it is later established that an error was made on a particular form or if a patient subsequently wished to change their consent, the existing forms could not be amended on the portal, new forms would need to be completed.

On the clinic facing portal, clinics can review all the forms on their dashboard and see what stage the patient is at with their consent form. They can also view an audit log tracing the activity on a patient's account, including when they logged in, what forms they signed, what videos they watched and for how long etc. The completed forms are stored on the platform. Each signed form is saved and digitally sealed in PDF format which if tampered with will automatically become invalidated. The electronic signature aspect of the platform is hosted by a company called Ascertia, the sealing of documents is also enabled by the Ascertia technology which allows verification of signatures for many years into the future, though if clinics wanted to extend seal validation to more than 50 years this can be provided at a cost. The Fertility Consent platform can also integrate with EMR systems used by fertility clinics, which would allow them to download the forms locally.

Fertility Consent allows each clinic to set individual rules for how long they want a consent form to be valid. A clinic could decide that they wanted a new WP form to be signed every cycle, but a WT form to be signed every 6 months, and so on. In this way new consent forms will only be issued to the patient's portal based on specific clinic/form rules. However, when an individual comes back to a clinic for a new treatment, their demographic registration form will be asked questions such as if the patient has had a baby since they last attended the clinic, if their marital status changed, if they are seeking treatment with someone new etc. If any changes are identified based on these questions the clinic will received an alert to inform them that they must check, and it may be necessary to issue new consent forms.

EngagedMD and DocuSign

EngagedMD is a US based company who set up clinics with their own portal to carry out the consent process. Clinics using EngagedMD include Leeds Fertility and Manchester Fertility. The clinic sets up accounts for patients using the patient's name and email and if they have a partner then the partner also set up with an account. The patient and partner must have separate email addresses. Based on the patient's treatment pathway, the clinic chooses which modules that patient should view, and which forms they need to sign. Modules include videos which aim to educate patient on medical matters, the IVF

[4] Though not every consent form, most notably the LC and WC forms

[5] The platform does not currently accommodate donor forms.

procedure as well as the consent process (see this link for sample videos). When a patient is added, they automatically receive an email to their personal email inbox that prompts them to set up their EngagedMD account. Their username is their email address and they create their own password. The clinic can also require SMS authentication and would need to enter the patient and the partner's (if they have one) mobile numbers. Once the patient sets up their login, the patient can view all of their patient education modules that have been assigned to them by the clinic.

After viewing a module, the patient is then asked a series of questions[6] to test whether they understood the material and their scores are sent to the clinic who can then assess if the patient needs more appointment time to perhaps discuss in more detail issues that they scored badly in. The system can be set up in such a way that the patient cannot complete the consent forms until they have completed the e-learning and answered the corresponding test questions.

EngagedMD is integrated with a platform called DocuSign for e-signing. The clinic decides, based on the patient's treatment, which forms the patient needs to sign. The forms are grouped into an "Envelope" and that envelope is given an ID number. The ID numbers are several characters long and is the unique identifier for that specific set of forms. The patient then needs to log into EngagedMD to complete and sign the consent forms. EngagedMD offer dual authentication via e-mail and SMS in order to access the patient's secure area on the portal. Further authentication is available to implement, but they leave level of authentication up to the clinic to decide.

The patients complete the form and the form uses conditional logic so that patients are directed to the relevant parts of the form. This can make the process of filling out form simpler for a patient because in the paper-based system they may still fill in a part of the form that they were supposed to skip by mistake, whereas with conditional logic they cannot complete that part because the system will not allow them to. However, if there is an error in the conditional logic then there is a risk that the form will be incorrectly completed. Clinics have the option to pre-populate the forms with personal details such as name, date of birth etc., information which would be sourced from the patient's account. Clinics can opt to have the form either signed online or in person in the clinic. Once the form is signed, all those involved are notified by email. Consents are received electronically via e-mail as well as accessible through the platform. The platform can integrate with EMRs to send completed documents for storage, and also provide other mechanisms to print/save PDFs. Completion of the form is captured in a "Certificate of Completion" which records information about each signer including the signer's IP address and other identifying information, signature image, and event timestamps. We were told that the Certificate of Completion is a court admissible document.

DocuSign

DocuSign is a company that provides electronic signature technology as opposed to e-consent technology to a number of industries including the healthcare sector. EngagedMD uses the back-end technology of DocuSign to capture patient's signatures and the elements of DocuSign are described above. However, we have identified that a clinic can use the DocuSign e-signature system separate to the EngagedMD platform the difference being that the online videos and learning modules that we have seen in Fertility Consent and EngagedMD are absent so that the focus is more on management of the consent forms and capturing the signature.

The DocuSign platform can apply electronic seals to documents which certify the integrity and origin of documents, though it is not clear on their website if these seals are temporary. The HFEA could require consent forms are sealed to ensure their authenticity.

[6] This wasn't present in the Fertility Consent platform