Human Fertilisation & Embryology Authority

Authority meeting - agenda

24 January 2018, Church House

Agenda item		Time
1.	Welcome, apologies and declaration of interests	12.30pm
2.	Minutes of 15 November 2017 **HFEA (24/01/18) 862** For decision	12.35pm
3.	Chair's report (verbal)	12.40pm
4.	Chief Executive's report (verbal)	12.50pm
5.	Committee chairs' updates (verbal)	13.00pm
6.	Performance report **HFEA (24/01/18) 863** For information	13.10pm
7.	Forecast Model **HFEA (24/01/18) 864** For information	13:40pm
8.	Regulation of groups of clinics **HFEA (24/01/18) 865** For decision	14.00pm
9.	Intelligence strategy 2017-20 **HFEA (24/01/18) 866** For decision	14.30pm
	Break	**15.00pm**
10.	Ovarian hyperstimulation syndrome **HFEA (24/01/18) 867** For information	15.15pm
11.	Code of practice update **HFEA (24/01/18) 868** For information	15.40pm
12.	Any other business	15:55pm
13.	Close	16:00pm

Minutes of Authority meeting 15 November 2017

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☐ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	2		
Paper number	HFEA (24/01/18) 862		
Meeting date	24 January 2018		
Author	Siobhain Kelly, Senior Governance 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 15 November 2017 held at 10 Spring Gardens, London SW1A 2BU

Members present	Sally Cheshire (Chair) Kate Brian Dr Anne Lampe Anthony Rutherford Bishop Lee Rayfield	Yacoub Khalaf Margaret Gilmore Anita Bharucha Bobbie Farsides Ruth Wilde
Apologies	Dr Andy Greenfield	
Observers		
Staff in attendance	Peter Thompson Nick Jones Juliet Tizzard Richard Sydee Caylin Joski-Jethi	Siobhain Kelly Helen Crutcher Paula Robinson Anna Quinn Catherine Drennan

Members

There were 10 members at the meeting, 6 lay members and 4 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 last meeting of 2017. As with previous meetings, it is audio-recorded and the recording is 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 Dr Andy Greenfield.

1.3. Declarations of interest were made by:

- Anthony Rutherford (Person Responsible at a licensed centre)
- Kate Brian (Regional organiser for London and the South East for Infertility Network UK)
- Yacoub Khalaf (Person Responsible at a licensed centre)

2. Minutes of Authority meeting held on 13 September 2017

2.1. Members agreed the minutes of the meeting held on 13 September, for signature by the Chair of the meeting.

3. Chair's report

3.1. The Chair summarised the events that she has attended since the last Authority meeting on 13 September 2017.

3.2. On 21 September, the Chair attended the formal launch of the Elizabeth Bryan Multiple Births Centre at Birmingham City University. Jane Denton, a former member, has played a key role in the establishment of this centre and has been one of the most prominent advocates of our work on reducing multiple births.

3.3. On 22 September, the Chair spoke to participants on the Health and Care Leadership, Aspiring Directors programme in Ashridge. The aim was to encourage programme participants to reflect what they have learned about the health and care system with senior panel members of NHS Chairs and NEDs.

3.4. On 5 October, Peter Thompson and the Chair met Phillip Dunne (Minister of State for Health). This was a useful and positive introductory meeting where a wide range of topics was discussed, including:

- Patient safety
- NHS commissioning and fairer access
- Research and innovation in the life sciences.

3.5. On 24 October, the Chair attended the PGD policy workshop organised by the policy team. The Chair thanked the Policy Manager who organised the session. The Chair was particularly pleased to see Authority members and staff, clinicians, embryologists and other stakeholders at the workshop and the feedback was very positive. It is hoped one of the outcomes will be an improved process from the 20 PGD clinics currently making applications for authorisation to the Statutory Approvals Committee (SAC).

3.6. On 16 October, the Chair attended the Scientific and Clinical Advances Committee (SCAAC) meeting.

3.7. Lastly, the Chair informed the members that the Authority's independent Appeal Committee met 16 - 19 October to hear an appeal brought by three licensed clinics. The Hearing did not reach a decision, since the matter was settled by agreement. The Authority will be working with the clinics involved to progress the agreement.

4. Chief Executive's report

4.1. The Chief Executive informed members that on 19 September, he and Nick Jones met representatives from Healthcare UK, an arm's length body set up to promote UK healthcare abroad, to discuss the promotion of UK fertility services overseas.

4.2. On 22 September, the senior management team (SMT) had the quarterly accountability meeting with the sponsor team at the Department of Health (DH).

4.3. On 3 October, the Chief Executive attended the Audit and Governance committee (AGC) meeting.

4.4. On 4 October, the Chief Executive attended the Health and Care Leaders Senior Talent Board which was set up to identify and develop talented individuals within the health sector.

4.5. On 9 October, the Chief Executive took part in a debate at the Royal Institution on genome editing, as part of Biology Week. A range of views were expressed but there is broad support for the Authority's regulatory regime, and agreement that it is flexible to allow innovation while providing assurance to the wider public.

4.6. On 16 October, the Chief Executive attended SCAAC and on 24 October, he attended the PGD workshop with the Chair.

4.7. Following interviews in October, an interim Head of HR was appointed for three months. Interviews for a permanent Head are imminent.

4.8. On 1 November, The Chief Executive took part in a panel discussion on NHS commissioning. This was organised by the Fertility Network UK as part of National Fertility Awareness Week.

Press coverage

4.9. The Chief Executive informed members that was an upturn in press coverage on fertility over the last couple of months, culminating in extensive coverage during he recent National Fertility Awareness Week.

National Fertility Awareness Week

4.10. The Chief Executive reminded members that a press release with some new data in support of the initiative was released, which attracted some coverage. The lead piece of information was the 300,000 IVF baby statistic, and that a third of IVF babies were born in the last six years. This shows a real acceleration in treatment numbers. Other information released included a breakdown of treatments by region to attract the attention of local and regional press, with some success.

40th anniversary of IVF

4.11. Members were informed that one of the themes of Fertility Awareness Week was the 40th Anniversary of IVF. The Chair gave an interview to the Daily Mail discussing the impact of IVF.

4.12. Members noted more generally, that a new and improved monthly Communications report on all activity will be circulated to members. This will include, but not be limited to, all the latest media stories. This will be developed further and discussion will take place around how this will be complemented by reporting at Board meetings.

5. Committee Chairs' updates

5.1. The Chair of the Statutory Approvals Committee (SAC) reported that the committee met on 28 September and 26 October. In September the Committee considered two PGD items, one of which was approved. In October the Committee considered one mitochondrial donation application and six applications for new PGD conditions. The minutes of that meeting were not yet finalised.

5.2. The Chair of the Licence Committee advised members that the committee met on 9 November and the minutes were yet to be signed off by the Chair.

5.3. The Chair of AGC informed the Authority that they met on 3 October and welcomed two new external members, Geoffrey Podger and Mark McLaughlin. In addition to the usual standing items, the committee discussed progress against strategic delivery by the Strategy and Corporate Affairs Directorate, received updates on the Data Submissions Project, business continuity, resilience and cyber security and reviewed the risk register.

5.4. The Director of Strategy and Corporate Affairs advised members that the Executive Licensing Panel (ELP) met four times since the Authority last met; on 22 September, 6 October, 20 October and 3 November, and considered 28 items. There were six renewal inspection reports, 17 interim inspection reports, four licence variation applications and one whistleblower report, which found no evidence of the problems raised by the whistleblower. In addition, five variations and one voluntary revocation were approved by the Licensing Officer.

5.5. SCAAC met on 16 October and discussed genome editing research, informed by a speaker from the Francis Crick Institute research group, new patient information on treatment add ons, and the work of the Register Research Panel, with some proposals for improving access to data for researchers.

6. Performance report

Compliance and Information

6.1. The Director of Compliance and Information reminded members that the Data Submission project is still underway, with launch scheduled for April 2018. AGC is providing ongoing scrutiny.

6.2. Members noted that most clinics have a third-party system which stores treatment data. As a consequence, the HFEA has to work closely with these suppliers to ensure that the HFEA data submission integrates effectively. These suppliers have received details of the new system this week and will have six months to work on integration.

6.3. On data migration, our risk management is focused on moving the Register into the new environment. There is a robust plan in place and risks are being mitigated. The migration will not occur until we are ready. AGC will receive an update in December.

6.4. The Chair of AGC stated that assurance had been provided that key staff will be concentrating on this work without distraction.

6.5. On the red indicators in the report, members noted that complexity and volume of committee items are still affecting compliance with key performance indicator (KPIs) targets. Members heard that staff continue to aim to meet KPIs on PGD applications because they know there is a patient awaiting each decision. Alongside this, elements of the administrative process continue to be reviewed, to ensure any issues are identified and resolved.

Strategy and Corporate Affairs

6.6. The Director of Strategy and Corporate Affairs informed members that the new website is now attracting 30,000 visitors per month. Steps are also being taking to increase the presence of the website on search engines.

6.7. Members heard that National Fertility Awareness Week has raised the HFEA's profile and our impact is amplified when we work together with stakeholders.

6.8. Members noted that the HFEA now has over 4,000 followers on Twitter, which is a good channel for reaching professionals. The HFEA now has a Facebook presence, also launched in fertility awareness week, which helps us reach patients.

6.9. The Director of Strategy and Corporate Affairs reported that staff attended the Fertility Show in November. Members agreed it is very important for the HFEA to have that presence at the show to provide unbiased, free, reliable information to patients, and heard there was good take-up of printed materials. Members thanked staff for attending the show.

6.10. Members were informed that the HFEA's annual conference will be held on 15 March 2018, the day after the March Authority meeting.

6.11. Members noted that the 9th edition of the Code of Practice will be launched in October 2018 with the draft code being available in the Spring for consultation. The Authority will consider the revisions to be incorporated into the new Code at future meetings.

6.12. Members heard that an evaluation on the new patient ratings service will be presented to the Authority in March 2018, reporting on the pilot period. Clinics that are investing effort in encouraging this feedback are getting good results.

6.13. Members touched on the price of treatment. Although pricing is not within our regulatory remit, inspectors check that costed treatment plans are provided to patients. Members heard that patient feedback to date suggests that such costings may not always be accurate.

6.14. Members raised the issue of waiting times for egg donation and how time critical this is for patients, and that delays could push patients to consider going abroad for treatment. Members were assured that this would be put on the future development list for Choose a Fertility Clinic (CaFC).

6.15. Members discussed the presentation of clinics' own data on their websites and noted that this is something that is checked by the Inspection team. Going forwards, the HFEA will be more robust with clinics if there is inaccurate or misleading data presented. This issue will also feature in the 9th edition of the Code.

6.16. Members discussed the verification process to ensure our data is accurate for CaFC, which in the past has been very time consuming for clinics. The impact of the Information for Quality (IfQ) programme will be felt here, in that the new system will allow less scope for incorrect data to be submitted in the first instance. How verification will take place in the future will be discussed at the January Authority meeting.

Finance and Resources

6.17. The Director of Finance and Resources introduced the financial information in the performance report. Members heard that in relation to staffing and capacity, opportunities to address resourcing pressures were being explored.

6.18. Members discussed the surplus and the practical difficulties in spending it or reducing it by reducing treatment fees. The HFEA was subject to Government rules about balanced budgets, which meant that the aim would always be to arrive at a net balance of zero at year end.

6.19. Members noted that 75-80% of the HFEA's income comes from treatment fees. That money is used directly in our work to support patients. The rest of our income comes from DH in the form of grant-in-aid. Like all public bodies, the HFEA aims to be as efficient as possible, spending wisely and accounting for what is spent appropriately.

6.20. Members noted the Performance Report.

7. Draft business plan 2018/19

7.1. The Head of Planning and Governance presented the draft business plan for 2018/19. This will be year two of the strategy, and the plan will remain a work in progress over the next four months, with further discussion taking place at the Corporate Management Group (CMG).

7.2. Members noted the main activities under our strategic aims for safe, ethical, effective treatment; consistent outcomes and support and improving standards through intelligence.

7.3. Members heard that the Secretary of State's shared delivery plan highlights quality and safety for patients, and members agreed that the business plan should demonstrate that the HFEA's work is in step with a wider DH approach.

7.4. Members agreed that the HFEA should be bold and be prepared to work at the limit of our legal boundaries. The way we do things is just as important as what we do.

7.5. The Head of Planning and Governance agreed to incorporate comments from members about values, providing more explicit linkage between the business plan and the strategy. In addition, members felt that since the IfQ developments will be available for use during the next business year, there should be emphasis in the plan on what elements will be new.

7.6. Members raised whether there is capacity and resilience to deliver this business plan and were assured that the plan had been drafted with resources in mind.

7.7. Members agreed that it was good to see a business plan with a focus on the patient's experience at the very heart of it and thanked the business planning team for this draft as presented.

7.8. Members:

- approved the draft Business Plan 2018/19
- noted the final version will return to the Authority in March 2018 for sign off.

8. Fertility sector report 2016/17

8.1. The Director of Compliance and Information introduced the report reminding members that this version followed endorsement of the structure and format of the report at the September 2017 meeting of the Authority. Following comments at the meeting the report was revised to make it clearer how we regulate; to add context about the UK fertility sector; to emphasise the quality of service and compliance; the addition of good practice 'vignettes' identified by Inspectors; and the sections on minimising multiple births, learning from incidents and patient experience were now part of a new chapter on 'areas of focus'.

8.2. Members were invited to discuss the key messages that would be incorporated within the summary of the report. Suggestions included:

- A focus on clinic leadership, and how we can encourage clinics to improve performance from 'good to great'
- A strong message that many clinics have a five-star rating, and improvements to pregnancy outcomes
- Acknowledgement that whilst patient feedback levels are low (with an acceptance that the new website should address this over time) more explanation of this would be helpful
- Even more emphasis on the reduction of the multiple birth rate, whilst at the same time no drop in success rates – together with a reminder of the importance of the policy.

8.3. It was agreed the final draft will be shared with a few members for final oversight prior to publication in early December 2017.

8.4. Members:

- approved the publication of this report
- agreed the report should be embargoed until publication.

9. Strategic risk register

9.1. Members received a presentation of the revised Strategic Risk Register for the first time, noting that AGC has already commented on this version. Members heard that the two new external AGC members were impressed with this risk register and commented that it is as good a format as they have seen in their other roles.

9.2. Members heard that two risks were above tolerance. One related to organisational change, which is drawing to an end as most of that change has been implemented. Members heard that the executive had reassessed the organisational change risk since the register was reviewed by AGC. The residual risk had been reduced slightly following successful recruitments and the near completion of all planned redundancies. This meant that the risk was at tolerance. This risk will be removed as a separate risk once all of the organisational changes have been completed, by the end of the business year. The remaining above tolerance risk was capability and capacity, for related reasons.

9.3. Members noted the Strategic Risk Register.

10. Scientific and Clinical Advances Committee annual report

10.1. Members received a presentation from the Policy Manager who supports the committee, which meets three times per year.

10.2. The key functions of SCAAC are to consider:

- Horizon scanning
- Updates on key areas of research
- Patient information
- Policy development
- Novel processes.

10.3. Horizon scanning occurs annually, and the relevance of any new issues is established by asking a standard set of five questions. In 2017, the international panel discussed the following:

- The use of ICSI
- How to define and register success in assisted reproduction
- Pre-implantation genetic screening for frozen embryos
- Embryo culture media.

10.4. Members heard that some clinics use ICSI in up to 90% of their treatment cycles. SCAAC discussed how research shows that ICSI does not improve treatment outcomes compared to IVF alone in the absence of male factor infertility.

10.5. Members heard that despite media interest, only one research group is using genome editing techniques on human embryos. It would be important for SCAAC and the Authority to stay abreast of these developments to ensure there is awareness of the wider debate.

10.6. New technologies in embryo testing, next generation sequencing, karyomapping and mosaic embryos were also discussed.

10.7. Members were informed that in the coming months, SCAAC will be looking at:

- Patient information for three new treatment add-ons
- Revisiting previous novel processes applications
- Horizon scanning for 2018.

10.8. Members agreed that the SCAAC meetings address interesting and important topics, and asked that committee Chairs be invited whenever the subject matter was relevant.

10.9. Members agreed that the Policy Manager who supports the committee should contact members to see if they would like further information on any of SCAAC's recent activity.

10.10. Members noted the annual report from SCAAC.

11. Register Research Panel annual report

11.1. Members received a paper and presentation from the Head of Intelligence which was an annual update, reported to the Authority in its role as the oversight committee.

11.2. Members heard there had been two applications to the Register Research Panel since January 2016. One study is looking at the long-term effects of assisted reproduction technology on the health and well-being of women and their children. The other study is examining educational outcomes in children born from ART.

11.3. Members also received an overview of the progress of all authorised research studies since the law changed in 2009, and the results of studies conducted using the anonymised dataset.

11.4. In addition, the Authority heard how the new Intelligence team aims to increase impact by showing how Register research has a role in ensuring patients get safe and effective treatment. This will be achieved by using external, specialist expertise.

11.5. Members supported the development of an intelligence strategy and suggested further thinking on what the HFEA's role could be in signposting findings of studies to the patients who might benefit from that information. Members also felt that linking Register research with the work of SCAAC is an excellent new approach.

11.6. Members noted that better information for clinics and better information for patients would lead to safer, better care.

11.7. Members agreed that it is positive that the HFEA is making such connections and welcomed the direction of travel proposed by this new team.

11.8. Members:

- noted the report of Register Research Panel activities since 2016
- approved the suggested ways for extracting greater value from the data held.

12. NHS commissioning of IVF services

12.1. Members were given a summary of NHS treatment commissioning for each of the four nations of the UK. Although IVF is regulated on a UK-wide basis, commissioning is devolved to national level and, in England, to the local level.

12.2. Members heard that in England, the clinical guideline published by NICE is not implemented consistently, and access and pricing are variable. The Director of Strategy and Corporate Affairs demonstrated the worsening picture in England with respect to Clinical Commissioning Groups (CCGs) following the NICE guideline. In 2013, 76% of CCGs did not follow the guideline. In 2017, the figure had risen to 88%.

12.3. Members were surprised to note that 49% of CCGs use their own definition of an IVF cycle, not the NICE definition. The definitions used by CCGs often meant fewer frozen transfers, reducing success rates and potentially exposing patients to more ovarian stimulation and egg collections than are required, which is an undesirable outcome for patients. Many CCGs also have their own individual social eligibility criteria.

12.4. On pricing, since there is no national tariff members heard that CCGs negotiate locally with providers. There are examples of private providers undercutting NHS ones.

12.5. In 2016, NHS England commenced a project involving the HFEA, NHS Improvement, commissioning body representatives and fertility sector stakeholders which aimed to deliver three planned outputs:

- Guidance for CCGs on commissioning an IVF service, including standardised social eligibility criteria
- A benchmark price for IVF
- A national tariff including a performance incentive.

12.6. Members heard that progress has been made with these issues and reaffirmed the Authority's determination to ensure this works on the ground to improve commissioning, and therefore services for patients.

12.7. Members were informed that NHS England is unable to mandate CCGs to follow the NICE guidelines but they do have influence. The HFEA is committing to working closely with the sector and NHS England to use all opportunities for influence.

12.8. Members noted that IVF treatment accounts for less than one tenth of 1% of the NHS budget. Members agreed that there is no economic argument against providing IVF since there are now over 300,000 IVF babies who will contribute to our economy throughout their lives.

12.9. Members agreed that examples of best practice could be shared where effective treatment saves costs, demonstrated by singleton pregnancies and people not going abroad for treatment and subsequently returning with multiple births. This could also be evidenced by highlighting how funding is wasted on unnecessary tests.

12.10. Members also agreed that inefficiencies should be pointed out publicly, since the public debate is dominated by IVF being in competition for funding with lifesaving treatments. In addition, members suggested that, once the work on English commissioning is complete, we should look to address commissioning in Wales and Northern Ireland too. The position in Scotland is much better, with central commissioning and criteria, and a public commitment to provide three full cycles.

13. Any other business

13.1. Members thanked two members of staff who were leaving the HFEA for their years of dedicated service. Juliet Tizzard, Director of Strategy and Communications, and Siobhain Kelly, Senior Governance Manager would both leave prior to the next Authority meeting.

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 (24/01/18) 863
Meeting date	24 January 2018
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)	CMG reviews performance in advance of each Authority meeting, and their comments are incorporated into this Authority paper. The Department of Health reviews our performance at each DH quarterly accountability meeting (based on the CMG paper). The Authority receives this summary paper at each meeting, enhanced by additional reporting from Directors. Authority's views are fed back to the subsequent CMG performance meeting.
Organisational risk	☐ Low ☒ Medium ☐ High
Annexes	Annex 1: Performance report

1. Introduction

1.1. The attached paper mainly summarises our performance up to the end of October 2017, with financial data covering November 2018.

2. Reviewing performance

2.1. The Corporate Management Group (CMG) reviewed the October data at its December performance meeting.

2.2. Overall performance has improved significantly from September data. Four indicators are currently classified as red (down from eight in the last Authority report). There is a full discussion of these in the performance report.

2.3. CMG also reviewed the detailed key performance indicators for compliance and licensing to ensure that these best reflect actual performance and provide useful oversight. This has also led to two changes in the Authority's summary:

- The removal of the count of recommendations from inspection. Inspectors will of course still monitor this and it will be reported to Authority through the state of the sector report on an annual basis, which should better enable the identification of trends.
- The annualised PGD indicators have been replaced with 3 month rolling averages. This will allow CMG and Authority to review more useful trends in current performance, without this being conflated with issues with applications completed 12 months earlier, as it was felt that such a regular 'snapshot' did not allow for meaningful reflection or analysis.

3. Recommendation

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

HFEA performance scorecard

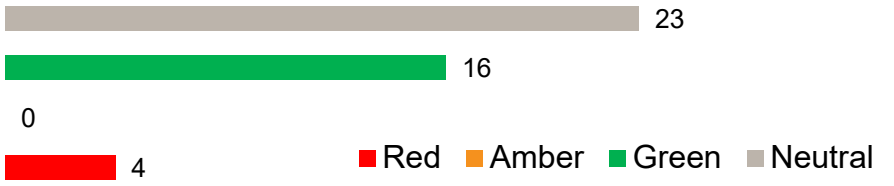
Dashboard – October data

People – capacity

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

⇔
Leavers: 1
(21.2%)

Overall performance – RAG status (all indicators)



Engagement – Website traffic

Website sessions this month
Arrow tracks performance since last month
(baseline to be established once the website has been active for a year)

⇧
33,252 sessions

Licensing end-to-end

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

★
40 working days

Money – budget

Summary Financial Position - November 2017

	Year to Date			Full Year		
	Actual £'000	Budget £'000	Variance £'000	Forecast £'000	Budget £'000	Variance £'000
Income	4,187	4,070	117	6,328	6,230	98
Expenditure	3,615	4,062	446	5,826	6,062	236
TOTAL Surplus / (Deficit)	572	9	563	502	168	334

Commentary

The above tables show our YTD position as at 30 November as an surplus against budget of £563k. This is an increase on that reported in September of £74k. There are significant underspends against planned expenditure, for which more information is provided in the detailed management commentary, the largest area of underspend is legal services.

Our forecast position takes some account fo current underspends but will be fully reviewed as part of our Quarter 3 accounts process in January 2018. These figures exclude the cost of the Systems upgrade project currently running.

Overall performance – October 2017

We reviewed the overall performance picture at the CMG meeting on 6 December. There were four red indicators. Two of these relate to PGD processing times, and the reasons for delays are discussed in more detail below. The other red indicators were the establishment leavers and Parliamentary questions.

CMG noted that there has been positive performance in the register team in addressing data errors, which have been reduced by 10%. The team have been chasing centres with the highest numbers of outstanding errors and this has caused the drop overall. The compliance team will consider options to ensure that the worst centres continue to improve.

There has also been a significant improvement in the licensing indicators and CMG noted the hard work of the team to achieve this.

In December, CMG reviewed all compliance and licensing figures, to rationalise these and ensure that they are meaningful measures that allow management to address performance. Key changes have been to reduce the number of neutral trackers reported at the CMG level and remove some areas of duplication of RAG indicators, especially around minutes. We have included trackers for mitochondrial donation applications and we will be reviewing these closely, with a view to setting a KPI in six months.

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

People and capacity – one red indicator

- Establishment ('unplanned') leavers per month. Our target is to remain within 5 - 15% establishment turnover for the year. Performance is the same as in September at 21.2%. This is still significantly above target and the overall planned and unplanned leavers for the year has also remained at 27.75%. We have recently completed a successful period of recruitments, which should mean that this reduces over the coming months.

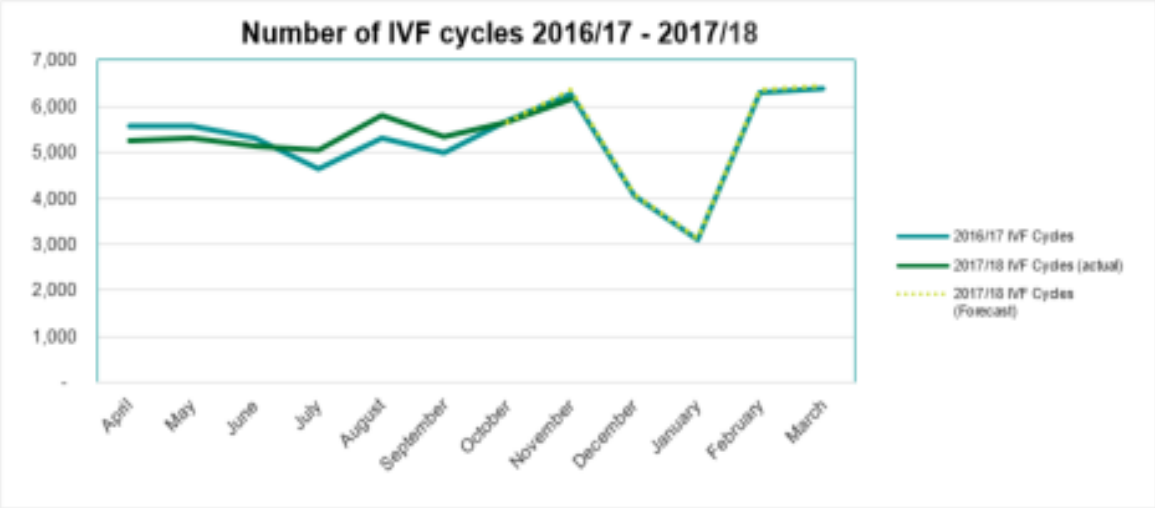
Information – one red indicator

- Percentage of requests for contributions to Parliamentary questions answered within Department of Health deadlines. Our target is 100% but in October we achieved 41%. This was because of the high number of PQs (17), including 12 received on the same day from one person. Parliamentary timeframes were still met.

Inspection and licensing processes – two red indicators

- Percentage of PGD applications processed within three months. Our target is 100% to be processed (ie, considered by SAC) within three months (66 working days) of receipt of completed application. October performance was 50%, although the average is within the target at 62 working days. This is a slight improvement on September performance. The delays were due in part to a system error which meant that a clinic had resubmitted an application but we were unaware of this. Another condition was bumped from August SAC to September due to other pressures on the agenda.
- Three month rolling average figure – Percentage of all PGD applications processed within 3 months for the three months to date. Our target is for 100% of applications to be processed within 3 months to date. Performance in October was 55%, which is a small improvement from September (53%).

2017/18 Income

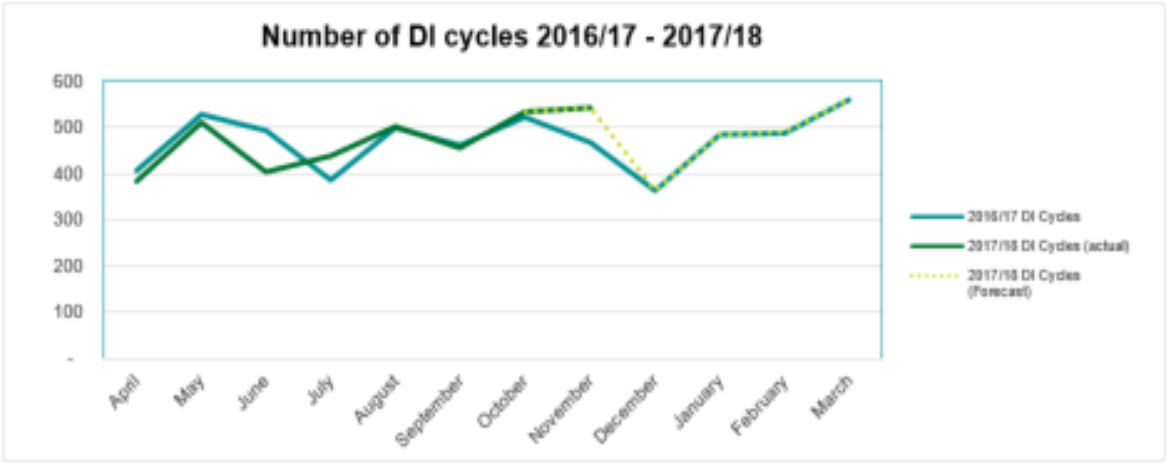


IVF Cycles

	YTD		YE / Forecast	
	Volume	£	Volume	£
2016/17 IVF Cycles	43,302	3,464,134	63,111	5,048,854
2017/18 IVF Cycles	43,681	3,494,480	63,664	5,093,082
Variance	379	30,346	553	44,229

As at November 2017, IVF Cycles are are increasing at a rate of 0.9% (slowing down) against those reported in 2016/17. Some work has been undertaken to try to explain what drives treatment cycles. This work will be shared with the Authority in the new year.

The forecast for the year shows a smaller increase in cycles in Q4. It is still too early to ascertain why or what causes this drop. However, for the whole year we are forecasting an increase.



DI Cycles

	YTD		YE / Forecast	
	Volume	£	Volume	£
2016/17 DI Cycles	3,758	140,925	5,651	211,913
2017/18 DI Cycles	3,762	141,075	5,657	212,138
Variance	4	150	6	226

DI cylces appear to be increasing all be it at a slower rate of 0.01% when compared to 2016/17.

HFEA Income & Expenditure

Nov-2017

	Year to Date			Full Year		
	Actual £	Budget £	Variance £	Forecast £	Budget £	Variance £
Income						
Grant-in-aid	469	469	-	933	938	(5)
Licence Fees	3,674	3,597	77	5,330	5,286	44
Other Income	2	4	(2)	3	6	(4)
Seconded Salary reimbursed	42	-	42	62	-	
Total Income	**4,187**	**4,070**	**117**	**6,328**	**6,230**	**98**
Revenue Costs						
Salaries (excluding Authority)	2,577	2,501	(76)	3,855	3,778	(77)
Staff Travel & Subsistence	103	137	34	180	200	20
Other Staff Costs	31	95	64	136	151	16
Authority & Other Committees costs	150	200	50	284	301	17
Facilities Costs incl non-cash	365	447	82	630	689	59
IT Costs	65	83	18	128	125	(3)
Legal / Professional Fees	228	490	262	406	638	233
Other Costs	96	108	11	210	180	(29)
Total Revenue Costs	**3,615**	**4,062**	**446**	**5,826**	**6,062**	**236**
TOTAL Surplus / (Deficit)	**572**	**9**	**563**	**502**	**168**	**334**

Management commentary

Income.

At the end of period seven (October), our Licence Fee income shows a positive variance against budget of £54k. Analysis of this shows that the majority of this variance relates to Treatment fees (£55k) with an increase in Research licence fee income of just under £1k which represent two licences. This is offset by a small reductions in application and storage annual licence fees.

Expenditure.

Year to date we are underspending by 11.9% (£428k), the majority of this variance relates to the following areas:

Staff Travel - is £28k lower than budget due to the profile of activity.

Other staff costs - made up of underspends in Training (£22k), Recruitment (£36k) and Payroll costs (£15k). The latter relating to pension charge that was expected in Q2 but as yet received. The underspend in recruitment due to use of online services rather than agencies.

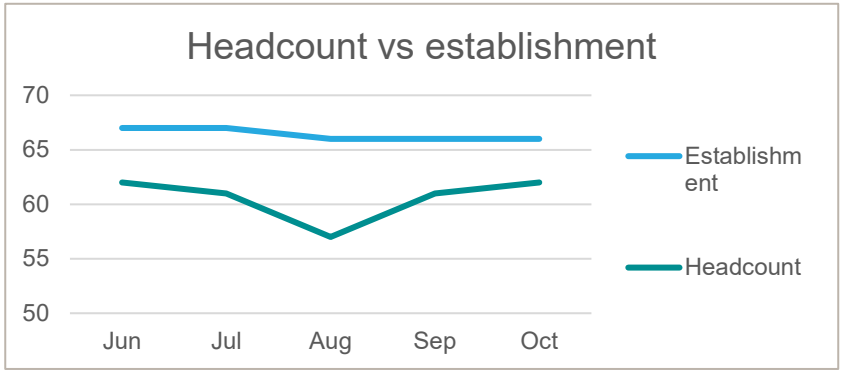
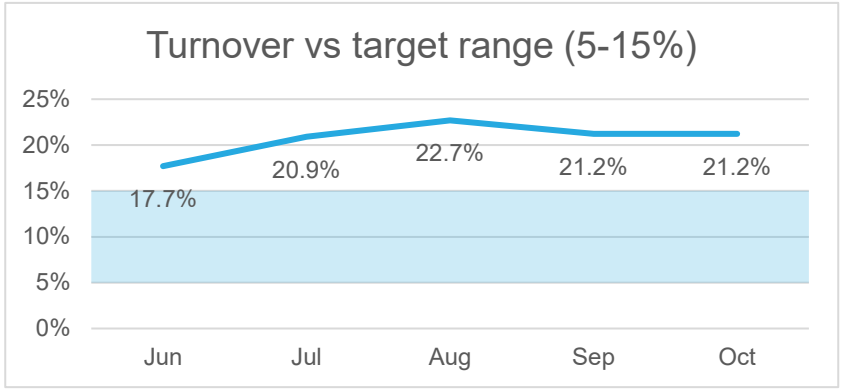
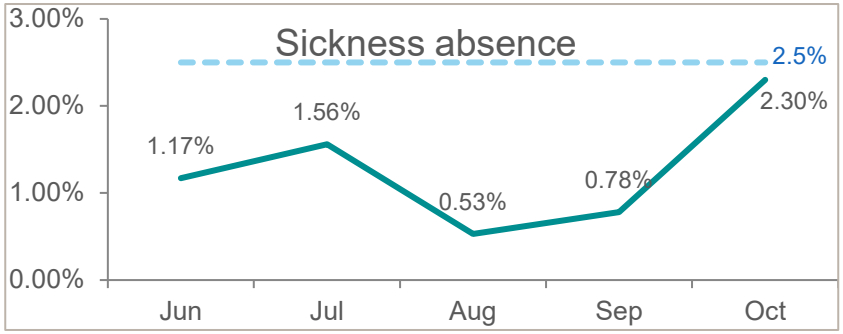
There is a significant under spend within our legal costs relating to litigation, representations and appeals. We have been accruing for costs relating to two cases, one of which has not materialised. The second we will not know for certain the impact on our costs and therefore have retained our accrual. A further review will be undertaken in November.

The overspend within salaries relates to additional reorganisation costs which were provided for last year but recalculations issued by Cabinet Office has required an additional accrual which we expect to crystallise by calendar year end.

Forecast

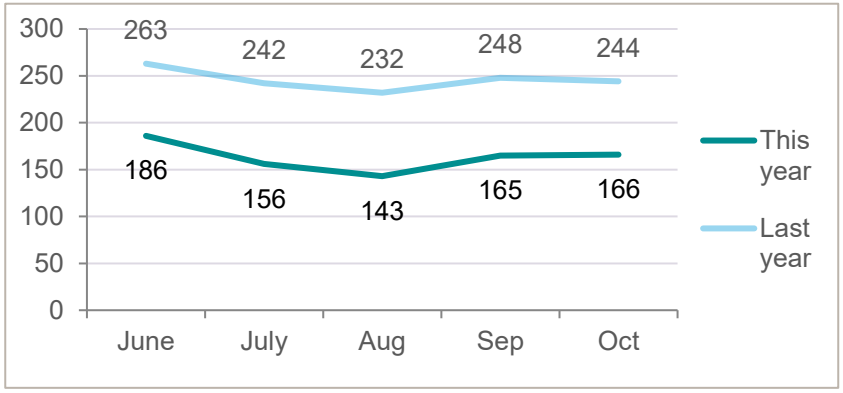
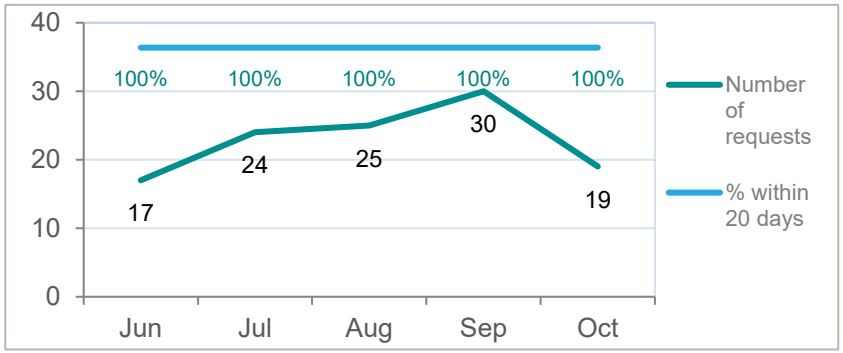
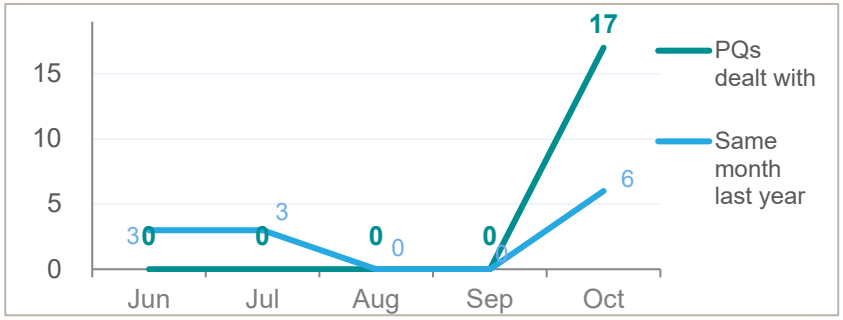
We are forecasting a year end surplus against budget of £502k. This is likely to change again after our our Quarter 3 financial review.

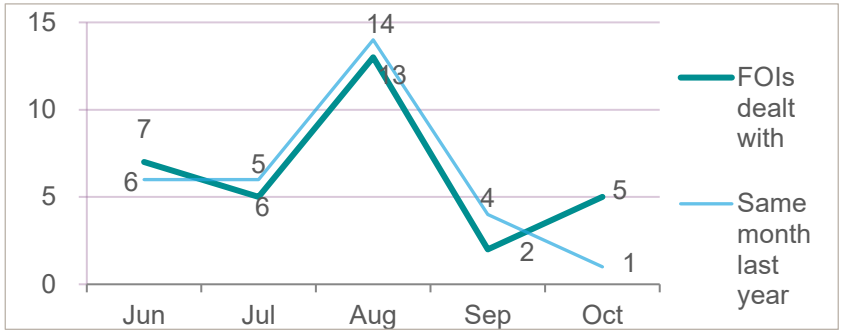
People – key performance and volume indicators

Indicator	Score	RAG	Recent trend[1]	Notes
Current headcount by month Headcount/ establishment	62/66	⇔		Overall volume (capacity) indicator. We are now using the new post-organisational change headcount of 66.
Turnover: Establishment ('unplanned') leavers per month (% establishment turnover for the year).	21.2%	⇔		KPI range: 5-15% turnover for the rolling year The public-sector average is 10% (Expert HR & CIPD research 2013) which therefore forms the basis of our target. This is worked out on a rolling basis each month.
Staff sickness absence rate (%) per month.	2.3%	★		KPI: Absence rate of ≤ 2.5%. Average rate of public sector sickness absence is 2.9%, central government is 2.4%. (Source: ONS data 2016)

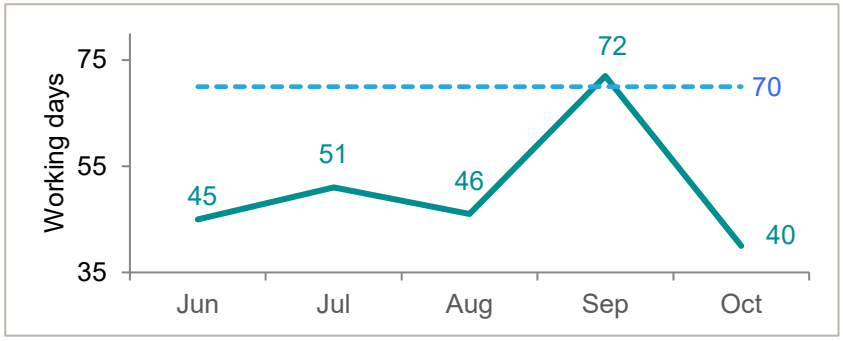
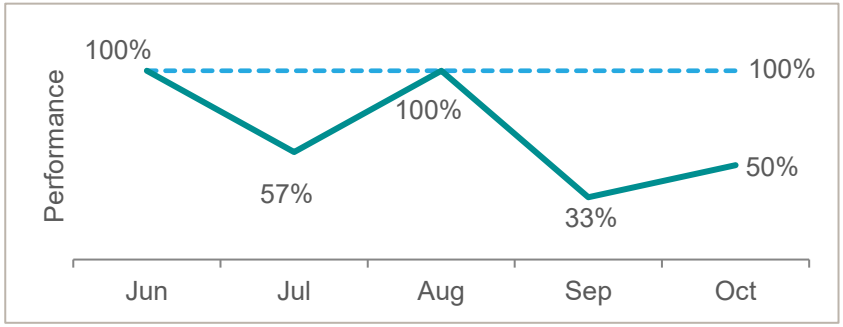
[1] KPIs, where applicable, are show as a blue dashed line in graphs. This line may be invisible when performance and target are identical (eg, 100%). Our establishment turnover KPI is a range, which is shown as a blue band in the graph.

Information – key performance and volume indicators

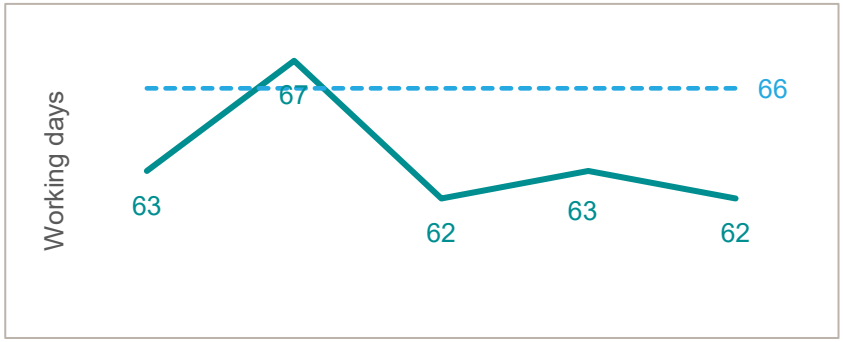
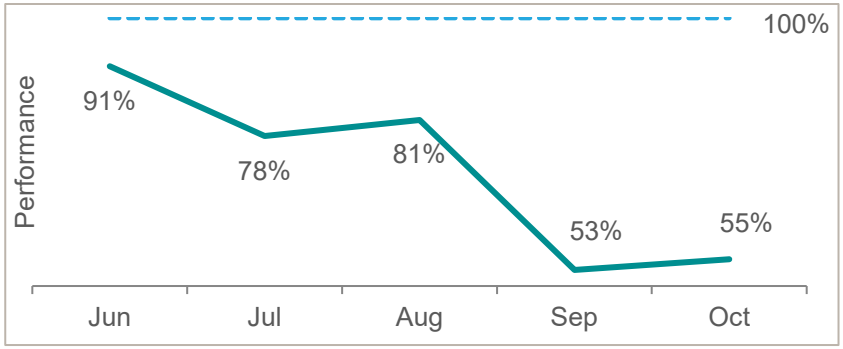
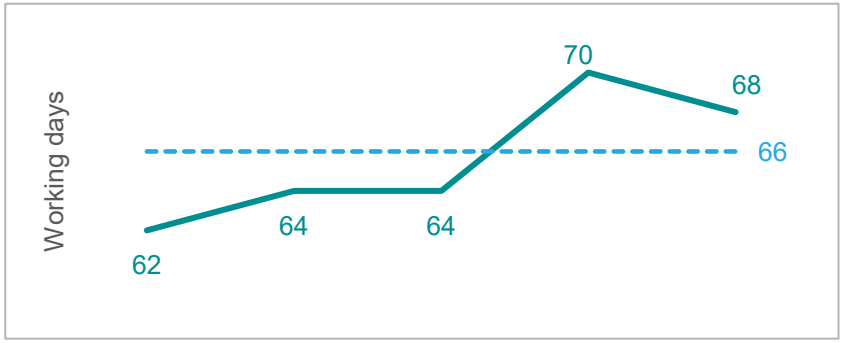
Indicator	Score	RAG	Recent trend	Notes
Number of emailed public enquiries received (compared with same month last year)	166	⇧		Volume indicator. We will soon begin to track telephone enquiries as well as those via email and these will be reported to CMG in their more detailed report. We are in the process of integrating the enquiries team with website development, to ensure it meets user needs.
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	17	⇧		Volume indicator. We had a period of six months without any PQs due to the general election and summer recess. Now that parliament has restarted, we have started receiving these again and this is reflected in October data.

Indicator	Score	RAG	Recent trend	Notes
Number of Freedom of Information (FOI) requests	5	⇩		Volume indicator. An increase in requests in August is a reoccurring trend and this can also be seen in 2015 data. The precise reasons for this are unclear, although it may relate to the summer parliamentary recess.

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)	40	★		KPI: Less than or equal to 70 working days.
Monthly percentage of PGD applications processed within three months (66 working days).	50%	⇧		KPI: 100% processed (i.e. considered by SAC) within three months (66 working days) of receipt of completed application. See commentary above.

[2] KPIs, where applicable, are show 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).	62	★		
Cumulative 3 month (rolling average) percentage of PGD applications processed within three month KPI (66 working days)	55%	⇧		KPI: As above. We are now reporting against a three-month rolling average rather than an annualised average, since this will allow us to see trends, without being affected by negative performance from a year ago which has been addressed.
Average number of working days taken (cumulative 3 month picture).	68	⇩		

Income forecasting

Strategic delivery:	☐ Safe, ethical, effective treatment	☐ Consistent outcomes and support	☒ Improving standards through intelligence
Details:			
Meeting	Authority		
Agenda item	7		
Paper number	HFEA (24/01/2018) 864		
Meeting date	24 January 2018		
Author	Richard Sydee (Director of Finance and Resources) Caylin Joski-Jethi (Head of Intelligence)		
Output:			
For information or decision?	For decision		
Recommendation	The Authority is asked to approve our intention to: • incorporate this model in to our financial and business planning for 2018/19, testing the validity of this model on our emerging 2017 data • keep fees for 2018/19 unchanged • bring a further update of the model to the Audit and Risk Committee in mid-2018		
Resource implications	In budget		
Implementation date	2017/18 business year		
Communication(s)	Publication on HFEA website.		
Organisational risk	☒ Low	☐ Medium	☐ High
Annexes	Annex A: Income forecasting methodology Annex B: Forecast methods		

1. Introduction

1.1. Forecasting trends in the number and type of fertility treatments is not straightforward. The level of treatments in any given year depend on a complex interplay of the amount of public resources available (which varies across the four nations of the UK), the spending power of patients (the majority of which pay for the treatments themselves), and the demographic profile of the patient population.

1.2. Yet accurate forecasting is of more than academic interest. For many years the HFEA has derived the majority of its income from a funding model which levies a charge against each treatment carried out (currently £80 per IVF cycle transfer and £35 for DI treatments). HM Treasury rules require the HFEA to recover the full cost of regulation and no more, subject to contingencies to cover salaries and the like if funding fell below expected levels. In recent years the HFEA has struggled to accurately forecast the likely number of treatments in any given year, with the result that it has regularly built up a surplus above and beyond what is required by Treasury rules. In response, the HFEA has reduced its fees to attempt to bring the budget into balance and it has used past surpluses to fund its Information for Quality (IFQ) programme, which has modernized the way in which we collect, verify, and use the data we hold, to the benefit of clinics and patients alike.

1.3. The analysis contained within the paper illustrates the trends in treatment activity over the past 10 years, and highlights the variation between different age bands and regions in terms of activity growth. This analysis is of significant interest and use in its own right.

1.4. This paper represents the first step in developing a new, more reliable, income forecasting model (attached at annex A). The model aims to identify the high-level factors that influence treatment activity and income. We will use it, and further planned work, to inform future discussion with the sector around fees, ensuring that we continue to recover our full operating and costs and provide value for money.

2. The model

2.1. The forecasting model (Annex A) demonstrates that the treatment rate per capita is 0.44% (2016) and has increased steadily since 2007. This treatment rate per capita means that around 44 women in every 10,000 had a chargeable treatment in 2016.

2.2. The prevalence of infertility in the UK population is around 14%[1] (around 14 in every 100 women; or 1400 in every 10,000) which suggests that, despite significant increases in the uptake of fertility treatment over the past 25 years,

[1] https://www.nhs.uk/conditions/infertility/

the sector is still a very long way from market capacity (even allowing for the fact that IVF is not suitable for all who have problems with their fertility).

2.3. The forecasting model shows that treatment rates vary by age band, and that different regions have shown different long-term trends in fertility treatment activity. These have not been incorporated into the model for reasons set out in Annex A.

2.4. The model is based on forecasting the projected rate from past performance (using either a linear forecast or ETS model, methods which are explained at Annex B). This approach was selected as a common and replicable forecasting method, with the additional benefit that that the projected rate can then be applied to variants of the ONS population projections. This means that the rate can be applied to alternative population projections which might include substituted demographic assumptions (for example, the impact of Brexit on international migration).

3. Key forecasts from the model

3.1. Both methods (linear forecasting and ETS) forecast increases in the number of chargeable treatments, based on historic patterns to date. By 2020, both suggest the number of treatments will increase from 67492 in 2016 to between 70906 and 78319. In the first 6 months of 2017/18, there have been 34,564 chargeable treatments – the ETS quarterly method forecasted 34,884 treatments: this was an error of only -320 treatments (+0.93%).

3.2. Treatment income is projected to increase from £4,850,819 in 2016 to between £5,454,427 and £5,896,934 by 2020, with the lower estimate for growth still providing an annual increase in income of c2% per annum.

3.3. Taking the lower 95% interval, we would still see growth of c£90k each year through to 2020 (based on 2016/17 outturn). Although very early the increase we have seen in the first 6 months of this financial year is very similar to this estimate: using the quarterly estimates, income in the first 6 months of 2017/18 has been £2,668,730, compared to a quarterly forecast of £2,665,138 (an error of £3,592, or -0.13%). The income is within the confidence interval of £2,527,770 to £2,802,505.

3.4. We've achieved a very high accuracy rate for short term forecasting using the methods selected. This exploratory work will inform whether we invest further resources into developing more advanced models.

3.5. The combined impact of the factors discussed in this document indicate a likely increase in demand for fertility treatment and therefore chargeable activity over the next 5 years. The current model in the first 6 months of 2017/18 is accurate to within 99.8%.

4. Recommendations

4.1. That we incorporate this model in to our financial and business planning for 2018/19, testing the validity of this model on our emerging 2017 data to determine if the results from the analysis provide realistic estimates of activity and income.

4.2. In terms of fee changes we propose keeping fees for 2018/19 unchanged. The sector appreciates stability in terms of our fees and the information presently at hand does not indicate we could reduce our fees materially for 2018/19 based on forecast increased activity.

4.3. We propose to bring a further update of the model to the Audit and Risk Committee in mid-2018, which will allow us to combine our improved income forecast model with the three-year financial plan and proposals for future fees from April 2019.

Annex A: Income forecasting methodology

1. Background

1.1. The HFEA derives its income primarily from charging a fee for certain treatments: presently £80 for an IVF cycle/transfer and £35 for DI treatments.

1.2. This report aims to identify the high-level factors[2] influencing income generated from patient fees at the HFEA and to explore the practicality of developing a simple forecasting model for treatment activity and income.

1.3. The fertility sector is a rapidly developing sector, responding to technical advances, market activity, national campaigns and increased public awareness. Therefore, forecasting techniques, which are based only on what has happened historically, will be most valuable where the historic market most closely reflects how we anticipate the market will continue to develop. This means that short term forecasts are likely to be more accurate than long-term forecasts, which might be affected by market changes that we can't currently anticipate.

1.4. By analysing the historic activity trends, we can begin to understand the factors that need to be considered when developing a future forecasting methodology. We have chosen to review chargeable treatment cycles across the sector since 2007 as the data across this period is consistent for both NHS and privately funded treatments and as such provide a statistically valid sample for analysis.

1.5. The output from this report and the further work we will undertake will be used to inform future discussions around fees, ensuring we continue to recover our operating costs and provide value for money.

2. Patient age variation

2.1. It's important to understand how treatment activity varies by patient age so that changes in the overall population demographic profile can be mapped to future fertility treatment activity (and therefore income).

2.2. The age profile shows that for all treatment types, and over time, the bulk of cycles take place for women who are between 31 and 40. The age profile is slightly lower for DI cycles compared to IVF, and there has also been a greater shift towards a younger profile for DI cycles when compared to 2012.

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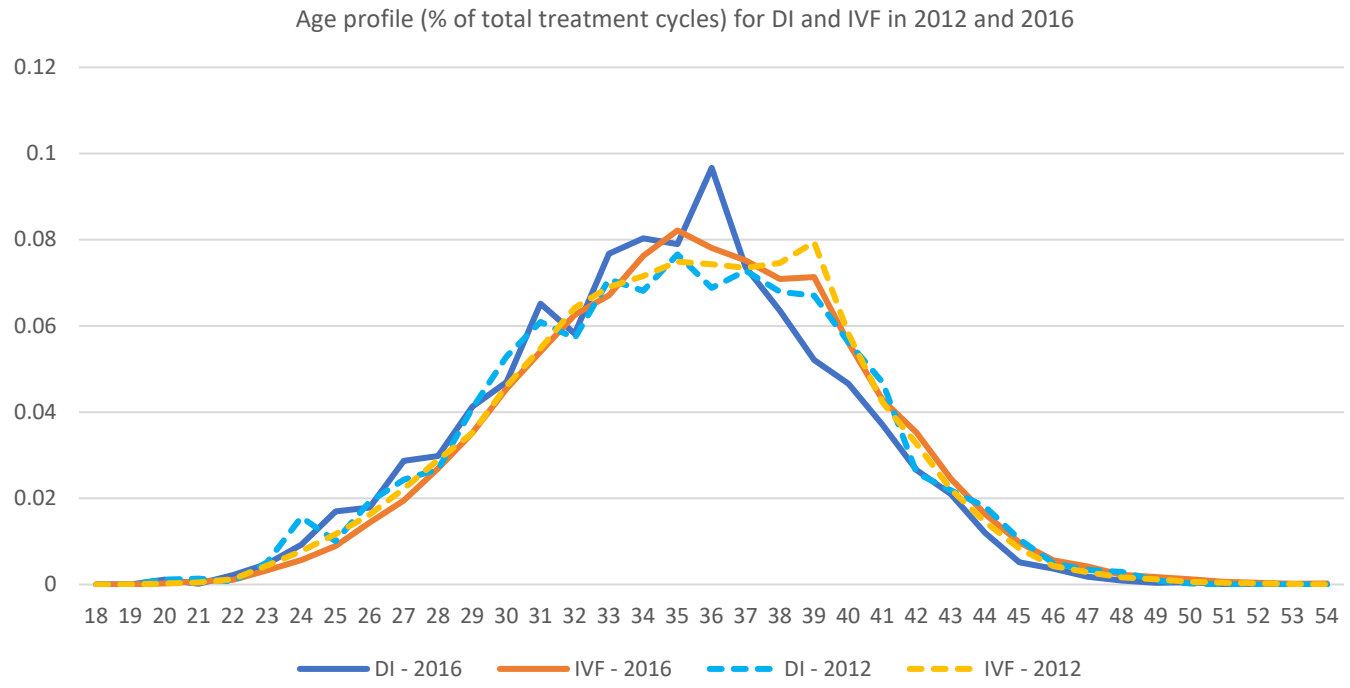
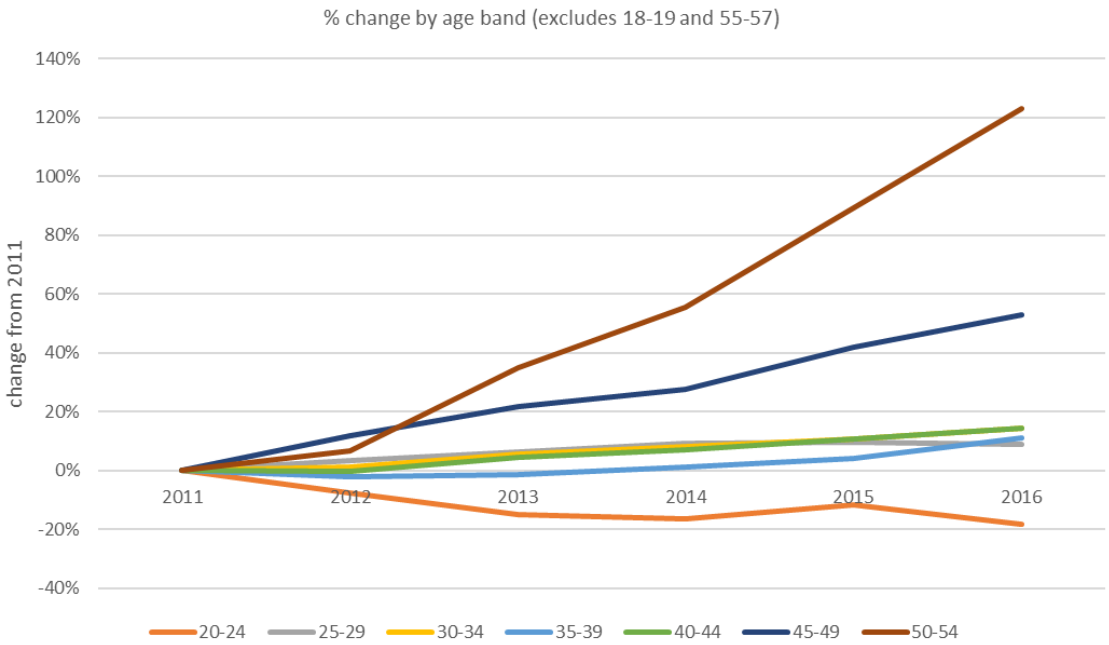
[2] The data used in the production of this report contains unverified data, and was extracted in October 2017. Data is subject to change over time as it is a live register. The term treatment, as used in this document, refers to a chargeable treatment cycle (typically one that involves a transfer of eggs, or DI, but may include other definitions).



2.3. The greatest rate of growth in number of cycles has been seen in the older age bands: 45 to 54, whilst the 20-24 age band has decreased. The high percentage increases seen in some of the smaller age bands (e.g. 45 to 54) have a relatively small real impact on the number of cycles over time, due to their small initial numbers; however, it does suggest that we should monitor and remain abreast of any changes within individual age bands as each shows difference patterns of change over time.

2.4. There has been consistent growth in treatment cycles for women aged 25 to 39 – also the age bands with the highest numbers of ferility treatments.



3. Regional variation

3.1. Understanding how treatment activity varies by region could allow us to develop more tailored forecasts.

3.2. There is significant variation in regional growth over the past 10 years, but we have not yet explored how this might impact on the overall forecast.

4. Treatment activity

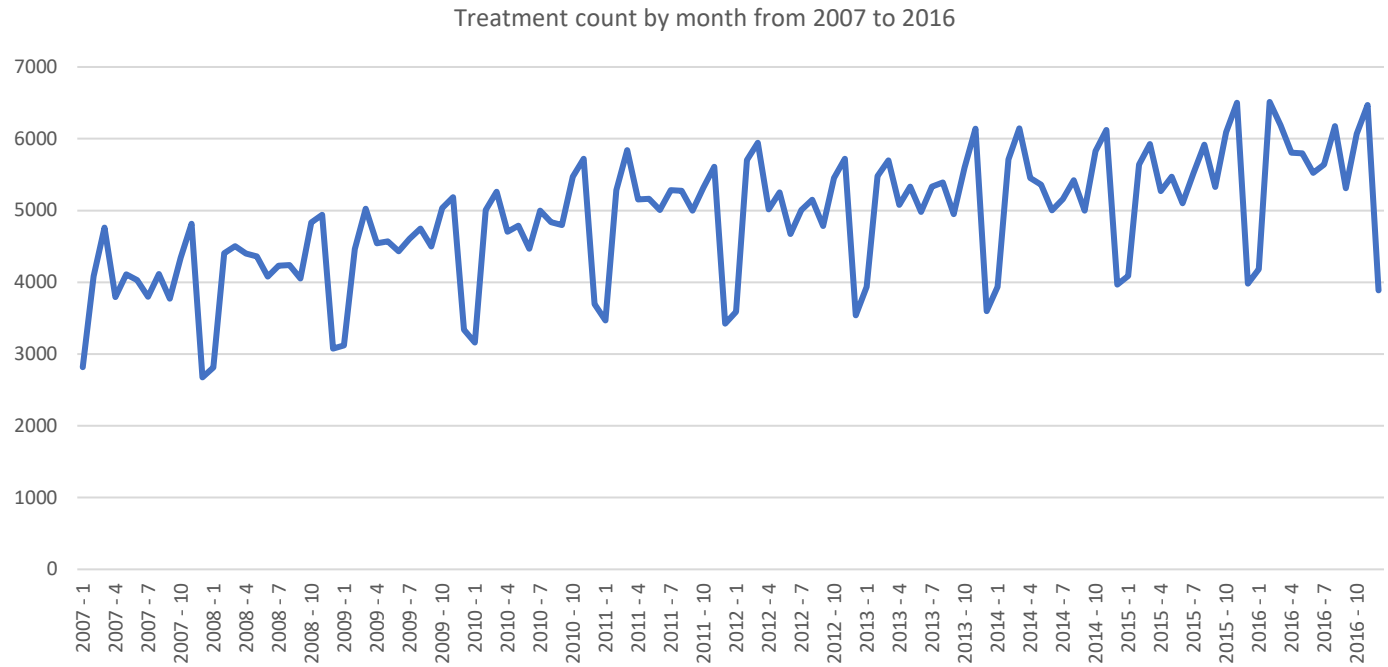
4.1. Knowing how treatment activity (and therefore income) fluctuates over time and throughout the year, enables us to plan efficient use of our resources within and across financial years.

4.2. The number of annual treatment cycles across the sector has increased by 39% for DI, and 44% for IVF from 2007 (an average of 4.3% and 4.9% each year respectively). The proportion of DI-IVF cycles has remained constant over time.

Year	DI	IVF	% IVF
2007	3,900	43,219	92%
2008	3,999	45,944	92%
2009	3,896	49,666	93%
2010	3,946	52,961	93%
2011	4,108	55,717	93%
2012	4,478	55,354	93%
2013	4,641	56,873	92%
2014	4,696	58,409	93%
2015	4,971	59,866	92%

2016	5,440	62,120	92%

4.3. There is a seasonal pattern in chargeable treatments for all patients. The same seasonal variation is observed across all regions, funding types and patient age. This is important to note as it means income is expected to fluctuate significantly each quarter, which may have implications on financial planning.



5. Funding of treatment

5.1. Although we don't include funding type in the final model, we explored changes in funding type over time, as national policy changes may have an impact on the number of patients able to access NHS-funded fertility treatment. If national policy did affect this, we would need to think about what the likely impact would be and how we would account for it in our forecasts.

5.2. The proportion of cycles funded by the NHS has remained stable from 2010 to 2016; a much higher proportion of IVF cycles are NHS funded than DI cycles. In the table below, 'unknown' funding has been excluded, so total treatments may not equal the total number of chargeable treatments.

	Private (IVF and DI)	NHS (IVF and DI)	% NHS (IVF and DI)	% NHS (DI)	% NHS (IVF)
2007[3]	5,072	1,676	25%	18%	26%
2008	32,286	13,345	29%	16%	30%
2009	33,556	19,466	37%	19%	38%
2010	34,701	21,899	39%	19%	40%

[3] In 2007, funding type was not routinely collected (there were a high number of 'unknowns'

2011	36,668	22,769	38%	18%	40%
2012	36,834	22,575	38%	16%	40%
2013	37,064	23,988	39%	16%	41%
2014	38,009	24,592	39%	15%	41%
2015	39,335	25,067	39%	17%	41%
2016	40,939	26,192	39%	16%	41%

6. Summary of demographic and activity data

- There has been a steady increase in the number of chargeable cycles over time.
- The proportion of cycles funded by the NHS remained steady between 2010 and 2016.
- Most cycles occur for women aged 31 to 40 years of age, and there is constant growth in this age band.
- There has been significant growth in the number of cycles for women aged 45 to 54.
- Regions show different trends in growth rates, of which the overall impact on activity is difficult to gauge.

7. Treatment rates using ONS population estimates

7.1. Rates per capita (a rate proportional to the number of persons in a population) should be used to understand if changes in the fertility trends are driven by changes in the size of the underlying population.

7.2. The ONS produces national population estimates, provided for single year of age and regions. The population bases used in the tables excludes 18-19 and 55-57 year olds for consistency, as there are very small numbers of patients accessing treatments in these age ranges.

7.3. The population estimates used are the ONS 2016 mid-year estimates, produced in June 2017[4].

7.4. One drawback of treatment rates per capita is that, based on the data we have used for this analysis, we are assuming a constant rate of repeat treatments, whereas in actual fact, as success rates of IVF and DI continue to rise, we are likely to have fewer patients having repeat treatments.

Overall Rate

4 https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/qmis/annualmidyearpopulationestimatesqmi

7.5. The overall chargeable treatment rate per capita (for 20-54 year olds) is 0.44%, at around 0.11% each quarter (or, if we assumed each treatment was for a separate individual, 0.44% of women had fertility treatment).

7.6. This has shown a steady increase from 2007: over the past 10 years the number of treatment cycles as a % of the total female population (for women aged 20 to 54) has increased from 0.32% to 0.44%, so growth in activity cannot be explained just by the change in the population size. Although the rate remained stable between 2011 and 2012; from 2012, which represents the most recent indication of trends in the developing fertility sector, the rate has consistently increased.

7.7. Estimates suggest that the incidence of infertility in the UK population is 1:7 to 1:6 (14% to 17%). Therefore, despite the very significant increase in the amount of fertility treatment undertaken over the past 25 years, the sector is still a very long way from market capacity (even allowing for the fact that IVF is not suitable for all who have problems with their fertility).

	Population	DI	IVF	IVF or DI	DI	IVF
2007	14,813,112	3,896	43,198	0.32%	0.03%	0.29%
2008	14,932,461	3,996	45,912	0.33%	0.03%	0.31%
2009	15,016,012	3,895	49,651	0.36%	0.03%	0.33%
2010	15,122,508	3,945	52,946	0.38%	0.03%	0.35%
2011	15,233,433	4,107	55,705	0.39%	0.03%	0.37%
2012	15,289,770	4,478	55,347	0.39%	0.03%	0.36%
2013	15,321,322	4,636	56,864	0.40%	0.03%	0.37%
2014	15,358,039	4,694	58,403	0.41%	0.03%	0.38%
2015	15,403,368	4,968	59,853	0.42%	0.03%	0.39%
2016	15,419,018	5,431	62,061	0.44%	0.04%	0.40%

Change in population, and change in treatment

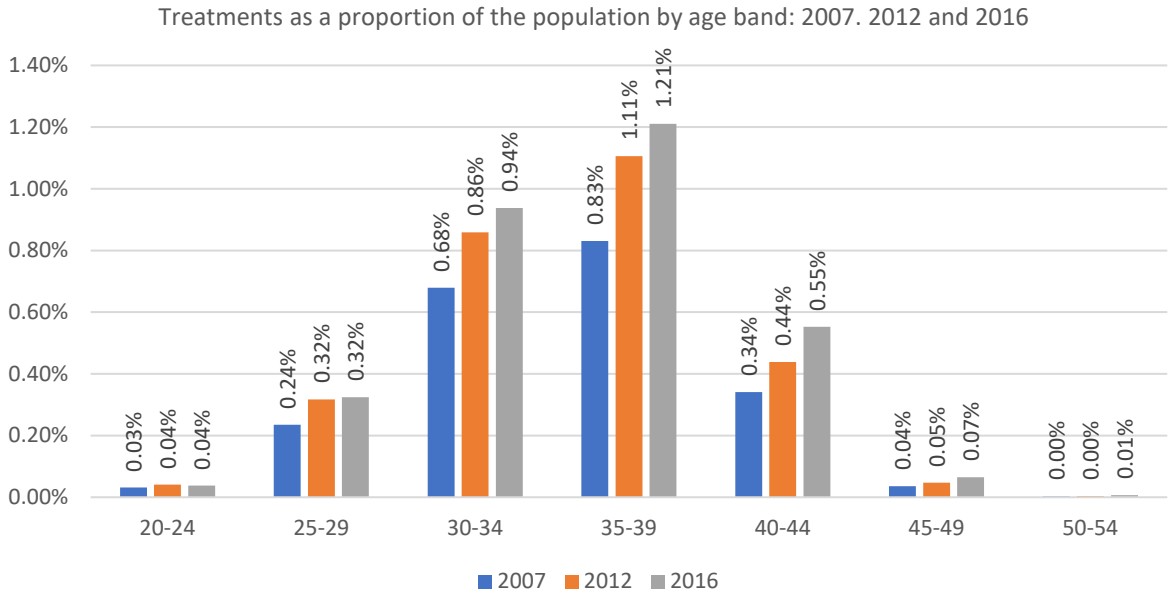
7.8. Overall, total population growth between 2007 and 2016 for 20 to 54 year olds has been +4.1%. Treatment activity, however, has increased by 43.3%, suggesting increased activity (and associated income) cannot be explained by population growth alone. This is also the case using more recent population and activity changes (e.g. between 2013 and 2016): treatment activity has increased at a greater rate than population growth.

Change period		20-24	25-29	30-34	35-39	40-44	45-49	50-54	All (20-54)
2007-2016	**Population**	2.0%	9.1%	10.9%	-8.9%	-11.8%	8.7%	24.3%	4.1%
	Treatment activity	23.0%	50.0%	53.1%	32.8%	43.2%	99.6%	205.6%	43.3%
2013-2016	**Population**	-2.3%	2.6%	1.4%	5.4%	-7.5%	-1.4%	7.1%	0.6%
	Treatment activity	-3.9%	2.4%	8.6%	12.5%	9.5%	25.8%	65.0%	9.7%

Rates by age band

7.9. The highest treatment per capita rate is for women aged 35-39 in which this treatment rate has also increased the most from 2007 (from 0.83% to 1.21%). Treatment rate per capita has increased considerably for women aged 30-34 and 40-44, whereas there does not seem to be much change for women aged 20 to 29 or 45 to 49, as a proportion of the total population.

7.10. The chart below shows treatments as a proportion of the total population within each age band.



8. Summary of treatment activity per capita

- The overall treatment rate per capita is 0.44% in 2016, which has increased steadily from 2007 (0.32%). The growth in treatment activity of 43.3% compared to a population increase of 4.1% indicates that population size is one of many factors driving increased activity.
- Rates vary considerably by age band, suggesting a more advanced forecasting model which incorporates age band trends could be developed. However, the need to do this should be balanced against the additional value gained from developing a more specified forecasting model (which does not always equate to better estimates).

9. Forecasting

Purpose and methodology

9.1. As the purpose of this paper is not to develop an advanced forecasting model, highly specified to the current context, the time series methods explored in the development of the model are simplistic, high level and described in Annex B.

Annual Forecast

9.2. The table below shows the rate forecasted using linear forecasting, exponential smoothing (default excel values), and for comparison, retaining a constant rate as seen in 2016 (0.44%).

9.3. There are minimal differences in the rate between a linear model and ETS model either short term or long term: both increase to 0.49% by 2020, and increase to 0.55% in 2025 and 0.61% in 2030. It is important to remember that current trends may not hold true when looking further than a few years into the future, so the 2025 and 2030 estimates are provided for context, as opposed to a likely outcome based on the information we currently hold.

9.4. We forecast that by 2020, the number of chargeable treatments is expected to increase to 74,919 (linear forecast) or 74,613 (ETS) with a 95% confidence range of 70,906 to 78,319.

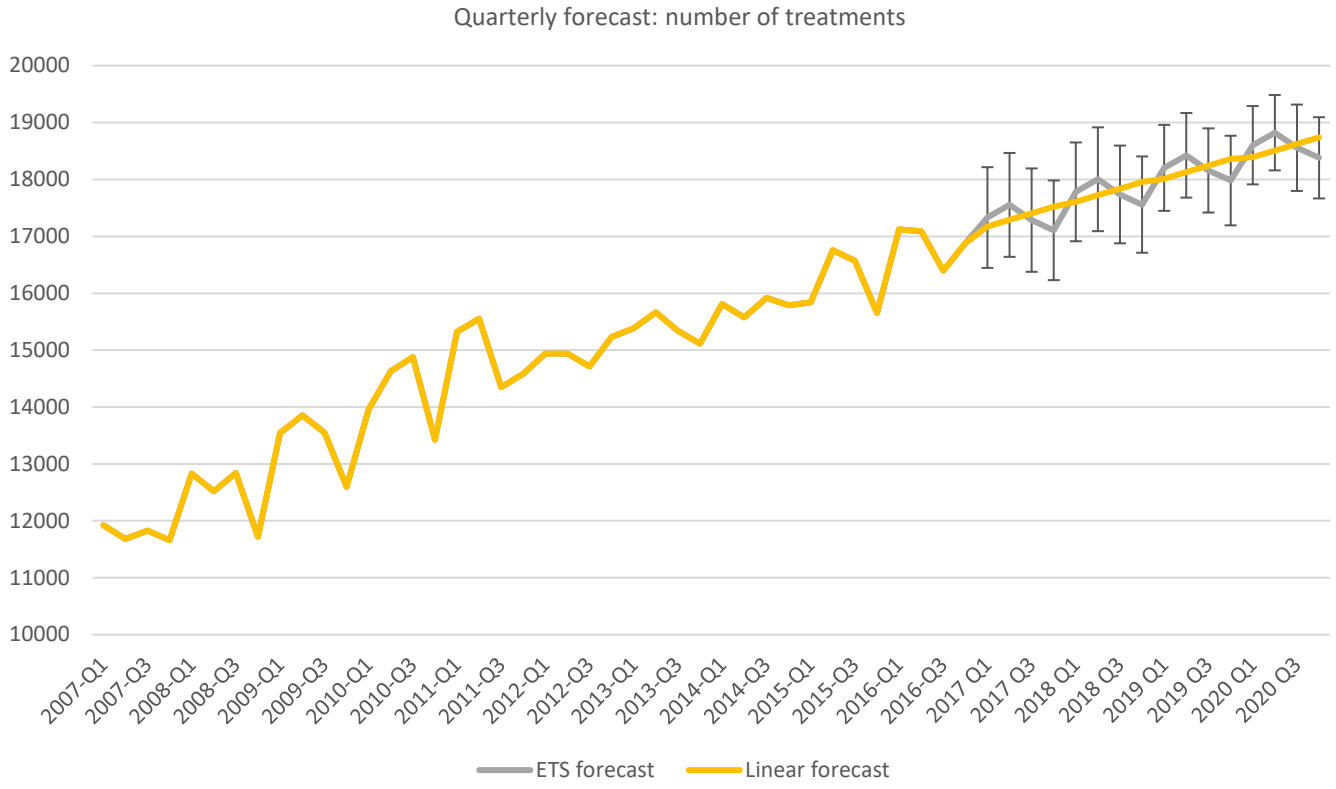
9.5. This forecast is supported by data from the first 6 months of 2017/18, during which there have been 34,564 chargeable treatments – the ETS quarterly method forecasted 34,884 treatments: an error of just -320 treatments (+0.93%).

	Total Population	IVF or DI Rate (linear)	IVF or DI Rate (ETS)	Forecast (assume constant 2016 rate)	Linear forecast	ETS Forecast	ETS confidence interval	ETS confidence interval (counts)	£ (ETS forecast) - assumes 100% IVF	£ (ETS forecast) - assumes 92% IVF, 8% DI	Lower 95% - assumes 92% IVF, 8% DI	Upper 95% - assumes 92% IVF, 8% DI
2007	14813112	0.32%	0.32%	47094	47094	47094	-	-	-	-	-	-
2008	14932461	0.33%	0.33%	49908	49908	49908	-	-	-	-	-	-
2009	15016012	0.36%	0.36%	53546	53546	53546	-	-	-	-	-	-
2010	15122508	0.38%	0.38%	56891	56891	56891	-	-	-	-	-	-
2011	15233433	0.39%	0.39%	59812	59812	59812	-	-	-	-	-	-
2012	15289770	0.39%	0.39%	59825	59825	59825	-	-	-	-	-	-
2013	15321322	0.40%	0.40%	61500	61500	61500	-	-	-	-	-	-
2014	15358039	0.41%	0.41%	63097	63097	63097	-	-	-	-	-	-
2015	15403368	0.42%	0.42%	64821	64821	64821	-	-	-	-	-	-
2016	15419018	0.44%	0.44%	67492	67492	67492	-	-	-	-	-	-
2017	*15415782*	*0.45%*	*0.45%*	*67478*	*69622*	*69309*	*0.01%*	*2009*	*5544720*	*5295208*	*5141720*	*5448695*
2018	*15412773*	*0.46%*	*0.46%*	*67465*	*71504*	*71193*	*0.02%*	*2703*	*5695440*	*5439145*	*5232636*	*5645654*
2019	*15385807*	*0.48%*	*0.47%*	*67347*	*73272*	*72963*	*0.02%*	*3249*	*5837040*	*5574373*	*5326150*	*5822597*
2020	*15335553*	*0.49%*	*0.49%*	*67127*	*74919*	*74613*	*0.02%*	*3707*	*5969040*	*5700433*	*5417218*	*5983648*
…												
2025	*15268671*	*0.55%*	*0.55%*	*66834*	*83984*	*83686*	*0.04%*	*5465*	*6694880*	*6393610*	*5976084*	*6811136*
…												
2030	*14954982*	*0.61%*	*0.61%*	*65461*	*91458*	*91173*	*0.04%*	*6664*	*7293840*	*6965617*	*6456488*	*7474747*

Quarterly Forecast

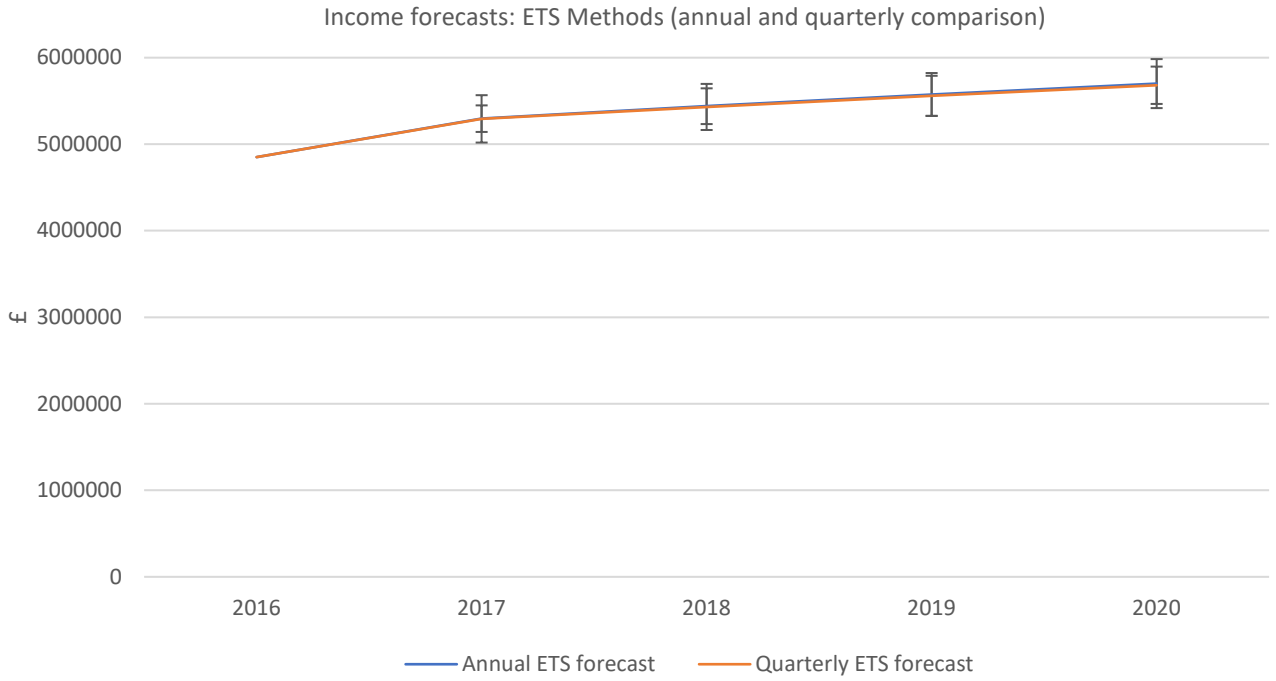
9.6. The chart below shows the rate forecasted using both linear regression and exponential smoothing (default excel values). As opposed to the annual forecast shown above, this version will provide information on how income might vary between quarters in the year, potentially allowing for better resource and business planning. We can observe from the chart the differences between the ETS model (which incorporates seasonal variation) and the linear model (which predicts only a straight line).

9.7. In 2020, aggregating each quarter, the projected number of treatments is 74263 (linear forecast) and 74361 (ETS) with a 95% confidence interval range of 71537 to 77185.



Income Forecasts

9.8. The following graph illustrates the increased income that would follow the forecast increase in treatment volumes. In 2016/17, treatment costs per cycle changes, so this may explain the 'bump' in income between 2016 and 2017 which disappears if the 2015/16 costs associated with treatments are used.



9.9. Under our model income is projected to increase from £4,850,819 in 2016 to £5,681,180 by 2020 (aggregated quarterly ETS). Over the first 6 months of this financial year we have seen growth of just over 1%. The table below provides the forecast income for the lower and upper 95% confidence intervals.

	Annual ETS forecast	Lower 95% - assumes 92% IVF, 8% DI	Upper 95% - assumes 92% IVF, 8% DI	Quarterly ETS forecast	Lower 95% - assumes 92% IVF, 8% DI	Upper 95% - assumes 92% IVF, 8% DI
2016	4,850,819			4,850,819		
2017	*5,295,208*	*5,141,720*	*5,448,695*	*5,292,686*	*5,018,945*	*5,566,428*
2018	*5,439,145*	*5,232,636*	*5,645,654*	*5,430,588*	*5,164,258*	*5,696,919*
2019	*5,574,373*	*5,326,150*	*5,822,597*	*5,559,475*	*5,328,289*	*5,790,662*
2020	*5,700,433*	*5,417,218*	*5,983,648*	*5,681,180*	*5,465,427*	*5,896,934*
…						
2025	*6,393,610*	*5,976,084*	*6,811,136*			
…						
2030	*6,965,617*	*6,456,488*	*7,474,747*			

9.10. Taking the lower 95% interval, we would still see growth of c£90k each year through to 2020 (based on 2016/17 outturn). Although very early the increase we have seen in the first 6 months of this financial year is very similar to this estimate: using the quarterly estimates, income in the first 6 months of 2017/18 has been £2,668,730, compared to a quarterly forecast of £2,665,138 (an error of £3,592, or -0.13%). The income is within the confidence interval of £2,527,770 to £2,802,505.

10. Summary of forecasts

- Both linear forecasting and exponential smoothing methods forecast increases in the number of chargeable treatments, based on historic patterns to date
- By 2020, both linear forecasting and ETS suggest the number of treatments will increase from 67492 in 2016 to between 70906 and 78319.
- Treatment income is likely to range between £5,454,427 and £5,896,934 by 2020, with the lower estimate for growth still providing an annual increase in income of c2% per annum.
- The forecasting methods are intentionally simplistic to account for this early exploratory work which will inform whether we invest further resources into developing more advanced models.

11. Next steps

11.1. It is important to note that forecasting isn't an exact science, but if done correctly, can predict with some accuracy the trends that tend to occur when dealing with volatile metrics such as treatment activity.

11.2. This report provides evidence for the factors which affect treatment and income activity across the fertility sector, in a way not previously analysed. It highlights the seasonal pattern across the year, and that the growth in treatment rates (per capita) vary by region and age band.

11.3. The combined impact of the factors discussed in this document indicate a likely increase in demand for fertility treatment and therefore chargeable activity over the next 5 years. More advanced modelling, accounting for differing trends within these factor levels could provide more sophisticated forecasts, but as the current model in the first 6 months of 2017/18 is accurate to within 99.8%, there is an open question as to what additional value this would bring. However, we are keen to add further ONS data, relating to the upward trend in the age of first live birth for the UK population, which is also likely to demonstrate a correlation with the growth in treatment over the past 10 years.

11.4. Our work to date has considered the data in terms of demand, we are yet to consider the impact of supply and policy in relation to how that base demand translates through to activity. In such a rapidly developing sector we must consider the possible impact that national policy changes may have on patterns of activity (e.g. NHS commissioning decisions) as well the potential impact of price and those seeking treatment abroad. In short, increased demand may not necessarily lead to increased activity if barriers to access increase alongside.

11.5. We will look to test the validity of this model on our emerging 2017 data to determine if the results from the analysis provide realistic estimates of activity and income.

11.6. In terms of fee changes we propose keeping fees for 2018/19 unchanged. The sector appreciates stability in terms of our fees and the information presently at hand does not indicate we could reduce our fees materially for 2018/19 based on forecast increased activity. We propose to bring a further update to the Authority in mid-2018, which will allow us to combine our improved income forecast model with a three-year financial plan and a proposal for future fees from April 2019.

Annex B: Forecast methods

1. Population forecast

1.1. Future treatment activity rates have been forecast, so that we can apply the same model to variants of the underlying (ONS) dataset, should we wish to model different population growth scenarios. The ONS population projections provide an indication of the future size and age structure of the population based on mid-year population estimates and a set of assumptions of future fertility, mortality and migration and are available at regional, and national level. These projections are widely used for resource allocation and planning. The 2014-based ONS national population projections[5] were used in this analysis (released May 2016).

2. Time Series Methods

2.1. Time series methods are forecasting techniques that base the forecast solely on the history of the item you are forecasting. These forecasting models are best suited to shorter-term forecasting due to their assumption that future patterns and trends will resemble current patterns and trends. This is a reasonable assumption in the short term but becomes more tenuous the further out you forecast. Both linear forecasting and exponential smoothing models are appropriate when you can assume a reasonable amount of continuity between the past and the future.

3. Linear Forecasting

3.1. Linear trend forecasting is used to impose a linear line of best fit to time series historical data. It is a simplistic forecasting technique that can be used to predict a variable.

4. Exponential Smoothing (ETS)

4.1. Exponential smoothing is a time series forecasting technique. Exponential Smoothing methods are a popular way to forecast and are among the leading methods that have become industry standards. The main advantages of using the ETS method are the ability to detect seasonality patterns and confidence intervals.

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5 https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationprojections/datasets/localauthoritiesinenglandtable2

The Regulation of groups of clinics

Strategic delivery:	☒ Safe, ethical, effective treatment	☐ Consistent outcomes and support	☐ Improving standards through intelligence
Details:			
Meeting	Authority		
Agenda item	8		
Paper number	HFEA (24/01/2018) 865		
Meeting date	24 January 2018		
Author	Nick Jones, Director of Compliance and Information		
Output:			
For information or decision?	For decision		
Recommendation	That we move to regulating groups of clinics (where there is demand) to promote further improvement in clinic performance. The Authority is asked to consider these proposals and endorse the approach set out.		
Resource implications	Within existing resources		
Implementation date	Immediately, in consultation with clinic groups		
Communication(s)			
Organisational risk	☒ Low	☐ Medium	☐ High
Annexes	None		

Human Fertilisation & Embryology Authority

1. Introduction

1.1. Over the last few years the number of licensed treatments that take place in clinics that are part of a 'group' of licensed clinics has increased markedly. These developments raise questions about the appropriate organisation of the regulatory regime, which is based on the model of separate, stand-alone clinics, whether in the NHS or the private sector, led by an identified person responsible (as required by the HFE Act).

1.2. To date, we have met the challenges posed by the growth of group structures by piloting an approach with the more integrated groups. This approach reflects the fact that groups take a variety of forms and are at different levels of maturity. While this approach has worked well, we now are of the view that the fertility market has reached a sufficient stage of development that we should set out a broad policy position on the regulation of group structures, and move to implement this where there is demand.

1.3. The steps we have taken in this direction have already paid dividends for the groups of clinics involved in terms of a reduction in some regulatory activity, involving, for example, the multiple assessment of shared quality management systems at different sites. Such an approach also meets the requirement placed upon us to undertake our regulatory activity proportionately and efficiently (for example, being aware of the 'business impact' of our inspection and monitoring activity). Adopting a more transparent policy position on these issues cements the benefits achieved so far and offers the prospect of more effective regulation still, focussing on better outcomes for patients.

1.4. This paper first outlines the current position of clinic groups within the overall landscape of licensed clinics and activity. It then sets out the steps we have taken to date to regulate some clinics at a group level, before going on to suggest a model which can be rolled out more widely.

2. Background

2.1. There are currently 87 licensed clinics providing comprehensive treatment and storage IVF services. Of those, 31 are located within NHS Trusts and are by their very nature not part of the group structures which are the focus on this paper. Of the 56 clinics in private ownership, some 38 are in a group structure of one form or another. They undertake an increasingly large proportion of treatment cycles undertaken, some 30,000 of nearly 78,000 (38%) of all cycles in the year-ending December 2017.

2.2. While the growth of group structures is relatively new, it is worth reminding ourselves that it has been a feature of the sector from its early years - for example, the Care group began to establish a presence in many cities in England in the mid-1990s (and has recently moved into Ireland).

2.3. The growth of clinic groups is, in large part, a response to the significant increase in activity levels which has led to opportunities for economies of scale

and an influx of private capital. However, the forms taken depend on a variety of factors which are often local and contextual – such as partnerships based on incremental, organic growth; partnerships formed because of relationships of senior clinicians/proprietors; and a more deliberate approach based on acquisitions and takeovers. Those involved see advantages such as sharing of expertise and knowledge; economies of scale (as noted above) and greater consistency, for example in the development of IT systems and websites; and enhanced purchasing power due to scale. Conversely, we are also aware that some are wary of too much integration as failings in one part of the group can have adverse reputational consequences on the others.

2.4. To illustrate further, and to show the scale of activity within such groupings, we have developed an informal typology or categorisation of the various group structures in the current UK fertility market. These are not hard and fast and there is some fluidity between the types.

- **Integrated model -** based on a common operating system with a high degree of central control: IVI Group (currently three clinics in England with plans for more); Create (four clinics and a satellite); Bourn Hall (three clinics and satellites – in the East of England) and Care group – six clinics. Approximately 13,500 cycles are performed annually by clinics in this arrangement.
- **Federated model** - based on an autonomous role for the individual clinics (and lead clinicians), with central services provided with permission and where it makes sense to do so (marketing, website, IT, purchasing): The Fertility Partnership (eight clinics across the UK); London Women's Clinic (four clinics in England and Wales). Approximately 12,000, cycles are performed annually by clinics in this arrangement.
- **Franchise** - consultant led model within the independent hospital operating model, with high local autonomy with marketing and legal services provided at a central level only: BMI (four clinics in England) and Nuffield (three clinics). Approximately [3,000] cycles are performed annually by clinics in this arrangement.
- **Location specific** - first encountered in 'research' clinics with different research projects licensed by the HFEA in the same institution, this model is now seen in treatment clinics located in separate premises but in the same broad vicinity. Typically, this model involves a high degree of shared processes and functions - for example, the three clinics within the ARGC grouping in London. Approximately 1,500 cycles are performed annually by clinics in this arrangement.

2.5. The development of group structures in the fertility market in the UK is for the most part outside of the regulatory regime. The HFE Act gives us no powers to approve commercial arrangements, although a change of ownership may lead to a change in the Person Responsible which requires our approval, or it may lead to questions as to the 'ownership' or the accountability for stored gametes and embryos, which again would trigger our intervention.

2.6. New group structures may also give rise to transitional issues where we do have a role - for example, senior and experienced staff may be affected by the changes and well-established ways of working may be subject to change, both of which have the potential to impact on the quality of services offered to patients. For all these reasons, we have tried to keep abreast of these developments and it should be noted that we are overall supported in this by clinic leaders who usually work hard to keep us informed

3. An outline model for the regulation of clinics in a group structure

3.1. As noted above, recently we have developed a set of operating procedures to better regulate groups of clinics, for example with the Care Group and Bourn Hall clinics. This approach has been developed with the respective corporate centres to reflect the model employed and is seen by both the clinics and us to be working well.

3.2. The HFE Act provides some constraints on what we can do - we must, for example, licence every separate premises even if they are within a group - but within the requirements of the law, our approach to the regulation of groups of clinics can be summarised as one of 'earned autonomy'. Where core activities, operating procedures and policies are shared we aim to reach a single group-wide assessment of those shared elements, simplifying the inspection process by reducing duplication, and allowing a focus on the elements that are particular to the individual clinic undergoing inspection. In return, where we find non-compliances in those shared elements we expect to see a group wide response.

3.3. As noted above, each group will have a distinct approach. At the same time, it is possible to undertake regulatory activity within a consistently applied framework. For example, in taking each component of the HFEA Code of Practice it is evident that some components can be assessed only at the local clinic level and others have a local clinic and group aspect – on a continuum. The table below takes each CoP component (at a high level – some have several sub-levels) and shows that some areas can be assessed at group level (once) and at local clinic level by way of checking or confirmation. Other areas will simply continue to be inspected at a local clinic level.

CoP	Clinic	Group	Notes
1	**Staffing**		Support to PRs provided by centre
2	**Counselling**		Local review in line with group policy
3	**Information and consent**		Information policies and technical infrastructure
4	**Multiple births**		Policy and performance comparisons

5	**Welfare of the Child**		Local review in line with group policy
6	**Embryo testing**		Local review in line with group policy
7	**Donation and surrogacy**		Local review in line with group policy
8	**Use of gametes and embryos**		Adherence to policies and performance comparisons across clinics in the group
9	**Research and training N/A research only**		
10	**Facilities and administration**		The role of the quality management system is crucial
11	**Treating people fairly**		Local review in line with group policy
12	**Record keeping**		Document control arrangements
13	**Mitochondrial donation**		N/a given scale

3.4. This approach means that in practice we:

- Identify a lead inspector for the group, for relationship management purposes;
- Ensure that the clinics' quality management system is operated within the respective clinics (and then to be tested at inspection);
- Ensure there are sufficient resources within the group to support a clinic's quality management efforts, for example in auditing and follow-up, in sharing good practice, and in the collection and reporting of performance information;
- Assess at renewal inspections how the overall arrangements for ensuring quality apply at that clinic – for example those activities that are led from the centre and those that are undertaken locally – and whether they are effective and well-supported;
- Take a lighter touch approach at the next renewal inspection within the group of those areas that were identified as working well elsewhere, but have higher expectations of those areas identified as requiring improvement.
- Expect to see the group using each clinic inspection as an opportunity for learning and improvement across the group.

3.5. We now believe that the number of groups within the fertility market has developed to a state where we can consider rolling out this model more widely. In saying this we need to recognise that not all groups will wish to move to this model, and much will depend on the maturity of the group, the extent of which processes are shared and the willingness to make changes across the group to non-compliances found in individual clinics.

3.6. In moving to this group regulatory model we propose to adopt the following operating principles:

- Intelligence-led: Building on the establishment of the intelligence team to consolidate our understanding of clinics within a grouping. Taking already available information from the risk tool and Choose a fertility clinic outcomes to form new insights about the performance of clinics within and across the group.
- Formed by relationship management: Formalise arrangements such that each identified group has a named Inspector, Senior Inspector, or in some instances Chief Inspector, with formal opportunities for discussion about the operation of the group, and clinics within it. The seniority of the individual is less important than the requirement to understand the relationship and share knowledge within the team.
- Tailoring inspections: Being more aware and have a greater understanding of which activities are undertaken where. This could involve the consolidation and streamlining of pre-inspection processes such as the completion of the self-assessment questionnaire, and the submission of standard information in line with general directions.
- Centring on the patient: That there is clarity as to accountability, so patients are clear who is providing a service. For example, some clinics are centralising - the patient contact function or their arrangements for investigating adverse incidents. Some groups may also direct patients toward particular locations for some licensed activity such as PGD, PGS or even standard IVF and ICSI treatments. We need to understand those flows and our reporting must provide clarity relating to such arrangements such that patients can see we are acting to protect their interests always, regardless of arrangements put in place by clinics.
- Meet our statutory requirements: That we continue to inspect at a two-yearly interval (as required by legislation) and to license the premises to which a licence applies, but that we do so intelligently and considering the way that the clinics organise themselves and where the licensed activities take place.
- Promoting effective leadership: In the coming year, more broadly, we will have an increasing focus on leadership in clinics. In the light of pressures faced by clinics relating to growth and the need to maintain and grow market share, and in their ability to exercise control when the span of influence expands, we will want to explore leaders' capacity and ability to maintain and improve performance.

4. Next steps

4.1. If the Authority is content with these proposals we will work up the detail and write to all the clinics in each group to test their appetite to move to this evolving regulatory model.

4.2. For those clinics that choose to move down this path we will take the opportunity of the forthcoming reallocation of clinic portfolios across the inspectorate to identify new relationship management arrangements. We will also work alongside intelligence and Register colleagues and begin to put in place group baseline reports that will describe arrangements and form the basis for future inspection reporting.

5. Recommendation

5.1. That we move to regulating groups of clinics (where there is demand) to promote further improvement in clinic performance. The Authority is asked to consider these proposals and endorse the approach set out.

Intelligence Strategy 2017-2020

Strategic delivery:	☒ Safe, ethical, effective treatment	☐ Consistent outcomes and support	☒ Improving standards through intelligence
Details:			
Meeting	Authority		
Agenda item	9		
Paper number	HFEA (24/01/2018) 866		
Meeting date	24 January 2018		
Author	Caylin Joski-Jethi, Head of Intelligence		
Output:			
For information or decision?	For decision		
Recommendation	The Authority is asked to comment on and approve the HFEA's Intelligence strategy for 2017-2020.		
Resource implications	In budget		
Implementation date	Throughout 2017/18-2019/20 business years.		
Communication(s)	Publication on HFEA website.		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex A: Intelligence Strategy 2017-2020		

1. Summary

1.1. Our 2017-2020 vision for high quality care for everyone affected by fertility treatment sets out a bold new ambition to improve standards through using intelligence.

1.2. We recognise that we are 'information rich'. We maintain the world's foremost Register of fertility treatments, have a unique insight into fertility clinics through our regulatory function, interact with patients, stakeholders and the public through various channels, and hold a range of other specialist knowledge. The new Intelligence team has been created in the recognition that improvements will not come from information alone, but from high quality analysis and an organisation-wide focus on using this information to make decisions which improve standards for patients.

1.3. This strategy sets out how we will build on the successes of the Information for Quality programme, supporting the organisation to get the most value out of the new clinic portal and website, enhanced patient feedback mechanisms, the restructured Register of treatments and outcomes, and new data submission system.

1.4. This Intelligence strategy places patient experience at its heart by developing services which enable patients to act as their own advocates and involving them in shaping aspects of sector development. This reflects our aim to recognise that patient experience, alongside the expertise of care professionals, is a valuable tool that can be used to improve standards. We will also use the full extent of our organisational knowledge to ensure robust evidence is used by all stakeholders to drive sustainable self-improvement in clinics.

2. Development of the strategy

2.1. The Intelligence team developed its strategy through a process of reviewing existing systems and worked closely with teams across the organisation to identify areas to build upon.

2.2. We also took advantage of early opportunities to gain input into the strategy with key stakeholders, which included the Scientific and Clinical Advances Advisory Committee (SCAAC), Authority and members of the research community. This means elements of the strategy have already been agreed in principle by the Authority.

2.3. We would like to thank everyone involved in developing the strategy, recognising that it required significant investment beyond everyone's existing workloads. We are confident in our strategic direction, and ready to agree the final document so that we can begin delivering the outcomes we have committed to, and subsequently publish it on our website.

2.4. The executive's corporate management group (CMG) has agreed the approach, and considered the implementation of the strategy across the next two annual business plans through to the end of the 2017-2020 strategy.

3. Delivery of the strategy

3.1. The Intelligence team's ability to deliver the strategy relies upon strong collaborative relationships and robust information sharing processes across the HFEA.

3.2. Our commitments in the Intelligence strategy (Annex A) are aligned with the aims set out in our 2017-2020 organisational strategy. A summary of the Intelligence strategy is provided below, and a few elements are discussed in detail.

3.3. We set out a programme of publications which respond to emerging policy areas, feedback from patients and enhance related workstreams, such as ensuring greater awareness of research and evidence-based practice.

3.4. We will deliver on two programmes of work relating to good value fertility services: one, working with NHS England and others to promote equality of access and incentivising improved performance; and the second, to inform future discussions around HFEA fees, ensuring we continue to recover the full cost of regulation and provide value for money.

3.5. We aim to synthesise the broad range of evidence held across the organisation, using this to enhance our understanding of factors driving changes in performance and being responsive to emerging needs, resulting in more targeted interventions and patient information.

3.6. We will work in partnerships with patients and individuals affected by assisted reproduction to understand their experiences, perceptions and needs. We will use this to inform our publications and incentivise improved quality of patient care in clinics.

3.7. We will capitalise on recent system improvements to deliver more standardised approaches to information sharing and provision, facilitating relationships with the research community, and working with data producers, users and stakeholders in other organisations to meet best practice standards and deliver joined up approaches to problems.

4. Patient-focused publications

4.1. The strategy contains a proposal for two new publications whose scope and titles are in development.

Media stories and research: what does the evidence tell us?

4.2. This report will provide a 'myth-busting' approach to public information needs, offering a patient-friendly evidence-based discussion around stories and perceptions within the media. This aims to promote greater societal awareness of evidence-based practice, support our wider work relating to treatment add-

ons, raise understanding of the role of research in driving improvements and fulfil our commitments to ensure patients can make informed choices.

Patient voices: what does good practice in clinics look like?

4.3. This report will build on feedback from patients, inspectors and the information available on the new website, drawing together the factors that patients should consider when choosing a fertility clinic and highlighting examples of good practice. It could provide an evidence-base for patients against which to benchmark elements of patient care being offered at clinics, helping patients to advocate for improved services and incentivising a more equitable experience across the UK.

5. Patient care quality mark

5.1. This proposal builds upon the principles of co-production, which is gaining increasing popularity across the public sector, particularly within health, social care and education.

5.2. Co-production is defined[1] within the Care Act as when "an individual [influences] the support and services [they] receive, or when groups of people get together to influence the way that services are designed, commissioned and delivered".

5.3. Co-production acknowledges that individuals affected by ART have knowledge and experience that can be used to help make services better, not only for themselves but for other people who need them. It means that power is shared more equally between those who use services and those who provide them.

5.4. There is currently no blueprint for high quality patient care above and beyond compliance with the Code of Practice, however, through working in partnership with patients, it is believed we could create a framework of commonly agreed principles which define excellent patient care.

5.5. This proposal for a 'patient care quality mark' recognises that for patients, regulatory compliance against the Code of Practice only forms part of their experience, satisfaction and outcomes.

5.6. The quality mark would be a voluntary scheme for those clinics that want to benchmark their patient care quality. Once clinics are able to demonstrate they have met the framework criteria, they can be assessed and awarded the mark.

5.7. We recognise the long-term commitment of this proposal, the need to engage widely with the sector, the public and individuals affected by ART, and the need to pilot and scope a range of options for delivery.

5.8. It is important to note that this is not proposed as a regulatory requirement for clinics and that there will be involvement from a range of stakeholders in determining the framework to ensure that patient expectations and desires are

[1] Department of Health. (2014). Care and Support Statutory Guidance: Issued Under the Care Act 2014

not prioritised above clinical safety or other relevant issues. There is also a need to recognise that this proposal represents a longer-term project that may not be fully completed, or improvements realised, within the period covered by this Intelligence strategy.

5.9. Some of the potential options for design and delivery could include:

- partnering with a patient-advocacy group to aid in delivery and roll out of the framework
- introducing 'patient inspectors' who could assess clinics against the framework
- embedding the patient care quality mark within the existing inspection process

5.10. Expected benefits of delivering a patient care quality framework under the principles of co-production include:

- delivering a framework which clinics can use to audit, plan and evaluate their services
- supporting our leadership drive in which PRs should aspire to excellent quality care for patients
- power and control is fairer and more equally shared to ensure that individuals affected by fertility treatment have a say in deciding how services should work
- giving clinics the confidence that their service is based on evidence informed by patients
- improving the experiences of people using services provided for ART
- building stakeholder networks and ensuring that assets, including individuals, are better valued and used

6. National patient survey

6.1. The intelligence strategy offers a commitment to help clinics gain more value from their own feedback by, for example, facilitating a national patient feedback survey. This proposal could gather opinions from patients about their experience of fertility treatment, asking them to provide honest feedback on their experiences.

6.2. It could provide an influential source of public information about fertility treatment and offer patients a collective voice to help shape the future of the sector and their institution for current and future patients.

6.3. Results from the survey could help provide a broader picture of the quality of fertility services across the UK which would complement our clinics level patient feedback mechanisms, raise awareness of the HFEA and our role, and raise awareness of the CaFC Rate Your Clinic pages.

6.4. Additional benefits from a national patient survey could include:

- Clinic-level data used to identify areas of strength and weakness, and used to effect changes designed to improve patient experience
- Reduced variation nationally in the quality of patient care
- Results feeding into the HFEA's quality assurance and inspection process to target the inspection process
- Validating our CaFC patient feedback and inspection processes to ensure that patients are able to make informed decisions

7. Next steps

7.1. The strategy, once approved by the Authority, will be published on our website and used to inform our programme of work until 2020.

8. Recommendation

8.1. The Authority is asked to comment on and approve the HFEA's Intelligence strategy for 2017-2020.

Intelligence Strategy 2017/18-2019/20

Improve standards through intelligence

Our 2017-2020 vision for high quality care for everyone affected by fertility treatment sets out a bold new ambition to improve standards through using intelligence. We define intelligence as going 'beyond the data', turning insight - gained from synthesising and analysing a broad range of information - into actionable recommendations for how we, as an organisation, can improve standards.

We recognise that we are 'information rich'. We maintain the world's foremost Register of fertility treatments, have a unique insight into fertility clinics through our regulatory function, interact with patients, stakeholders and the public through various channels, and hold a range of other specialist knowledge. The new intelligence team has been created in the recognition that improvements will not come from information alone, but from high quality analysis and an organisation-wide focus on using this information to make decisions which improve standards for patients.

This intelligence strategy places patient experience at its heart by developing services which enable patients to act as their own advocates and involving them in shaping sector development bridging the gap between patients, the HFEA and clinics to improve standards. Alongside this, we will use the full extent of our organisational knowledge to ensure robust evidence is used by all stakeholders to drive sustainable self-improvement in clinics.

Principles upon which we will work

Impact: we will pursue ideas and work in ways which generate impact for patients, the sector and society as a whole

Transparent: we will share knowledge within the context of promoting an open, enquiring, and informed society, recognising that this fosters the progress of research and benefits patients, the sector and society as a whole

Targeted and accessible: we will ensure the information and services we provide are evidence-based, accessible and that more people receive the information they need in a meaningful way

Collaborative: we will build strategic partnerships within, and external to, the HFEA and foster excellent relationships with patients to promote sustainable sector-wide improvement

How we will achieve our aim

Our aims support our 2017-2020 strategic objectives and describe how we will work towards our vision by focusing on patient experience and sector-level monitoring.

Aim: Use our data and intelligence to drive quality improvements for patients

What will we do?

Publish high quality and accessible information:

- Fertility trends report on treatment outcomes
- State of the fertility sector report on performance in clinics and laboratories
- Treatment specific information, such as on egg freezing and donor conception treatment
- Media stories and research: what does the evidence tell us?
- Patient voices: what does good practice in clinics look like?
- Ad hoc briefings on emerging topics of interest

What difference will it make?

- We will be more focused on analysing information and using what it's telling us to inform our priorities, policies and future work
- Patients will be informed in an accessible and meaningful way about the effectiveness and safety of services
- Clinics will be able to benchmark their performance and identify how to self-improve
- People will continue to turn to us for clear, unbiased and trusted information
- There will be evidence to drive change and inform public and sector debates

Aim: Patients and NHS commissioners receive good value fertility services

What will we do?

- Work with NHS England and other organsations to deliver a benchmark price, commissioning guidance and outcomes-based tariff
- Explore the views of patients on their financial expectations and experiences
- Share benchmark data with NHS commissioners
- Use available data to understand the factors driving treatment activity and deliver an income forecasting model to inform treatment fees

What difference will it make?

- Reduced variation in the price of treatment
- We will continue to support the NHS in its endeavor to pay a fair price for fertility services
- Patients will have realistic expectations for the cost of treatment
- An evidence-based assessment for future income
- Patients are provided with value for money and transparent information about HFEA fees

Aim: Targeted and responsive regulatory interventions in the interests of quality

What will we do?

- Regularly review enquiries, complaints, FOIs and PQs, incidents, inspection reports, and qualitative feedback from all stakeholders
- Develop key indicators and use these for regular sector-level reviews of statistical outcomes to understand how overall performance is changing

What difference will it make?

- A shared understanding of 'good sector performance' across the organisation
- We will be more focused on analysing information and using what it's telling us to inform our priorities, policies and future work
- Increased quality and consistency across clinics
- Increased value for money

- Develop a more risk-based approach to inspections, where we spend less time on low-risk clinics

Aim: Increase insight into patient experience and encourage good practice based on feedback

What will we do?

- Explore what 'quality care' means to patients and communicate this so that patients are empowered to advocate for improvements
- Co-produce a 'patient care quality mark' with patients
- Develop feedback mechanisms to gain insight from clinic staff, researchers and other stakeholders
- Share patient feedback on how emotionally difficult infertility and treatment can be
- Help clinics gain more value from their own feedback by, for example, facilitating a national patient feedback survey or facilitating links between different clinics

What difference will it make?

- We will introduce new patient-driven mechanisms to incentivise effective, safe, ethical services
- Patients and the public will be empowered to work in partnership with the HFEA to improve priorities that are important to them
- An improvement in patients' experience of treatment
- New and expanded evidence will inform the way we approach quality improvements across the sector
- Clinics will have the ability to benchmark their performance and identify how to self-improve resulting in increased quality of care

Aim: Work more smartly with our resources, and capitalise on recent system improvements

What will we do?

- Build on the capacity of the new website to engage with a wider audience
- Publish more, standardised data internally and externally and in a wider range of formats along with guidelines and standards
- Represent the end user and guide the development of internal reporting tools
- Redesign the application process for using identifying information in research, so more insight can be gained using external, specialist resources
- Develop a new anonymised Register informed by stakeholder engagement
- Ensure compliance with data protection and statutory reporting requirements
- Work more closely with data producers, users, and stakeholders in other organisations to meet best practice standards and deliver joined up approaches to problems

What difference will it make?

- People will continue to turn to us for clear, unbiased and trusted information
- Information is more useful, accessible and consistent in the way it is used and reported
- Improved presentation and public understanding of our published data
- A larger, high quality evidence base, will inform our approach to improving standards across the sector
- Improved and more consistent outcomes in clinics
- Patients will have confidence in their clinic and the HFEA as life-long information guardians
- Provide greater value for money for the HFEA's resources, for patients and other organisations
- Support improved public health decisions

Ovarian Hyperstimulation Syndrome

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

Details	
Meeting	Authority
Agenda item	10
Paper number	HFEA (24/01/2018) 867
Meeting date	24 January 2018
Author	Hannah Verdin, Head of Regulatory Policy

Output	
For information or decision?	Information
Recommendation	That the Authority considers whether OHSS is being reported accurately (section 2) and the proposed actions for improving reporting (section 3).
Resource implications	Within budget
Implementation date	Over time, dependent on issue
Communication(s)	Over time, dependent on issue. Some strands tied to Code of Practice review for October 2018 implementation. Some strands can be communicated through Clinic Focus and stakeholder publications during Spring/Summer 2018.

Organisational risk	☐ Low	☐ Medium	☒ High

1. Introduction

1.1. Ovarian Hyperstimulation Syndrome (OHSS) is a potentially serious side effect which some patients develop in reaction to the drug treatment necessary for IVF. As a consequence, we require licensed clinics to report all 'severe' and 'critical' cases of OHSS to us. In May 2017 a national newspaper alleged that there was under-reporting by clinics of OHSS evidenced by the wide disparity between the number of cases reported to the HFEA and the number of hospital admissions apparently due to OHSS reported to NHS Digital. 60 cases of serious or critical OHSS were reported to us in 2015 and a further 38 cases in 2016; compared with the 865 admissions to hospital for OHSS in England, 836 of which were emergency admissions.

1.2. Our initial assessment of the issue was presented to the Authority in September 2017, as part of a wider paper. The Authority agreed the following actions in respect of OHSS:

- **Work with NHS Digital** to:
  - analyse the data to establish, as far as possible, how many of the 865 hospital admissions were severe and critical OHSS because of IVF treatment
  - set up an arrangement to receive regular updates on hospital admissions relating to OHSS, to check whether the number of cases reported to us is in line with those figures (while acknowledging that the different statistical definitions employed means that the figures are unlikely to be identical) and in relation to their proportion of the overall number of cases.
- **Meet with the RCOG (Royal College of Obstetricians and Gynaecologists) and the BFS (British Fertility Society)** to discuss:
  - what proportion of mild, moderate, severe and critical cases we should expect to see, bearing in mind there are no reporting requirements for mild and moderate OHSS
  - whether there is any room for improvement/update of our definitions (in guidance note 27 – Adverse incidents, taken from the RCOG Green-top guideline), and how RCOG promotes its guideline to ensure it reaches the appropriate clinicians
  - whether implementation of a specific OHSS incident form would be useful, or if the information we glean from our reviews of severe and critical cases is sufficient
  - the possibility of requiring clinics to have procedures for the prevention and management of OHSS.
- As part of the **review of Code of Practice guidance** regarding information which clinics are required to provide patients, we will consider **what information clinics should provide patients on OHSS**, including reporting requirements and information which patients should give an Accident and Emergency clinician or any other clinician involved with their

care. This should encourage patients to alert their treating centre if they suffer from OHSS (and are admitted to hospital).

- Depending on the outcomes of the actions above we may wish **to review what inspectors ask clinics about their application of the OHSS/adverse incident definitions** (guidance note 27) and/or the **information clinics provide patients about OHSS**.

1.3. This paper updates the Authority on our work undertaken regarding OHSS since then, including outcomes of a meeting with stakeholders (including representatives of the BFS and the RCOG) held on 13 December 2017.

2. Are clinics underreporting cases of OHSS?

Our analysis of NHS Digital data

2.1. As noted above, clinics are required to report all cases of 'severe' or 'critical' OHSS to us. Our analysis of the NHS Digital hospital episode statistics, and discussion with stakeholders, reveals that this data includes all women admitted to hospital where it is judged that they have OHSS. The vast majority of these women have mild or moderate OHSS, admissions which currently do not need to be reported to the HFEA. We are also certain that the diagnosis a patient received cannot be properly deduced from this data as it is also likely that cases were labelled as OHSS when it was possible the patient did not receive a diagnosis of OHSS.

2.2. In considering this issue it is also important to bear in mind the limitations of the coding used in hospital episode statistics. In 2004, the payment by results system was introduced to the NHS in England. In this system, a tariff is paid for each activity, for example clinic attendance, emergency admission, a procedure or operation. It is known that coding information varies greatly in accuracy and veracity, and is not designed to capture information that may be more relevant for our purposes here. This is consistent with the view the Authority expressed at its September 2017 meeting and findings of a study referred to below.

2.3. Whilst it is agreed, on examining and discussing this data with stakeholders, that few conclusions can be drawn from these NHS Digital data, it was agreed it would be useful to review it on an annual basis to keep an eye on any trends. This is not to ignore the issue and in any event, it raises significant concerns and questions about the safety of patients undergoing IVF – and which the next section explores further.

So how many cases should we expect to see reported?

2.4. In discussion with stakeholders it was agreed that the data on incidence of OHSS (Delvigne and Rozenburg, 2002) referred to in the RCOG Green-top guideline no.5, 'The Management of Ovarian Hyperstimulation Syndrome' (February 2016) is out of date and does not take account of the impact of recent changes in practice. For example, the use of egg freezing will have led to a reduction in the cases of OHSS.

2.5. We were advised, and accept, that overall clinics are aware of what 'severe' and 'critical' cases of OHSS look like, and there is good awareness of the reporting requirements. However, we cannot assume that the number of cases reported to us is always accurate.

2.6. Here, it is relevant to reflect on findings of an audit carried out at St. Mary's Hospital Manchester, specifically undertaken in response to our concerns following the media allegations[1].The study was carried out to investigate whether the discrepancy in the hospital admission data and the number of cases of OHSS reported to the HFEA was due to errors in the admission code, or actual under-reporting of cases. The study proposed that incorrect coding may arise because emergency admissions are often handled by a relatively junior clinician who may not have sufficient experience of OHSS. The audit was carried out in a tertiary hospital with an affiliated (and large) IVF clinic performing 1100 fresh non-donor IVF cycles annually. It was identified that there were 55 emergency attendances resulting in 33 admissions of patients coded for OHSS (on the hospital coding database) in 2016. Following review of these cases two were considered to be severe OHSS, although only one was reported to the HFEA. Of the remainder of cases 12 were mild, 11 moderate and the remaining admissions were incorrectly coded, based on the RCOG classification system (Green-top guideline no.5, February 2016). This study concludes (as our initial assessments did – as set out in 2.1) that the NHS coding system does not appear to be a reliable method of identifying cases that meet the criteria for reporting, so attempting to draw conclusions about the adequacy of incident reporting from data concerning admissions is only likely to mislead.

2.7. In summary, this single-centre study covering admissions for one year did not find evidence of systematic under-reporting of OHSS. It recommended that further work across a number of acute trusts and covering a longer time period is required to see whether this finding can be generalised. We agree.

2.8. On discussing this further with stakeholders it was agreed that in order to get a better idea of whether or not there is underreporting of severe and critical cases similar audits should be carried out at a number of clinics. These audits would involve a fertility clinic contacting its primary local hospital(s) to see how many patients they have seen with OHSS in a given year and to consider the reasons for these cases, what definitions (in the RCOG green top guideline) the cases fall under and whether or not they were admitted. We will be seeking volunteer clinics to carry out these audits.

[1] Sood and Mathur, 2018:'Are fertility clinics "covering up" the incidence of OHSS?', Poster presented at Fertility 2018

3. What can we do to improve reporting?

Change to reporting requirement and form

3.1. Currently HFEA Directions 0011 requires that OHSS "which requires a hospital admission and has a severity grading of severe or critical" is reported to the HFEA.

3.2. On discussion with stakeholders it was agreed that a change should be made to this reporting requirement: clinics will be required to report all severe and critical cases of OHSS to the HFEA *irrespective of whether or not they involved a hospital admission*. This will bring the reporting requirements more in line with the criteria for assessing and classifying the severity of OHSS set out in the RCOG green top guideline. Hospital admissions and the length of time spent in hospital is not part of this classification system and is therefore not in itself an indicator of severity.

3.3. It was also agreed that a new proforma specifically for severe/critical OHSS case reviews should be developed in the coming months. This proforma could ask for more detail than is currently collected - eg, how many follicles were present, what stimulation protocol was used, how was the risk of OHSS assessed etc. and will be sent to centres to complete when they report a case of severe or critical OHSS. Information gleaned from these completed forms will be analysed by the HFEA, in conjunction with the BFS and RCOG, to ensure appropriate clinical interpretation and recommendations, then themes/learning points will be reported on in a thematic review (possibly every two years) to make it easier for clinics to learn from their incidents.

Agreement between IVF clinics and local hospitals

3.4. One reason for potential underreporting is that hospitals do not inform fertility clinics when patients are admitted. One way round this is for fertility clinics to build up relationships with their local hospitals and for clinics to follow up at risk patients so they know when they are admitted, these ideas could be further explored with the sector.

Inspections

Discussion with stakeholders suggest that the best way to check for unreported cases of severe or critical OHSS will be at inspection. The trigger for this is likely to be clinics who have not reported any cases of OHSS. This might be a particular issue where clinics have a number of cases of patients with a high number of follicles (eg, more than 20-25). However, it's important to bear in mind that a high number of follicles is not always an accurate predictor of OHSS. There was discussion about targeting clinics with high success rates and no or low OHSS incident reporting (in particular high pregnancy rates in fresh treatment). This will be considered as part of the next review of inspection themes/notebook.

Information for patients

3.5. Stakeholders were in agreement that more could be done to encourage patients to report cases of OHSS to fertility clinics. For example, including more guidance in the Code of Practice outlining what clinics should include about this in patient information. This will be considered s part of the current review of the Code of Practice, which will come into force in October 2018.

3.6. Even though hospital admission is not an indicator of severity of OHSS the fact that there were 865 hospital admissions, apparently as a result of fertility treatment, in England in one year, is of obvious concern, even if most of them were classified as mild or moderate (and many of these admissions would have been precautionary or for assessment, and not emergency). Given this, we will consider whether or not the risk of hospital admission (even though this affects a very small percentage of total treatment cycles) is accurately reflected in patient information on the HFEA website.

Raising awareness of RCOG green top guidelines

3.7. The definitions in the RCOG green top guideline were discussed with stakeholders. It was agreed that in practice it is hard to distinguish between mild and moderate cases and it should be accepted that there may be some slight variation in the interpretation of definitions in the guideline. Given this, we should recommend that clinics should take a precautionary approach to reporting and report cases which are borderline moderate/severe.

Patient follow-up

3.8. In addition, clinics should also be encouraged to follow up patients after they become pregnant. It is possible that patients who do not have good follow-up contact with their clinics are more likely to seek help from emergency services and potentially a lack of specialist knowledge will mean a low threshold for admission. Improving post treatment follow-up may help to reduce the number of hospital admissions.

3.9. The points outlined at 3.7 and 3.8 will be conveyed to clinics in a Clinic Focus article alongside the new form for reporting OHSS incidents and in any relevant stakeholder publications.

4. What can we do to reduce the number of cases of OHSS?

4.1. Reducing the incidence of OHSS is not simply the responsibility of the regulator. The professional bodies recognise that they too have a role to play, that work has already started. In addition the BFS will survey its members on the measures they currently take to prevent OHSS, follow-up mechanisms and risk reduction strategies/management. This would cover measures in cases recognised as 'high-risk' prior to start of stimulation and in cases which are only recognised during stimulation or after egg collection as 'high-risk'. This will give

an idea of current UK practice and how far it reflects BFS guidelines, and possibly focus minds on the issue.

4.2. The BFS and RCOG will use their various publications to promote the green top guidelines and strategies for preventing and managing OHSS: bulletins, a scientific impact paper and an article in The Obstetrician & Gynaecologist (TOG) journal will be suggested to the editor.

4.3. The wording in the Code of Practice guidance regarding OHSS management protocols will be checked to make sure its sufficiently clear that clinics should have protocols in place for the prevention of OHSS. Currently guidance note 15 states that “centres should, where appropriate, have documented procedures that cover ….superovulation regimes and management of ovarian hyper-stimulation syndrome”.

Code of Practice update

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

Details:

Meeting	Authority		
Agenda item	11		
Paper number	HFEA (24/01/18) 868		
Meeting date	24 January 2018		
Author	Erin Barton, Policy Manager		

Output:

For information or decision?	For information		
Recommendation	The Authority is asked to note the areas of guidance being reviewed as part of the next Code of Practice update and the plan for stakeholder engagement.		
Resource implications	In budget		
Implementation date	Ongoing		
Communication(s)			
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes			

1. Introduction

1.1. The Authority is required to publish a Code of Practice to provide licensed clinics and research establishments with guidance on how they should carry out licensed activities in line with legislation. The Code of Practice is reviewed regularly to update existing, or incorporate new, requirements. Although we call it a Code of Practice update, the policy decisions involved can lead to other regulatory tools such as General Directions, consent forms and best practice guidance, being updated too.

1.2. At a previous meeting the Authority was made aware that a new, major update was in preparation, looking at a number of policy areas and at the format and structure. This paper provides a summary of the areas of the Code that will be revised and the engagement processes that will help shape the work. We aim to launch a new 9th edition of the Code of Practice for 1 October 2018.

2. Areas of guidance

2.1. The following areas of guidance are being reviewed as part of the next update. The areas of focus arise in part from a desire to ensure that the Code better supports the Authority's strategic ambitions for 2017-20, and in part from enquiries we have received from inspectors and clinics, policy projects, and from general discussions.

Information provision to patients

2.2. As part of promoting safe, ethical and effective treatment, one of the aims of the HFEA 2017-20 Strategy is to increase patients' understanding of the science and evidence base behind treatments and added extras known as treatment add ons. We have already produced clear, evidence based information about treatment add ons for the HFEA website, we now want to make sure that clinics are providing patients with similarly clear, evidence based information about the treatments they are offering through updated guidance in the Code of Practice.

Donor screening and quarantine requirements

2.3. Donor screening and quarantine requirements are an area that the sector has long struggled with, in part due to conflicting or unclear guidance from a variety of professional bodies or organisations. We aim to provide greater clarity in this area, particularly in respect of different interpretations of guidance relating to quarantine requirements for donor sperm when Nucleic Acid Amplification (NAT) testing is used.

Egg sharing

2.4. When the Code of Practice was updated in April 2017, the guidance on egg sharing was changed to explicitly rule out "egg giving". This is when a woman undergoes two cycles of stimulation and the eggs from one cycle are kept, and one set are donated. However, the guidance does make a provision for "exceptional circumstances" where all eggs could be "given", rather than

shared, if undergoing treatment at this time would be harmful for the egg giver, and freezing the eggs is not possible. We have been asked to consider whether there are enough examples of what could constitute "exceptional circumstances" for this to be useful, and whether this provision could still be harmfully misinterpreted.

2.5. We are also reviewing our guidance on egg sharing after concerns raised last year about about the way in which some clinics have promoted their egg sharing arrangements. Our own inspections into these allegations concluded that there was "some evidence of an overly informal culture about the provision of information to patients in relation to donation treatment" and that there is "work to do to further emphasise the special nature of egg donation and egg sharing".

Obtaining and retaining electronic consent

2.6. Practice in clinics is changing and the NHS is going paperless in 2020. We are considering how we should update our guidance to reflect this, with consideration to the law and its stance on written consent.

Consent to data research

2.7. We are currently looking at ways to increase the proportion of patients that consent to the use of their identifying information for use in research. One strand of this project is to consider whether guidance in the Code of Practice on consent to disclosure to researchers could be improved to support clinics seeking consent from patients.

Extending storage for gamete providers

2.8. Current guidance in the Code of Practice is sometimes misinterpreted by clinics and relied on to allow the extension of storage for gamete providers in circumstances where the regulations do not envisage extended storage. We aim to clarify guidance in this area.

Leadership

2.9. The Authority has already signalled its desire to see greater leadership in clinics to improve the quality of care. As part of that work we aim to review our Code of Practice guidance on the responsibilities of a Person Responsible (PR) and leadership more generally within the clinic. (There are other elements to this work which sit outside of the Code of Practice update including a training programme, revised PR Entry Programme test, and updated inspection tools.)

Implementing the EU Directive on import and export of gametes or embryos

2.10. The purpose of the new Directive is to ensure that there are procedures for verifying the standards of quality and safety of gametes and embryos that are imported into the UK from non-EU establishments. The importing relationships will need to be approved by the HFEA, and as a result we will need to amend the requirements in the Code of Practice on factors which the clinic will need to reassure itself before importing or applying to establish an importing

relationship. We are also reviewing the policy on compensation and consent requirements for overseas donors in parallel to introducing the requirements of the Directive.

Emotional support

2.11. Improve the emotional experience of care, before during and after treatment or donation, is one of the Authority's key strategic aims. We have established a project to identify the key constituents of a service that offers good emotional support and consulting, and we are collaborating closely with a range of external stakeholders to identify good practice and different ways of sharing and promoting it across the sector. Various potential outputs will be explored with stakeholders during the course of the project, including updated Code of Practice guidance.

Other

2.12. In addition, we will be addressing a range of minor issues that have been identified since the last update through enquiries we have received from inspectors and clinics, and from general discussions. We will conduct an audit of issues raised in Clinic Focus articles, Chair's or Chief Executive's Letters published since the last time they were reviewed as part of a Code of Practice update, and check that external links within the Code, for example links to professional body guidelines, are up to date.

2.13. We are also using the opportunity of the 9th edition to make sure that the code is fit for purpose in today's clinic or laboratory, by gathering feedback on its format, structure and usability. We will check that guidance is where it should be, that it isn't too lengthy and that it is written in plain language. We will also assess whether any guidance can be removed or if anything should be added, for example reintroducing a glossary of terms.

3. Engagement plan

3.1. We have established a working group comprising a range of clinic and laboratory staff, including nurses, embryologists, quality managers, doctors, counsellors and administrators. The function of the group is to advise the Executive in developing the next edition of the Code of Practice, to comment on draft sections of the Code, and to provide feedback and suggestions on the format, structure and usability. The working group have met in December and January, and will meet again in March.

3.2. We will be holding workshops in February in London, Edinburgh, Manchester and Bristol to hear stakeholders' views on the various areas of guidance under review, and on the format, structure and usability of the Code.

3.3. We will also be adding some questions to our Opinion Leader stakeholder survey, asking for more general feedback on the Code and our regulatory tools.

3.4. A draft version of the Code will be circulated in April for around four weeks to allow stakeholders to comment, and the Authority will receive a paper on the

outcomes of the workshops and engagement so far in May. All proposed changes will then be presented to Authority in June for approval. Subject to sign off by the Secretary of State the new version of the Code will go live in October 2018.

4. Recommendation

4.1. The Authority is asked to note the areas of guidance being reviewed as part of the next Code of Practice update and the plan for stakeholder engagement.