Human Fertilisation & Embryology Authority

Authority meeting - agenda

15 November 2017, 10 Spring Gardens, London SW1A 2BU

Agenda item		Time
1.	Welcome, apologies and declaration of interests	12.45pm
2.	Minutes of 13 September 2017 **HFEA (15/11/17) 854** For decision	12.50pm
3.	Chair's report (verbal)	12.55pm
4.	Chief Executive's report (verbal)	13.05pm
5.	Committee chairs' updates (verbal)	13.15pm
6.	Performance report **HFEA (15/11/17) 855** For information	13.25pm
7.	Draft business plan 2018/19 **HFEA (15/11/17) 856** For decision	13.50pm
8.	Fertility sector report 2016/17 - Final **HFEA (15/11/17) 857** For decision	14.05pm
9.	Strategic risk register **HFEA (15/11/17) 858** For decision	14.25pm
10.	**Break**	**14.45pm**
11.	Scientific and Clinical Advances Committee annual report **HFEA (15/11/17) 859** For information	14.55pm
12.	Register Research Panel annual report **HFEA (15/11/17) 860** For information	15.15pm
13.	NHS commissioning of IVF services **HFEA (15/11/17) 861** For information	15.30pm
14.	Any other business	15:55pm
15.	Close	16:00pm

Minutes of Authority meeting 13 September 2017

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☐ Demonstrating efficiency economy and value

Details:	
Meeting	Authority
Agenda item	2
Paper number	HFEA (15/11/17) 854
Meeting date	13 September 2017
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 13 September 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 Dr Andy Greenfield
Apologies	Ruth Wilde	
Observers	Steve Pugh (Department of Health)	
Staff in attendance	Peter Thompson Nick Jones Juliet Tizzard Richard Sydee	Siobhain Kelly Sharon Fensome-Rimmer Paula Robinson Catherine Drennan

Members

There were 10 members at the meeting, 7 lay members and 3 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 fifth 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 Ruth Wilde.

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 28 June 2017

2.1. Members agreed the minutes of the meeting held on 28 June, 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 28 June 2017.

- On 29 June, the Chair, the Director of Strategy and Corporate Affairs and the Head of Regulatory Policy visited Birmingham Women's Clinic. This visit was not part of the formal inspection cycle but is more to understand what the clinic does well and where they can improve. The Chair thanked the clinic for hosting the visit.
- On 27 July, the Chair and the Chair of the Audit and Governance Committee (AGC) interviewed for two new members of AGC. The Chair is pleased to announce that two successful candidates, Geoffrey Podger and Mark McLaughlin, will start their respective terms of office on 1 October 2017.
- On 5 July, the Chair and the Director of Strategy and Corporate Affairs met Veronica English and John Chisholm of the British Medical Association.

4. Chief Executive's report

4.1. The Chief Executive informed members that there had been an staff away day on 10 July. This was held to review progress against commitments made at the last away day in December and to look ahead in the context of the new strategy, the completion of the Information for Quality programme (IfQ) and the organisational restructure. Feedback was positive generally, but there is still progress to be made around staff morale following the restructure.

4.2. The members heard that the Chief Executive met with the CEOs of the Human Tissue Authority (HTA) and the Health Research Authority (HRA) on 11 July. These quarterly meetings are a useful opportunity to discuss the wider impact of system changes on smaller organisations.

4.3. Members heard that on 13 July, the Chief Executive attended the Health and Care Leaders senior talent board meeting chaired by the Chief Executive of Public Health England. These meetings are focused on how to develop and keep talent within the healthcare system.

4.4. On 14 July, the Chief Executive met the new chair of the Association Clinical Embryologists (ACE), Jason Kasraie, at his NHS clinic in Shrewsbury. The Chief Executive thanked both Mr Kasraie and the Trust Clinical Director for hosting the visit.

Press coverage

4.5. The Chief Executive informed members that it had been a quiet period in terms of media interest in the fertility sector, due to the election and other significant world events.

4.6. Recently, media interest had picked up on sperm donation, in particular unregulated donation. As a consequence, the Head of Regulatory Policy spoke to the Economist about HFEA rules around donation and the impact on donation levels.

4.7. Members raised concerns about patients' sourcing sperm themselves and the implication for safety and parental responsibilities of going outside the regulated system and that the pitfalls should be highlighted to those who might consider this option.

4.8. The Chief Executive confirmed that the HFEA only has jurisdiction over sperm donation and IVF treatment that takes place in a licensed clinic in the UK, and assured members that there is information about this issue on the website.

General Data Protection Regulation

4.9. The Chief Executive informed members that the General Data Protection Regulation (GDPR) will come into force 25 May 2018. The Authority, like other public bodies, is already subject to a range of statutory rules around data protection and this is a substantial update on those rules. Members heard that the Authority will need to be more proactive in this area, with larger fines for non-compliance and greater requirements to notify breaches than there is at present.

4.10. Members queried whether the regulations would apply to the HFEA Register, and whether an individual would have the option to have their name removed from the Register. The Chief Executive confirmed that collecting IVF data for the Register is a statutory duty for the HFEA and that the submission of patient's data to the HFEA is part of having IVF treatment. The GDPR applies to personal information that is not part of the Register. Whilst confidentiality and protecting data is at the heart of the HFEA already, preparing for the GDPR is going to be a significant piece of work.

Staffing

4.11. Members were informed that staff turnover is still higher than the desirable range for a number of reasons, notably public sector pay restraint and the organisational change programme redundancies. Recruitment is happening and a number of high calibre appointments have taken place. Pressure arising from turnover is being actively managed.

4.12. Finally, the Chief Executive informed members that over the summer, twice the amount of licensing activity (including PGD) has taken place. The Chief Executive thanked all the staff involved in this significant bulge of work and the members who sit on the licensing committees.

5. Committee Chairs' updates

5.1. The Chair of the Statutory Approvals Committee (SAC) reported that the committee met on 29 June, 27 July and 31 August. At the June meeting, it considered seven preimplantation genetic diagnosis (PGD) applications in March and one request for Special Directions. Four of the conditions were approved, two adjourned for more information and one was refused. At the July meeting, three PGD applications were approved and one was approved for a specific family. The special directions application at the July meeting was refused. The minutes from the August meeting have not yet been published.

5.2. The Chair of the Licence Committee advised members that the committee met twice, on 13 July and 7 September. At the July meeting one initial research application was approved, two research renewals were approved, one interim research licence was continued and a variation to a licence was approved. The committee also added a condition to a licence following an investigation report, considered an Executive update and continued a licence following an interim report and grade 'A' incident. The minutes from the September meeting have not yet been published.

5.3. The Director of Strategy and Corporate Affairs advised members that the Executive Licensing Panel (ELP) met six times since the Authority last met; on 30 June, 14 and 28 July, 11 and 25 August and 8 September. The panel considered 42 items across these meetings including one new centre application, nine renewals, twelve interim inspection reports, six variations and several licence variations. The Licensing Officer approved three licence variations.

5.4. The Chair thanked all the staff who support these committees and prepare the papers as well as the members who sit on these committees.

6. Performance report

Strategy and Corporate Affairs

6.1. The Director of Strategy and Corporate Affairs informed members that the dashboard at the front of the Performance Report is designed to be a snapshot of performance at a high level. Members noted that measurement of delivery against the strategy used to be demonstrated by a 'totaliser' which did not work in practice as effectively as the Executive hoped. As an alternative, from now on the Executive will report back on packages of work (this meeting being leadership and culture) that the members had asked for the Executive to deliver.

6.2. Members agreed that this will enable the Authority to assess effectiveness as well as milestones met and welcomed this change in approach. Members noted that sometimes this will be a progress report and a particular work package may not be complete as this is a three-year strategy, however, this arrangement will mean that members will have better oversight on progress.

6.3. One of the four indicators on the dashboard relates to Opening the Register requests (OTR) being processed within 20 working days. Members heard that this KPI, because of its obvious impact on the donor conceived, is always met, so it is not necessarily a meaningful indicator to have on the dashboard. It will of course continue to be a priority and be measured, but the Executive propose replacing this indicator with one that measures website traffic.

6.4. Members heard that the website launched successfully in July due to that hard work and dedication of the Communications team. Early analysis shows that website sessions and pages visited are lower than this time last year. This is to be expected as it takes time for the search engines to index the website.

6.5. Members heard evidence that demonstrates better engagement with the content on the new website compared with the old one. The average length of a page visit is now is three and a half minutes, as opposed to just under two minutes on the old website, and the number of pages visited per session is more than double what it used to be.

6.6. Members also heard that 76% of visitors come from the UK as opposed to 50% on the old site and that phones and tablets are being used to access the site. Choose a Fertility Clinic and information on fertility treatments, as expected, are the most popular pages and most visitors come through search engines.

6.7. So far we have received 252 patient ratings of clinics and posters and leaflets for clinics are proving to be popular and should drive up the number of ratings.

6.8. Members were keen to ensure that user testing will continue on the website and that this should involve both qualitative and quantitative analysis. Members heard that there are plans for the next 12 months for ongoing monitoring to assess the 'reach' of the website, user engagement and how interesting users find the website.

6.9. Finally, Members heard that the Policy team has started the project to deliver the ninth version of the Code of Practice.

Compliance and Information

6.10. The Director of Compliance and Information informed members that the licensing process has been very busy over the summer. Whilst the end to end target from inspection to minutes being issued is still under the 70 day target, there have been some stresses and strains delivering the business. The components under pressure have notably been processing PGD applications and minute production and the red ratings relate to this.

6.11. Additionally, members heard that clinics have had a few problems clearing errors and this can be attributed to HFEA staff being busy and not being available to assist the clinics in addressing these errors.

6.12. Members raised concerns about staff pressures and wanted confirmation on the nature of the risks related to staff as missing KPIs can seem like failure or mistakes. Members probed whether these issues related to overload, capacity or lack of experience. Members praised the hard work and dedication of staff during this peak in activity.

6.13. The Director of Compliance and Information informed members that there are a number of factors. PGD will continue to be busy and complex, but the other inspection/licensing activity is more likely to be a bulge that is going to level off. New staff are joining the HFEA and being trained and the workload of existing staff will continue to be monitored and managed.

6.14. Members were encouraged that despite these issues and a lengthy, complex process, PGD applicants are not being kept waiting for a decision.

Finance and Resources

6.15. The Director of Finance and Resources introduced the financial information in the performance report. Members were asked to note there is an underspend of £250,000 which is related to higher than expected vacancies and an underspend on legal costs. Forecasts will not be adjusted at this stage.

6.16. Members heard that income is volatile and is difficult to predict and is lower than last year. The members who work in the sector agreed that income is difficult to predict for clinics too. The market has changed with NHS funding being withdrawn and patient's choices changing.

6.17. Members heard that it was important to try to balance fee income with the operating costs the HFEA needs, though it is very difficult to pitch this at the right amount. This will as always, stay under review, as fees paid by patients should be justified.

6.18. Members noted:

- The Performance Report and approved the addition of the website metric to the dashboard of the Performance Report

7. Data Submission Project

7.1. The Director of Compliance and Information reminded members this project is the package of work left over from IfQ programme aimed at moving the Register data to a new structure and improving the data entry experience for clinics. The team have already been working on this as the programme was not run in a sequential way.

7.2. Members were shown an example of the new patient led system which will be rolled out to clinics. There was agreement that this will not only be easier for clinics to send us treatment data, but will ensure there are fewer errors.

7.3. Members heard that the IfQ lessons learned report will go to AGC and expressed agreement that doing this quickly is good practice following the closure of a big programme. The biggest lesson that has been learned is balancing business as usual with a huge change programme and the impact of drawing from the same pool of staff.

7.4. Members heard that the migration of Register data is making slower than expected progress and there are still challenges balancing delivery of this work and business as usual. Members expressed the hope that staff working towards delivering the data migration would be able to concentrate on doing so without interruptions. Members heard that the two new Head appointments should be a positive contribution in this regard.

7.5. The Director of Compliance and Information advised members that user testing with six clinics will be critical to the success of the new data entry system. Members were also advised that an extra £350k has been authorised however, there continues to be staff challenges.

7.6. The Chair thanked the staff involved in the data migration for the work they have done so far.

7.7. Members noted:

- Good progress on the new data submission system
- Slower than expected progress with data migration
- The budget update and spending to date which is in line with plans
- Key risks and issues

8. Draft business plan 2018/19

8.1. The Head of Planning and Governance introduced the cycle of business planning for 2018/19. A CMG discussion has informed this paper. This business plan will be delivered under the strategy in place until 2020.

8.2. Members were given the opportunity to give an early steer on the business plan. The objectives are brigaded under the strategy areas of;

- Safe, ethical, effective treatment
- Consistent outcomes and support for patients and donors
- Improving standards through intelligence

8.3. Members noted the access to donor gametes item, under consistent outcomes and support, and expressed the view that safety should be part of this aim.

8.4. Members raised a concern about the impact that staff retention might have on the delivery of this business plan and were informed that a lot of thinking about this had already occurred and informed a people strategy, which is still in draft at present. The people strategy, which will be launched shortly, will include developing and supporting staff to ensure that the HFEA can deliver its strategic aims.

8.5. Members were informed that a detailed business plan will be provided in November.

8.6. Members approved the outline objectives for 2018/19 as the basis for drafting the next business plan.

9. Fertility sector report 2016/17

9.1. The Chief Executive introduced a draft report, due to be published in the next few weeks, which provides an overview of the performance of the sector in 2016/17.

9.2. Members heard that every September, the Authority receives a summary of compliance activities and a report on incidents. This new report, in a change of emphasis, recognises the largely compliant nature of the fertility sector and tries to provide a better balance between where the sector is doing well and where it needs to improve.

9.3. This will be one of two annual reports and will sit alongside the Fertility Trends report. The report covers a summary of the sector, leadership and staffing, regulatory compliance, safety and patient experience.

9.4. There had been consolidation in the sector and a third of treatments are now being carried out by just ten clinics with 45% of treatments taking in place in clinics in London. In contrast to other areas of medicine in the UK two thirds of treatments are self-funded.

9.5. Members were informed that there is a lot of positive news about the sector's performance that is presented in this report. Multiple births have come down from 1 in 4 to 1 in 10 and the pregnancy rate in 2016/17 stands at 32% as compared to 24% in 2008.

9.6. Incident numbers are consistent with the volume of treatments with a fall in grade B incidents and only one grade A incident reported.

9.7. In the report there is a summary of regulatory compliance arising from the 81 inspections carried out, with information about what the clinics are doing well, areas that have improved and critical/major non-compliances. Of the 299 non-compliances all but 10 are now closed demonstrating the effectiveness of the regulatory activity.

9.8. Members agreed that the sector will welcome this report. One member noted that some in the sector have expressed frustrations over the continuity of assessments over time: one inspection report can be good and then the next inspection find many non-compliances. Of the 299 non-compliances, members probed whether these were new issues or issues that had been raised with clinics before.

9.9. Members heard that detailed analysis had not been carried out on whether non-compliances found were new or persistent, and noted that work had gone in to ensuring Inspection teams are consistent. The inspection is a snapshot in time and other inspection tools indicate there can be a drop off in performance between inspections. Members were assured that if inspectors find a non-compliance that has been identified before, it will be graded as a more serious non-compliance in the subsequent inspection report.

9.10. Members noted that as inspectors become more experienced and established they are likely to find more non-compliances. In addition, the inspector's portfolio of centres only changes every few years, so it's likely the inspection is being carried out by the same lead Inspector.

9.11. Members suggested that other positive sector information could be included in this report through vignettes, for example around the world class research carried out in the UK. Members also wondered whether the research sector should be included in this report.

9.12. The Chief Executive agreed to discuss further whether research should be covered in this report, or whether there should be a separate report on embryo research.

9.13. Members agreed that case studies are a good way of sharing learning, with the Grade A incident mentioned in this report, being a good example. Members welcomed this report as a method of achieving this.

9.14. Members felt that this report has the potential to be a 'go to' document for people writing about the sector more broadly and hoped that the social media would be deployed to promote the publication of the report.

9.15. Members suggested that the decision by commissioning groups, not to follow NICE guidelines on the provision of IVF, could also be touched on in this report as this will be factor in the reporting of how many cycles are self-funded.

9.16. Members agreed that the tone of the report centred around information and learning is the right one and that the language used should be clear to a wide audience, in particular, the information around multiple births and success rates. Further, members agreed that it is appropriate to highlight what clinics are doing well and how some of them are going beyond good compliance.

9.17. Members further agreed that a stronger narrative might be provided to point out that there are six clinics which are outliers in multiple births and explain why patients should actively not choose these clinics.

9.18. Members also agreed that where non-compliances are identified and action taken this is a positive story for the sector. Members noted that the executive summary, which as yet is unwritten, could bring together the positive comments about the sector, highlights and trends.

9.19. The Chief Executive thanked members for their comments and informed them that some of their suggestions will be fleshed out in the other scheduled report, Fertility Trends. In addition, he stated that the Executive will read across both reports for consistency and balance.

9.20. Members heard that further comment would be welcome in the coming weeks and a decision will be made as to how best to let members have sight of the final draft before publication.

9.21. Members:

- Endorsed the decision to move away from a focus on clinic non-compliances

- Agreed the scope and coverage of the report
- Agreed the final report should be published in the autumn.

10. Investigation into fertility clinics

10.1. Members received a presentation from the Chief Inspector regarding the follow-up to the allegations made by the Daily Mail regarding five clinics. This paper explores, following normal regulatory investigation, if there are any wider policy implications.

10.2. Members heard the allegations include:

- Financial inducement for egg donation/egg sharing
- Exaggeration of frozen egg success rate
- Loans for treatment
- Overcharging for drugs

10.3. Members were informed that in addition, it was alleged is felt that there is widespread under-reporting of ovarian hyper stimulation syndrome (OHSS).

10.4. Members heard that verbal information on egg donation/sharing was not reflected in the written information given to patients in the clinic investigated. However, there is evidence that counselling is always offered.

10.5. A Member noted that egg sharing often only happens if treatment for a patient is unaffordable, though agreed that all clinics egg sharing/donation programmes should be fit for purpose, with good information being central to this. Members noted the good practice on independent counselling that is taking place in clinics which is a significant step forward for the sector.

10.6. Compliance will monitor information on websites around this area and ensure that patient feedback is scrutinised where these types of treatment have been accessed.

10.7. Members also heard that in the clinics investigated the success rates of frozen egg treatment were usually based on their own data which runs the risk of not being statistically robust owing to the small numbers involved. Again, it was found that written information could be clearer, enabling patients to decide themselves.

10.8. Members agreed that egg freezing is no longer an experimental treatment but the numbers are still low. It is not unreasonable for clinics to present their own data but it should be within an ethical framework with no bias either way.

10.9. Members noted that Compliance will be looking at the presentation of success rates on clinic websites, as part of the review of guidance on information for patients.

10.10. Members heard that loans in the case investigated are being offered for treatment without regulatory oversight. The Financial Conduct Authority (FCA) responded very quickly to this, as did the loan company involved, and there is a plan for the HFEA and the FCA to work together in future. Members agreed that there are other clinics offering financial packages, within a framework backed by the FCA, and these can work for patients.

10.11. Members agreed that whilst the HFEA has limited power on pricing, costed treatment plan can help, and the HFEA is working with NHS England on a benchmark price.

10.12. Members noted that in the cases investigated, patients are not being informed that they can take their prescription elsewhere to get cheaper medication. Patient feedback in future will include a question about expected costs versus actual cost. Members agreed it is essential that clinics are transparent.

10.13. Members were informed that OHSS only is reported to the HFEA when severe and critical, with between 60-80 cases being reported per year. When compared to hospital admissions ascribed to OHSS via data from NHS Digital, it suggests there is under reporting taking place.

10.14. Members agreed though, that some patients admitted to hospital do not have OHSS and have been misdiagnosed. If this is the case, the recording of the diagnosis by the hospital would not necessarily be changed which may account for some of the discrepancy in the data.

10.15. Members were informed that Compliance will work with NHS Digital to probe the data further to establish which of the 865 hospital admissions are severe and critical cases related to IVF treatment. Further, once the data is understood it will determine whether the discrepancy in reporting is because fewer of the patients had OHSS than data suggests or if there are serious cases slipping through the net.

10.16. Members noted that the HFEA will work with the Royal College of Obstetricians and Gynaecologists (RCOG) and British Fertility Society (BFS) to improve definitions in guidance notes and consider a form for OHSS reporting.

10.17. Members heard that the Code of Practice will be updated to ensure that clinics provide correct information to their patients on what they need to do in the event of an OHSS case, and what information the patient needs to provide the hospital they are attending. In addition, inspectors will ask questions about OHSS handling on inspection.

10.18. Members wondered if it is possible to establish where a patient had been treated using the NHS Digital data (especially if that treatment had occurred abroad), but at present this data is not collected.

10.19. Members asked for an update on the position with OHSS as soon as it is available.

10.20. Members noted the range of recommendations of the different issues investigated on:

- Egg sharing and egg donation
- Success rates from egg freezing
- Promotion of loans to pay for treatment
- Drug pricing
- OHSS

11. Leadership in clinics

11.1. The Director of Compliance and Information explained that this paper builds on the Chair's speech at the last HFEA annual conference, where she challenged the sector to reflect on what constitutes good leadership in their clinics.

11.2. Although the responsibilities of the Person Responsible (PR) are well understood in clinic, there are now a growing set of complex ownership/partnership structures in place which can impact on leadership in clinics. In addition, there have been examples of poor leadership practice.

11.3. In the past, the HFEA has taken a rather narrow assessment of leadership focused on qualifications and membership of professional bodies. Indeed, the Act only refers to the responsibilities of the PR and not to more generic leadership qualities.

11.4. Members agreed that this could be an opportunity to drive up quality of care at source via clinic leadership. This direction of travel is also being pursued by the Care Quality Commission (CQC) and NHS Improvement who are turning their focus to what a well led service looks like.

11.5. Members heard that Inspectors will need the tools, and as importantly the confidence, to step in to this area in order to make assessments about PRs.

11.6. Members agreed that the sector on the whole is broadly compliant, with lots of very good practice and good patient care, but there are still pockets of poor leadership practice.

11.7. Members agreed that this step will be a big ask of the sector as in the past PRs were appointed for reasons that are different to the holistic approach set out in the paper. Members hoped that the planned dialogue with the sector will help address this.

11.8. Members felt Inspectors should also try to understand what the governance structure that supports the PR is; though they are legally responsible, they are usually part of a leadership team.

11.9. Members expressed the importance of a PRs character and the challenge of assessing that for Licence Committee. It is very difficult to ascertain how that person affects the culture in a clinic and, some PRs may not actually be based at the site they are responsible for.

11.10. Members agreed that in thinking about leadership there should be no distinction between NHS and private clinics. As the Act is 25 years old, the HFEA needs to get around any technical/legal constraints by influencing, incentivising and bringing people together, as many of the leadership qualities we want to see are not required by law. PRs embracing leadership in clinics will improve patient care, and that is the benefit the clinics will gain by engaging with this initiative.

11.11. Members supported this piece of work and agreed that it is appropriate to be collaborative and sensitive when introducing this to the sector. In addition, they urged the Executive to identify metrics that might measure leadership.

11.12. Members noted that there is new leadership at ACE and BFS (in the new year) and relatively new leadership at the RCOG, and these are the partners with which the HFEA will have to work to get this initiative off the ground.

11.13. Members noted and agreed the proposed approach to leadership in the sector.

12. Any other business

12.1. There was no other business raised.

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 (15/11/17) 855
Meeting date	15 November 2017
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 summarises our performance up to the end of September 2017.

2. Reviewing performance

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

2.2. Overall performance remains good. Although 8 indicators are currently classified as red, it is worth noting that 6 of these relate to different elements of the inspection and licensing process. There is a full discussion of this in the performance report. One of the other red indicators relates to capacity and the Authority will recall the full discussion of turnover at its last meeting. The position has improved since then, with the recruitment of a number of new staff, but we have left the indicator at red as it takes time for new starters to get up to speed.

2.3. CMG is continuing to review key performance indicators from across the organisation to ensure that these best reflect actual performance and provide useful oversight. Before the Authority next reviews this report, CMG will review the compliance and licensing indicators, to ensure that these remain valuable.

3. Recommendation

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

HFEA performance scorecard

Annex A

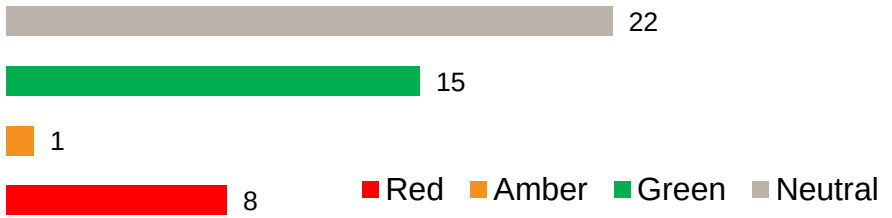
Dashboard – September data

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
(baseline to be established once the website has been active for a year)

28,649 sessions

Licensing end-to-end

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

⇧
73 days

Money – budget

Summary Financial Position - September 2017

	Year to Date			Full Year		
	Actual £'000	Budget £'000	Variance £'000	Forecast £'000	Budget £'000	Variance £'000
Income	3,184	3,108	75	6,328	6,230	98
Expenditure	2,716	3,129	413	6,016	6,062	(14)
TOTAL Surplus / (Deficit)	468	(21)	489	311	168	112

Commentary

The YTD position (September 2017) shows a surplus against the planned budget of £489k. There has been a small increase in the surplus against that reported in July. Against this we are running a significant underspend on expenditure. Specifically we are underspending against our legal and accommodation budgets.
Our forecast position has been revised after detailed discussions with directorates and reflects changes in plans for the remainder of the financial year. In January we will undertake a further review of planned expenditure for the remainder of this financial year.

Overall performance – September 2017

We reviewed the overall performance picture at the CMG meeting on 11 October. There were 8 red and one amber indicator. We noted that many of the indicators where we missed KPIs in August continued to be red. CMG discussed red indicators in detail and a full discussion of each of these is set out below.

CMG discussed the continuing process of bedding in the new organisational structure and we considered the people indicators at length. From August data, we are using the post-organisational change headcount of 66 and as new staff join there is an improving picture of headcount. Although the unplanned turnover percentage for the year has slightly decreased, we agreed that it is still too early to change the indicator from red to amber. This also reflects the wider people context, as the total of planned and unplanned leavers has risen since August to 27.75% in September. CMG recognises the risk of high turnover and has discussed ways of improving organisational knowledge handover and induction. We will need to consider this further following the appointment of the interim head of HR.

CMG discussed the staff sickness indicator and noted that despite the pressure staff have been under in terms of capacity, this remains low. Since the CMG meeting, we have reissued the sickness policy to ensure that all sickness is dealt with and recorded properly, which should help ensure that the low rate is not due to under-reporting.

On information, we have maintained excellent performance around Opening the Register (OTR) requests. Although the volume has been double the usual number, performance remains at 100% and this has been due to the hard work and conscientiousness of colleagues in the OTR/Register team, including the relatively new Donor Information Manager.

Now that we have received patient applications for mitochondrial replacement therapy, we will be monitoring our performance on these. Initially we will track these and later we may wish to set a KPI.

The 8 red key performance indicators (KPIs) shown in the 'overall status - performance indicators' bar chart on the dashboard are as follows:

People and capacity – 1 red indicator

- Establishment ('unplanned') leavers per month. Our target is to remain within 5 - 15% establishment turnover for the year. Although performance is still well above target at 21.2%, we are now seeing a slight improvement in this figure from August performance. Following the organisational restructure our staff complement has increased and the number of leavers has reduced. Although the picture is improving, we are still rating it as red, since it is still significantly above target and the overall planned and unplanned leavers for the year had reached 27.75% in September.

Information provision and engagement – 1 red indicator

- Outstanding errors in forms submitted by centres - 12 month running total. Our target is to decrease this number. If the number increases by more than 5%, we rate this indicator as red. Current performance is an increase of 7% in September to 3,222 errors that are 2-14 months old. In September, the Register and Information Team have proactively chased the worst six clinics in writing and will escalate matters via the PR and inspector if there is no improvement within 10 working days. These six clinics account for 54% of the outstanding errors.

Inspection and licensing processes – 6 red indicators

In September, two thirds of the red indicators relate to licensing and committee indicators, most of which are the same indicators as reported in July data. Not only has volume of business been an issue, but the complexity of decisions has also affected various parts of the process. Even when volume is reasonable, some minutes have been incredibly long and complex. It is not yet clear if the trend in the number of items is decreasing, but we plan to continue further close working between Compliance and Licensing to review the volumes of business and consider whether any remedial actions may be warranted.

- Average number of working days from day of inspection to the day the draft report is sent to the PR. Our target is 90% of reports to be sent within 20 working days. In September, no reports met this target and the average timescale was 26 working days. Because only two reports were sent this month, performance has been more affected by moderate delays.
- Average number of working days between ELP/LC/SAC date and minutes being finalised (signed by the Chair). Our target is for 100% of ELP/LC/SAC minutes to be finalised within 10 working days. In September, our performance was 47% completed in 10 working days, with an average of 12 days. This was due to large August meeting agendas, with some complex items. The subset of this data that relates to items following from inspections was similarly red for the same reasons. In September, our performance was 72% completed within 10 working days with an average of 9 days.
- Average number of working days taken between committee meeting date at which PGD decision is made, and decision being finalised (ie, minutes signed off by SAC Chair). Our target is 100% within 10 working days. September performance was 0 within 10 working days, with an average of 20 working days. This was due to the licensing team handling extremely high volumes of items in August (with SAC deadlines therefore falling in September), during holiday season. As well as a continuation of the high volumes of items seen in July through ELP, LC and SAC, August also included the Daily Mail investigations, some legally sensitive items, some complex PGD decisions and the first mitochondrial donation patient application.
- 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. September performance was 33%, although the average is within the target at 63 working days. The delays were due to a late peer review; items deferred to later meetings to accommodate the mitochondrial donation patient application; delays receiving an amended application and delays in finalising minutes. Two further applications which were due to be completed in September have not yet been processed completely and are going to SAC in October.
- Annualised rolling average figure – Percentage of all PGD applications processed within 3 months for the year to date. Our target is 100% processed (ie, considered by SAC) within three months (66 working days) of receipt of completed application, in the rolling year to date. September performance was 59%. Given the ongoing complexity of applications, it seems unlikely that 100% will be processed within the KPI in the future. The suitability of this KPI will be considered along with all other licensing indicators in November and December when their effectiveness will be reviewed by CMG.

There was also one amber indicator:

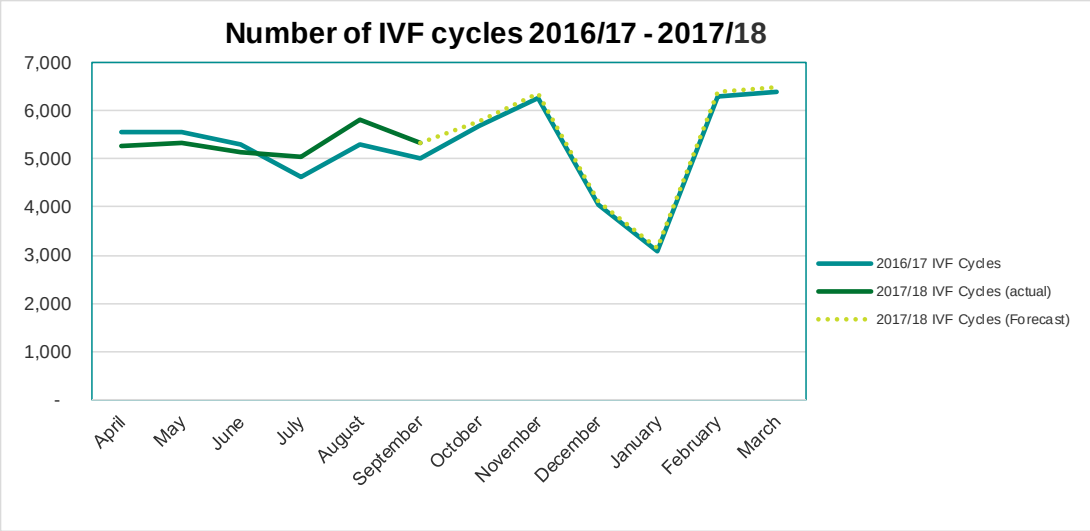
- Average number of working days taken for the whole process, from the day of inspection to the decision being communicated to the centre (including only items starting with an inspection). Our target is 70 working days. In September, our performance was 73 days. Due to the small number of reports contributing to the compliance figures in September, the whole licensing duration figure has been particularly affected by slightly longer than average processing times. The tail of committee work from June to August continued to affect September.

HFEA performance scorecard

Annex A

Budget status – September data

2017/18 Income

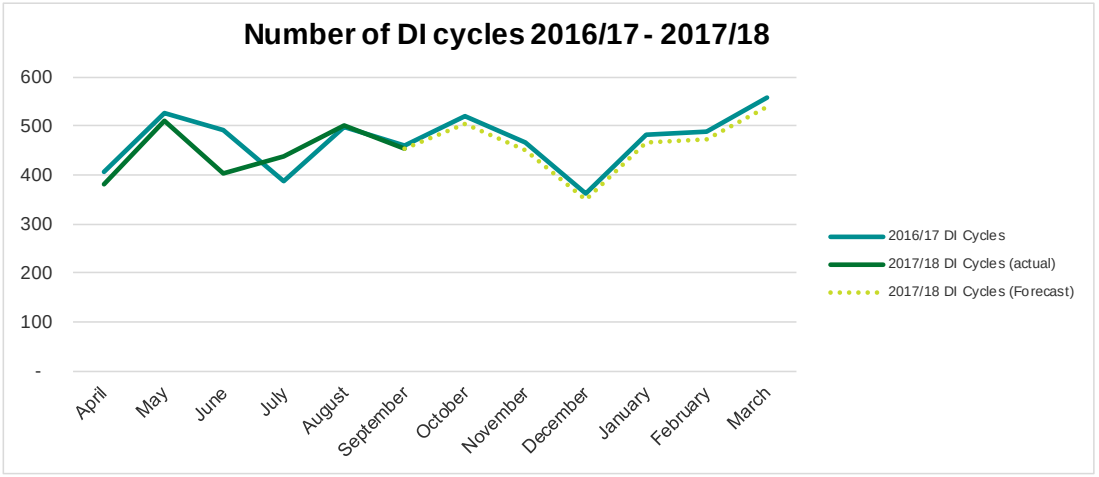


IVF Cycles

	YTD		YE / Forecast	
	Volume	**£**	**Volume**	**£**
2016/17 IVF Cycles	31,366	2,509,254	63,111	5,048,854
2017/18 IVF Cycles	31,876	2,550,080	64,138	5,131,000
Variance	510	40,826	1,027	82,146

We continue to track the volume of IVF cycles as part of the work we are undertaking to understand what drives cycles. For the six month ending 30 September we are reporting a 1% increase against 2016/17.

The trend developing over this year would suggest that our year end forecast position could result in an increase in income. We will continue to report and monitor this.



DI Cycles

	YTD		YE / Forecast	
	Volume	**£**	**Volume**	**£**
2016/17 DI Cycles	2,770	103,875	5,651	211,913
2017/18 DI Cycles	2,688	100,800	5,473	205,236
Variance	82	3,075	178	6,676

DI cycles have been following the pattern of IVF cycles for the start of this financial year, however whilst IVF cycles are increasing, DI cylces appear to be reducing albeit at a slower rate of 3% when compared to 2016/17.

Although fees from DI cycles are a much smaller proportion of licence income it is useful to note the overall trend in activity within the sector.

HFEA performance scorecard

Annex A

HFEA Income & Expenditure

Sep-2017

£000

	Year to Date			Full Year		
	Actual £	Budget £	Variance £	Forecast £	Budget £	Variance £
Income						
Grant-in-aid	469	469	-	933	938	(5)
Licence Fees	2,682	2,636	46	5,330	5,286	44
Other Income	1	3	(2)	3	6	(4)
Seconded Salary reimbursed	31	-	31	62	-	
Total Income	3,184	3,108	75	6,328	6,230	98
Revenue Costs						
Salaries (excluding Authority)	1,957	1,864	(93)	3,769	3,778	(52)
Staff Travel & Subsistence	80	106	26	180	200	20
Other Staff Costs	22	89	67	161	151	(8)
Authority & Other Committees costs	105	150	46	285	301	16
Facilities Costs incl non-cash	259	332	73	652	689	37
IT costs Costs	52	63	10	128	125	(3)
Legal / Professional Fees	187	436	249	638	638	1
Other Costs	54	90	36	205	180	(25)
Total Revenue Costs	2,716	3,129	413	6,016	6,062	(14)
TOTAL Surplus / (Deficit)	468	(21)	489	311	168	112

Management commentary

Income.

Year to date we are slighgtly above budget with a small surplus of £75k.
The incease is due to 1.7% increase in treatment fee income and income for staff costs for which there is currently no budget.

Expenditure.

Year to date we are underspending by 13.2% (£413k). Significant areas of underspend are within legal £255k where activity has been lower than expected. Within Finance and Facilities, we are underspending on our accommodation costs by £41k which relates to service charges (facilities costs). The balance of £31k relates to non-capital costs (depreciation).
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.

Overall

The year-to-date position overall is a surplus over budget of £489k assisted by continuing growth in income and reduced expenses as detailed above.

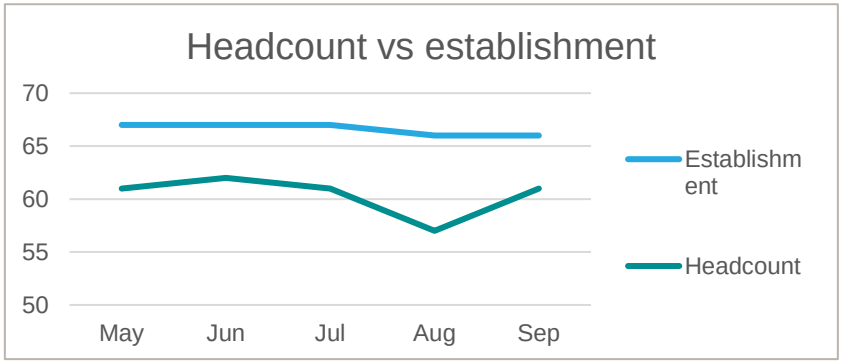
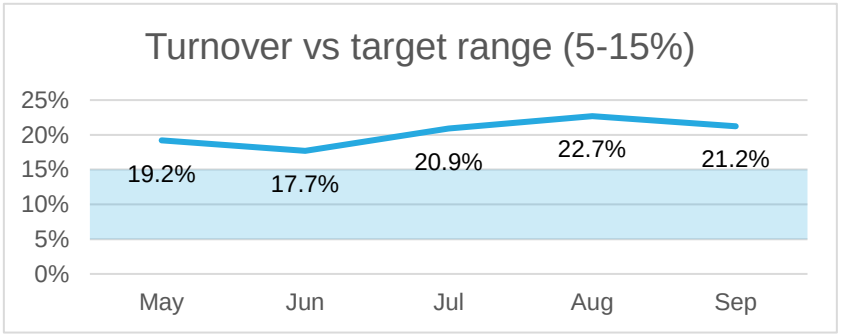
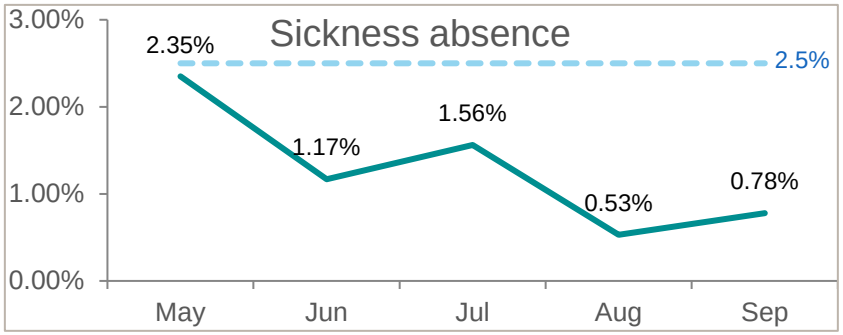
Forecast

We have conducted a review of our current and future costs and have reduced our forecast expenditure significantly from that reported at the September Authority meeting. The main area of amendment was within staff costs.

HFEA performance scorecard

Annex A

People – key performance and volume indicators

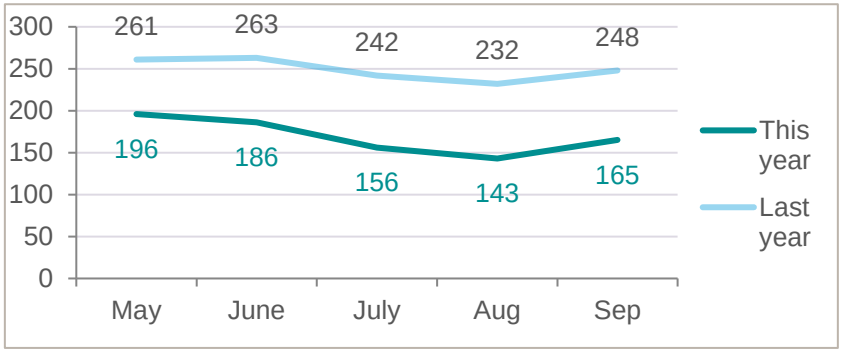
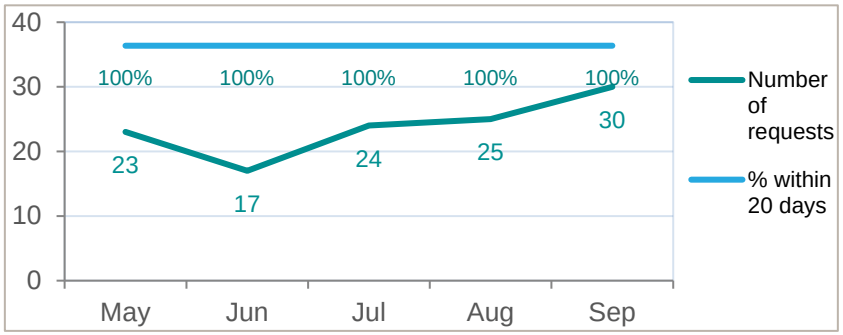
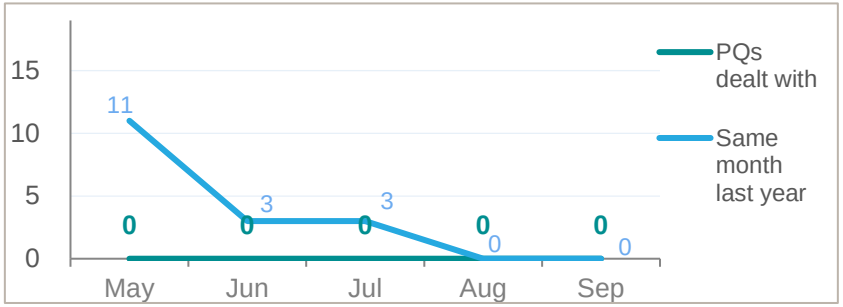
Indicator	Score	RAG	Recent trend[1]	Notes
Current headcount by month Headcount/ establishment	61/66	⇔		Overall volume (capacity) indicator. We are now using the new post-organisational change headcount of 66.
Turnover: Establishment ('unplanned') leavers per month (% establishment turnover for the year).	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.	0.78%	★		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.

HFEA performance scorecard

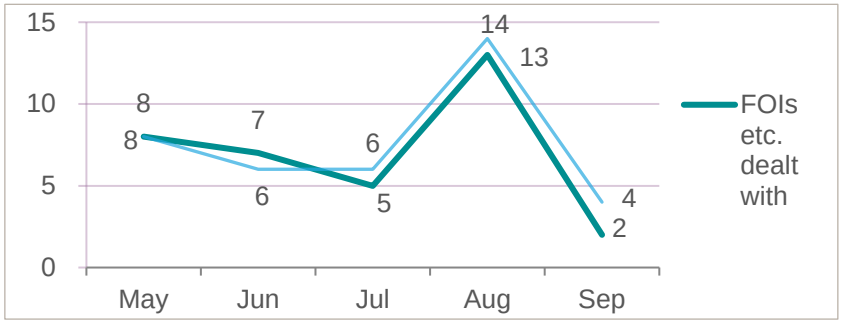
Annex A

Information – key performance and volume indicators

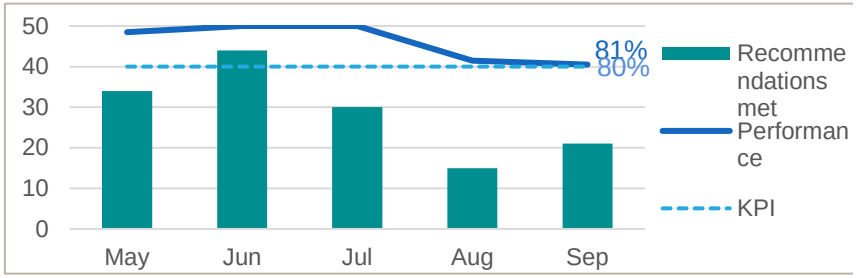
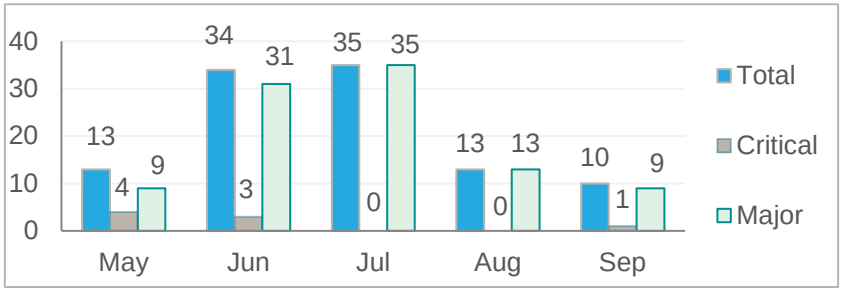
Indicator	Score	RAG	Recent trend	Notes
Number of emailed public enquiries received (compared with same month last year)	165	⇧		Volume indicator. We will soon begin to track telephone enquiries as well as those via email and these will be reported to CMG in their more detailed report. We are in the process 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	0	⇔		Volume indicator. We have 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 will be reflected in October data.

HFEA performance scorecard

Annex A

Indicator	Score	RAG	Recent trend	Notes
Number of Freedom of Information (FOI), Environmental Information Regulations (EIR) and Data Protection Act (DPA) requests	2	⇩		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.

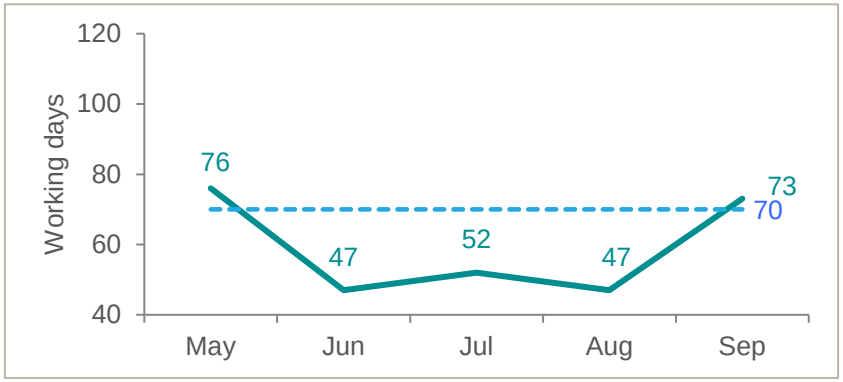
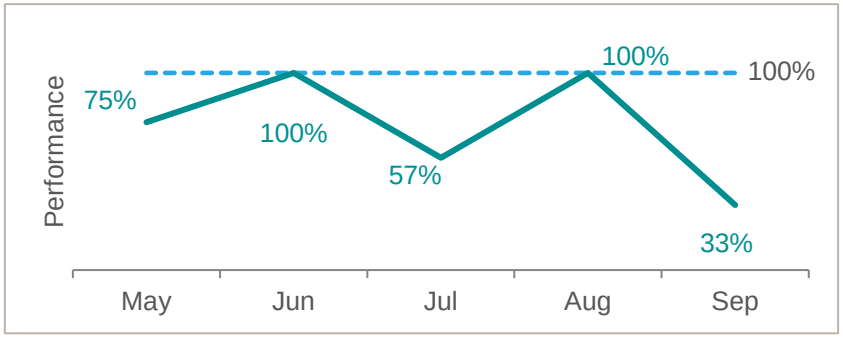
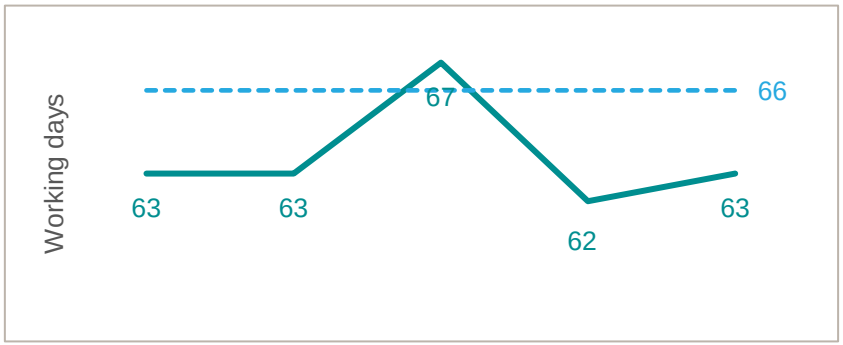
Inspection and licensing process – key performance and volume indicators

Indicator	Score	RAG	Recent trend[2]	Notes
Recommendations met by clinics following earlier inspections (No. met that month / No. due to be met that month)	81%	★		KPI: 80% of recommendations due that month, completed on time by clinics.
Average number of critical/major recommendations at clinics in inspection reports that were considered by ELP/LC that month	1	⇩		Volume indicator

[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.

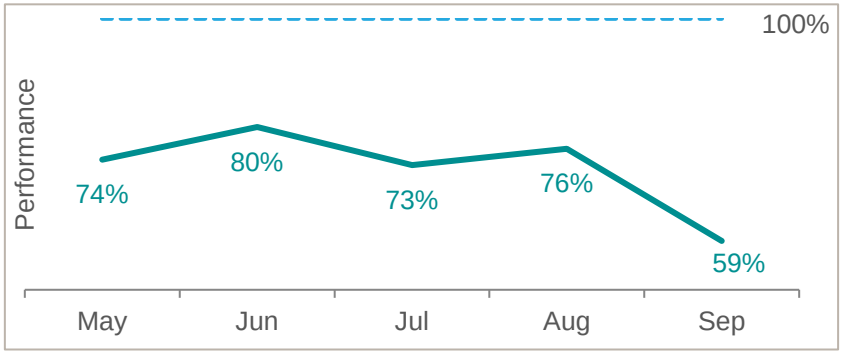
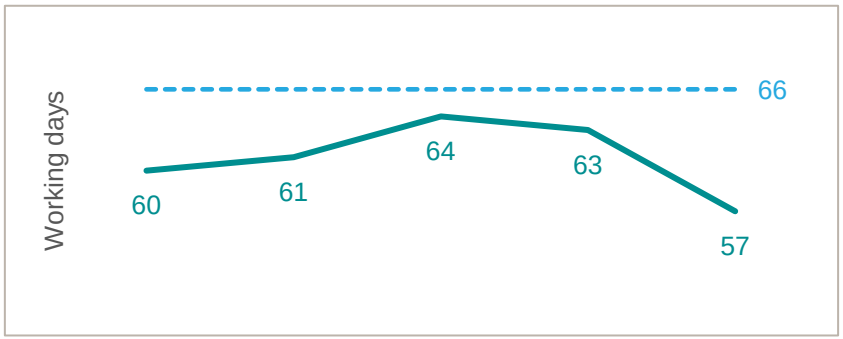
HFEA performance scorecard

Annex A

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 communicated to the centre.	73	⇧		KPI: Less than or equal to 70 working days. Although performance was below the KPI in September, this was particularly affected by outliers relating to inspection reports this month and this is unlikely to represent a trend in performance.
Monthly percentage of PGD applications processed within three months (66 working days).	33%	⇩		KPI: 100% processed (i.e. considered by SAC) within three months (66 working days) of receipt of completed application. See commentary above.
Average number of working days taken.	63	★		

HFEA performance scorecard

Annex A

Indicator	Score	RAG	Recent trend[2]	Notes
Annualised (rolling year) percentage of PGD applications processed within three months (66 working days)	59%	⇩		KPI: As above. (Annualised score). Dips in monthly performance across the preceding year will have an impact on the annualised figure. Compliance and licensing KPIs will be reviewed before the next CMG performance meeting.
Average number of working days taken.	57	★		

Draft business plan 2018-2019

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

Details:

Meeting	Authority
Agenda item	7
Paper number	HFEA (15/11/17) 856
Meeting date	15 November 2017
Author	Paula Robinson, Head of Planning and Governance

Output:

For information or decision?	For decision
Recommendation	To approve the draft business plan for 2018/19, in readiness for submission to the Department of Health.
Resource implications	In budget (to be agreed with DH in the usual way).
Implementation date	Across the 2018/19 business year
Communication(s)	The HFEA's business plans, once approved by the Department of Health, are published on our website.
Organisational risk	☒ Low ☐ Medium ☐ High
Annexes	Annex A: draft business plan 2018/19

1. Background

1.1. In September, the Authority approved an outline of the business plan for 2018/19. The next step in the process is for the Authority to receive a full draft of the business plan (attached at annex A), in readiness for submission to the Department of Health in the next two months.

1.2. Our business plans are designed to help us deliver our overall strategy, year by year. This business plan will deliver the second phase of our three year strategy.

1.3. As a reminder, the business planning cycle consists of the following main steps:

August	–	Early thinking by CMG (done)
October	–	First draft of 2018/19 business plan produced (done)
November	–	Draft approved by Authority (this meeting)
January	–	Draft submitted to Department of Health (DH)
February	–	DH budget discussions; DH feedback
March	–	Finalisation of budget with Authority and DH
April / May	–	Formal DH approval and publication on website.

2. Draft business plan

2.1. As agreed in September, the focus in our second year of the strategy will be on making the most of the new tools and capabilities introduced this year, as a result of the Information for Quality Programme and our organisational restructuring. Key pieces of strategic work will include:

Safe, ethical, effective treatment

- Working with the sector to focus on clinic leadership and to develop greater consistency in compliance standards between clinics, and throughout the inspection cycle.
- Refining the information published on our website to ensure that it meets users' needs.
- Monitoring the impact of the embryo research project completed in 2017/18.
- Improving research data consent information and consent rates.
- Consistent outcomes and support
- Analysing our data on success rates, with a view to increasing birth rates while avoiding adverse outcomes.
- Making use of new benchmarking information on price, working in collaboration with NHS England.

- Ensuring best practice in clinics on the emotional experience of care.
- Improving standards through intelligence
- Publishing more and better data.
- Making use of our data to inform targeted regulatory interventions.
- Analysing patient feedback obtained from our website (including Choose a Fertility Clinic ratings) and through social media.
- Ensuring we are an efficient and responsive regulator.

2.2. The current draft sets out our key activities for 2018/19. Some sections of the business plan are written later in the business year for practical reasons. The sections that will be produced later include:

- What we did in 2017/18
- Measuring our performance
- Financial picture.

3. Recommendation

3.1. The Authority is asked to approve the draft business plan for 2018/19, for submission to the Department of Health on request, and for further development.

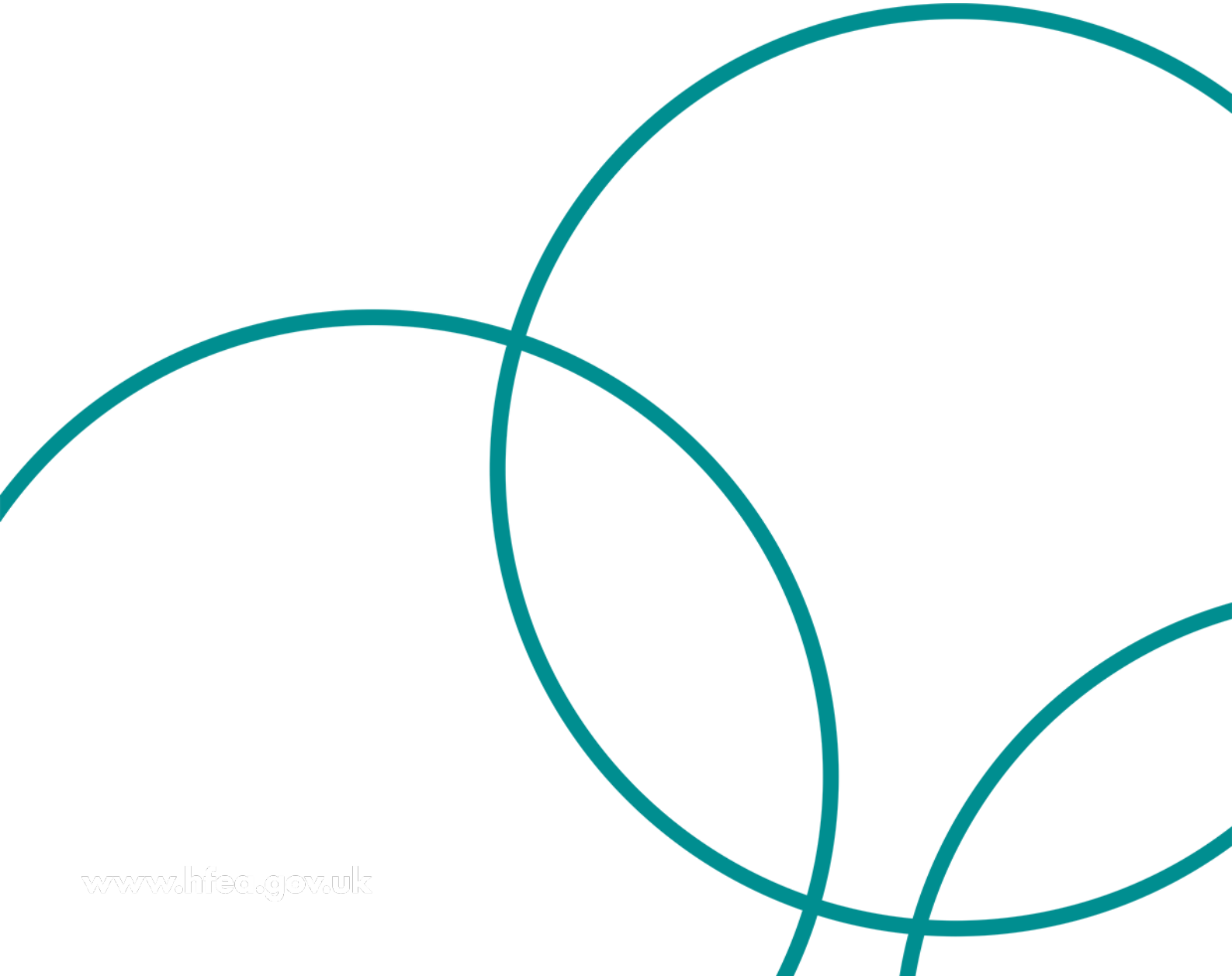
3.2. A near-final version of the business plan will come to March 2018 Authority for sign-off, prior to publication.

Annex A

Human Fertilisation & Embryology Authority

Business Plan (draft)

2018/19



www.hfea.gov.uk

Contents

Our role and strategic aims

Who we are

The HFEA is the regulator of fertility treatment and human embryo research in the UK. Our role includes setting standards for clinics, licensing them, and providing a range of information for the public, particularly people seeking treatment, donor-conceived people and donors.

Our vision for 2017-20 is:

High quality care for everyone affected by fertility treatment.

Patients, donors and donor-conceived people are at the heart of our strategy, and our work. We want them all to receive high quality care and support, at every stage in their journey through fertility services.

In setting our strategy, we considered people's needs at different points in their treatment journey.

Prospective patients (in particular) need to be able to find information to help them understand their options, know where to go for further advice and decide what steps to take next. People who have decided to have treatment (or to be a donor), and have contacted a clinic, need more detailed information to help them make decisions about treatment, and prepare for it. Patients and donors need good support during the treatment or donation process, and they need a deeper understanding of particular topics relating to their care. And people who have had treatment (whether it was successful or not), who have donated gametes, or who have been conceived through donation, need further information and emotional support at a later stage.

What can we do to achieve high quality care?

Our strategy for 2017-2020 focuses on three areas in order to meet these needs:

Safe, ethical, effective treatment

- High quality, safe care
- Effective evidence based treatment and treatment add ons that are well explained
- High quality research and responsible innovation

Consistent outcomes and support

- Access to treatment and donation
- The best possible treatment outcomes
- Value for money
- Support before, during and after treatment

Improving standards through intelligence

- Data and feedback used for improvement
- Targeted regulatory interventions
- Increased use of patient feedback
- A reshaped HFEA, to use our data well

This business plan sets out how we will work towards our vision in 2018/19.

Our legislation and functions

Our regulatory role and functions are set by two pieces of legislation:

- The Human Fertilisation and Embryology Act 1990 (as amended) – generally referred to as 'the 1990 Act'; and
- The Human Fertilisation and Embryology Act 2008 ('the 2008 Act').

Under this legislation our main statutory functions are:

- To license and inspect clinics carrying out in vitro fertilisation and donor insemination treatment.
- To license and inspect centres undertaking human embryo research.
- To license and inspect the storage of gametes (eggs and sperm) and embryos.
- To publish a Code of Practice, giving guidance to clinics and research establishments about the proper conduct of licensed activities.
- To keep a register of information about donors, treatments and children born as a result of those treatments.
- To keep a register of licences granted.
- To keep a register of certain serious adverse events or reactions.
- To investigate serious adverse events and serious adverse reactions and take appropriate control measures.

In addition to these specific statutory functions, the legislation also gives us more general functions, including:

- Promoting compliance with the requirements of the 1990 act (as amended), the 2008 act and the Code of Practice.
- Maintaining a statement of the general principles that we should follow when conducting our functions and by others when carrying out licensed activities.
- Observing the principles of best regulatory practice, including transparency, accountability, consistency, and targeting regulatory action where it is needed.
- Carrying out our functions effectively, efficiently and economically.
- Publicising our role and providing relevant advice and information to donor-conceived people, donors, clinics, research establishments and patients.
- Reviewing information about:
  - human embryos and developments in research involving human embryos
  - the provision of treatment services and activities governed by the 1990 act (as amended).
- Advising the Secretary of State for Health on developments in the above fields, upon request.

We also function as one of the two UK competent authorities for the European Union Tissues and Cells Directive (EUTCD). This directive regulates the donation, procurement, testing, processing, preservation and distribution of human tissue and cells for human application.

What we did in 2017/18

[Section to follow in March/April 2018]

Delivering our strategy in 2018/19

Delivering the strategy

Our strategic vision for the three years from April 2017 to March 2020 is:

High quality care for everyone affected by fertility treatment.

We aim to achieve this vision through delivering the following strategic objectives:

In this area…	We will…
Safe, ethical, effective treatment	1. Ensure that all clinics provide consistently high quality and safe treatment
	Our aim: • patients know clinics provide a high quality, consistent, safe service
	2. Publish clear information so that patients understand treatments and treatment add ons and feel prepared for treatment
	Our aim: • increase patients' understanding of the science and evidence base behind treatments and added extras known as add ons, and of their safety and effectiveness.
	3. Engender high quality research and responsible innovation in clinics
	Our aim: • improve the quality of treatment, by encouraging world class research and clinical trials.
Consistent outcomes and support	4. Improve access to treatment
	Our aim: • provide advice and information about access to treatment and improve access to donor conception treatment.
	5. Increase consistency in treatment standards, outcomes, value for money and support for donors and patients
	Our aims: • higher birth rates, without adverse outcomes. • patients and NHS commissioners receive good value fertility services • improve the emotional experience of care by clinics before, during and after treatment or donation
Improving standards through intelligence	6. Use our data and feedback from patients to provide a sharper focus in our regulatory work and improve the information we produce.
	Our aims: • use our data and intelligence to drive quality improvements for patients. • targeted and responsive regulatory interventions in the interests of quality and consistency. • increase insight into patient experience in clinics and encourage good practice based on feedback. • work more smartly with our resources, and capitalise on recent systems improvements.

The activities set out over the next few pages describe how we will meet these strategic objectives in 2018/19.

[An overview will be added once the following section is final, to sum up the year's work]

There is also an agreed shared delivery plan for all arm's length bodies and the Department of Health. This delivery plan gives high level clarity on objectives that reach across the whole health system. Since we are a specialist body, not all of the Department's priorities are relevant to our work, but our activities fit well within them – most notably in relation to the objective of creating the safest, highest quality healthcare services possible. Linkages with specific objectives in the shared delivery plan are indicated in the activities section setting out our plan of work for 2018/19.

Activities for 2018/19

Aims	Methods and channels	Benefits and outcomes	Timescale
Safe, ethical, effective treatment			
Strategic objective 1: **Ensure that all clinics provide consistently high quality and safe treatment**			
Ensure that clinics are well regulated and provide a high quality, consistent service. Outcomes in this area of work will contribute to the Department of Health's shared delivery plan (SDP) – objective 2: creating the safest, highest quality healthcare services.	Full programme of clinic regulation, encompassing all of our inspection, audit and licensing activities, with an increased emphasis on consistent standards across the sector, and between inspections. We will be clearer about what good performance looks like and will use our skills and our data to help clinics to be more compliant, more of the time.	All clinics and research establishments in the sector are appropriately inspected and monitored against the requirements of the Act and published performance indicators, and issued with licences for up to four years. Continued programme of unannounced inspections. Assurance of consistent standards and safety for the public and other stakeholders. A clear Code of Practice and other guidance for clinics, that is regularly updated. Positive overall impact on quality of care, outcomes, safety, support, and information clinics provide to the HFEA and publish (eg, on their websites). Patients know that all clinics are safe and appropriately licensed. Reduction in the number of critical, major and other non-compliances. Reduction in the number of clinic incidents, owing to learning from own and others' mistakes.	Throughout year October 2018

Aims	Methods and channels	Benefits and outcomes	Timescale
	Continued strong focus on learning from incidents, adverse events and complaints from patients, in dialogue with the sector. This will include a focus on incidents and clinics' learning culture during inspections, and publication of our annual review of clinical incidents.	Publication of 'State of the Sector' report for 2016/2017, including information about clinical incidents. Sector provided with useful information about learning points from incidents and adverse events. Learning gained, to inform future inspections. Patients' negative experiences used to make improvements and prevent recurrence. Better understanding of factors contributing to particular types of adverse event.	November 2018 Throughout year
	Proactively encouraging and supporting leadership in clinics, on inspection and through wider engagement with the sector.	Revised guidance in the Code of Practice setting clear expectations for clinics. Improvements in standards and consistency over time, both between one inspection and the next, and between clinics – so that more clinics perform at the level of the best clinics.	Throughout year
	Major revision of the Code of Practice.	Guidance for clinics is up to date and reflects latest scientific developments and policy decisions.	October 2018
Ensure that licensing decisions and other approvals are well governed. Outcomes in this area of work will contribute to the Department of Health's shared delivery plan (SDP) – objective 2: creating the safest, highest quality healthcare services.	Ensuring governance tools underpinning licensing and other decisions are in place and effective.	Efficient and effective decision-making is maintained. Decisions are evidenced and consistent.	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
	Processing applications for the licensing of preimplantation genetic diagnosis (PGD), human leukocyte antigen (HLA) and mitochondrial donation.	Growing area of work dealt with effectively and efficiently, with applications processed according to performance indicator timelines. Public confidence assured in the regulation of mitochondrial donation. Decisions on whether to authorise such treatments made, and communicated, in a proper and timely manner for the direct benefit of patients waiting for treatment.	Throughout year
	Policy project to review the current list of PGD conditions and ensure that all listed conditions still meet the statutory tests regarding seriousness and significance.	The list of conditions will be up to date and reflect latest developments in treatment for genetic diseases.	September 2018
Strategic objective 2: **Publish clear information so that patients understand treatments and treatment add ons and feel prepared for treatment**			
Make use of our website and other channels to increase patients' understanding of the science and evidence base behind treatments and added extras known as 'add ons', and of their safety and effectiveness. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 7: enabling people and communities to make decisions about own health and care; and objective 9: improving services through the use of digital technology, information and transparency.	Inclusion of up to date scientific content in our website so as to maintain our expanded range of information about current and future treatment options and treatment add ons, and the scientific evidence base for these.	Patients and others turn first to the HFEA for up to date, clear unbiased information. Prospective patients have clear information on which to base decisions about treatment or add ons. Patients feel safe, knowing they can expect certain standards in clinics, and are more aware of the potential risks of new/different treatments or add ons as well as the possible benefits.	Throughout year
	Guidance for clinics on what information they should publish on their own websites about the add on treatments they offer to patients.	Improved guidance in the Code of Practice. Information on clinics' websites is clear and transparent. Consensus statement with professionals setting out the appropruate way to introduce new techniques into treatment, through responsible innovation.	October 2018

Aims	Methods and channels	Benefits and outcomes	Timescale
	Refine the way we publish treatment information on our website, based on feedback from users.	Our information and site navigation better meets users' needs and preferences.	March 2019
	Responding to new scientific developments and associated reporting, correcting myths and misunderstandings where necessary.	Balance and accuracy provided when media coverage on scientific evidence is misleading or inaccurate.	Throughout year
	Conducting our annual horizon scanning exercise to ensure we identify relevant new scientific developments.	The Scientific and Clinical Advances Advisory Committee meets to discuss issues identified through horizon scanning three times per year. The horizon scanning panel meets once per year. Policy developments and website material are informed by expert input and an understanding of scientific issues and future developments. Future work planning is facilitated by early identification of upcoming issues.	Throughout year June/July 2018 Throughout year Throughout year
Strategic objective 3: **Engender high quality research and responsible innovation in clinics**			
Improving the overall quality of treatment, by encouraging world class data and embryo research and clinical trials. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 6: supporting research, innovation and growth.	Further work on embryo research, following the project in 2017/18 to produce better information about embryo research, streamline the application process and encourage collaboration between clinics and research centres. In 2019 we will carry out a review of embryo research, including the numbers of embryos donated, and whether the number of collaborations has increased.	Improvements in research information quality, applications and collaboration. To assess whether the decisions made at the June 2017 Authority meeting are having a positive impact.	September 2018 Spring 2019

Aims	Methods and channels	Benefits and outcomes	Timescale
	Focus on ensuring clinics explain research data consent adequately, record such consent properly, and report consents accurately to the HFEA.	The quality of research consent-taking, and the recording and reporting of consent, are improved. Higher rate of consent to research from patients.	Date tbc
	Information provision for researchers requesting access to Register data.	Information for researchers is provided within 90 calendar days of approval. Register information is used to best effect, to increase understanding and facilitate good research, and ultimately patient benefit.	Throughout year
Consistent outcomes and support			
Strategic objective 4: **Improve access to treatment**			
Providing advice and information about access to treatment, and improving access to donor conception treatment. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 7: Enabling people and communities to make decisions about their own health and care.	Publishing information and advice about accessing services, through various channels, and keeping this under review, taking into account user feedback. Providing information for those considering going abroad for treatment on how they might access services in the UK.	People understand the possibilities and the hurdles, and can weigh up the options open to them (measured through patient surveys). People can easily find relevant information and signposting on our website, to inform their next steps.	March 2019

Aims	Methods and channels	Benefits and outcomes	Timescale
	Collaborating with NHS Choices to put new patients in touch with better information about services when they first realise they may have a fertility issue.	New patients find relevant signposting and advice more easily. Quality and amount of information aimed specifically at new patients is increased. More informative signposting on our website, for those who are seeking preliminary information about fertility issues and options. Empowering patients, so they feel more equipped and are able to ask the right questions, regardless of the level of knowledge of their own particular GP about fertility issues and available treatments.	Throughout year
Improving access to donation, support for patients and donors and information about access to donor conception treatment. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 7: Enabling people and communities to make decisions about their own health and care.	Providing advice for patients about access to donor conception treatment, and encouraging better donation support for donors and patients, including those considering using unlicensed donor sperm services. Considering available data regarding availability of donor sperm and eggs.	People understand the process, and are prepared for donation and treatment (measured through patient/donor surveys). Donors and patients are better supported by clinics.	March 2019

Aims	Methods and channels	Benefits and outcomes	Timescale
Strategic objective 5: **Increase consistency in treatment standards, outcomes, value for money and support for donors and patients**			
Using our outcome data to improve the chances of successful treatment Outcomes in this area of work will contribute to the Department of Health's SDP – objective 2: creating the safest, highest quality healthcare services.	With the aim of increasing birth rates while avoiding adverse outcomes, we will analyse Register data on success rates, and work with our professional stakeholders to define and establish the factors that lead to successful outcomes, publishing our findings. Continuing to publish the annual fertility trends report. Using data more on inspection and in inspection reports.	More information published so that clinics can compare themselves more easily, based on different factors such as patient age. Fertility treatment in 2017 report published. Patients' chance of a live birth is maximised. Redesigned inspection reports focussing more on outcomes	March 2019 March 2019
	As part of the Code of Practice update for 2018, we will review the outcomes information on clinics' own websites, and provide revised guidance.	Revised guidance for clinics on the publication of outcomes data on their own websites. Clarity for the sector about how such data should be presented to prospective patients.	March 2019
Identifying and implementing ways of improving the quality and safety of care. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 2: creating the safest, highest quality healthcare services.	Continuing our focus on quality and safety of care in inspection activities – in particular through focusing on shortcomings in the taking and recording of consents, learning from incidents, medicines management and multiple birth rates. There will also be a greater focus on clinics' management of information responsibilities including meeting data submission and data security requirements, and ensuring information provided to patients generally and on clinics' websites is accurate and not misleading.	Improved compliance and a positive impact on the quality of care, outcomes and safety of patients. Tracking of non-compliances, and the responsiveness of clinics in completing actions arising from inspection recommendations, in order to measure our impact (through our internal strategic performance monitoring mechanisms). Clinics' understanding of, and adherence to, correct consent procedures (including those associated with legal parenthood) and their understanding of the importance of getting this right, is improved. Patients and donors have a better experience of being asked for consent, and feel fully informed.	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
		If an issue subsequently arises (such as the death of someone with gametes in storage), the correct consents are more likely to be in place and are legally clear and robust.	
	Continuing to evaluate areas of regulatory concern and identifying performance levers.	Improved levels of compliance. Inspection recommendations and advice or alerts targeting relevant issues, for maximum impact on quality of care, outcomes, and the safety of patients.	Throughout year
	Improved Register data quality, as a result of work done previously under the Information for Quality (IfQ) programme.	More 'right first time' data submission from clinics into the Register. Better service quality for Opening the Register (OTR) applicants. Fewer data submission and data accuracy related non-compliances found on inspection and audit.	March 2019
	To further develop the inspection regime to be more efficient and effective in the regulation of groups of clinics.	A clinic group's central Quality Management System (QMS) can be used to best effect across the whole group. A benefit in one clinic is shared to others in the group without needing to wait for the next inspection date - for the ultimate benefit of patients. A more efficient, effective and quality-driven way of working for the clinics involved and the HFEA.	March 2019
Improving value for money, for both patients and NHS commissioners. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 9: Improving services through the use of digital technology, information and transparency.	Make use of benchmarking information on price, working in collaboration with NHS England. Eliciting more feedback from patients as to whether they paid what they expected to for fertility services.	Patients know the price of a treatment at a given clinic at the start of treatment, and pay what they expect. Patients question costs, and particular additional costs, more often. Less variation in the price of treatment. The NHS pays a consistent and fair price for fertility services.	March 2019

Aims	Methods and channels	Benefits and outcomes	Timescale
Improving the emotional experience of care before, during and after treatment or donation. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 2: creating the safest, highest quality healthcare services.	Improving the emotional experience of care in clinics, by defining and encouraging best practice in clinics, and focusing on support at inspection. Ensuring that best practice is applied to donors and donor conceived people as well as to patients. (This will be implemented in the October 2018 Code of Practice update).	Clinics acknowledge how emotionally difficult infertility and treatment can be, and act on this. An improvement in the experience of treatment, with minimal emotional harm. Regardless of treatment outcome, but especially if it was unsuccessful, patients know they should expect care and support from the clinic beyond their final treatment. Clinics more aware of their responsibilities to patients beyond the immediate treatment setting.	March 2019
Evaluating the counselling support pilot for donor-conceived people wishing to access information held on the HFEA Register. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 2: creating the safest, highest quality healthcare services.	Evaluation of the third and final year of the pilot of counselling support services for Register applicants, including an assessment of provision and take-up.	Counselling support is offered for all Opening the Register (OTR) applicants (those seeking non-identifying information) and for donor-conceived applicants receiving donor identifying information, throughout the pilot period. Mediation services are in place for when donors and donor-conceived people meet. Basic mediation training and systems in place for dealing with identity release to donors and donor-conceived people. OTR applicants feel more supported and will be prepared to deal with the information they receive from us. Second annual evaluation of the pilot provided to the Authority.	Piloting continues through to June 2018. September 2018

Aims	Methods and channels	Benefits and outcomes	Timescale
Implementing new EU requirements relating to the import and coding of donor eggs and sperm. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 2: creating the safest, highest quality healthcare services.	Completion of projects initiated in 2014/15 to implement new EU requirements on the import of donor gametes and new EU coding requirements for human tissue and cells. (This work continues from the 2016/17 business plan, pending the resolution of Brexit.)	Improved clarity for clinics, patients and donors. Improved internal clarity and updated procedures for our decision-making committees. Compliance with the new EU directives. Robust processes in place to ensure the quality, safety and traceability of imported gametes and embryos.	October 2018
Improving standards through intelligence			
Strategic objective 6: **Use our data and feedback from patients to provide a sharper focus in our regulatory work and improve the information we produce**			
Driving quality improvements in treatment standards and outcomes by using our data and regulatory intelligence. Outcomes in this area of work will contribute to the Department of Health's shared delivery plan (SDP) – objective 2: creating the safest, highest quality healthcare services.	Developing our intelligence team and our analytical capability to extract more value from the data we hold, using the information strategy developed in 2017/18.	Information strategy delivery commenced. More outcome and other data published. Fertility Trends published. Donor information report published. Increased exposure of statistics and research using our new website.	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
Making more targeted and responsive regulatory interventions, in the interests of quality and consistency, based on our data. Outcomes in this area of work will contribute to the Department of Health's shared delivery plan (SDP) – objective 2: creating the safest, highest quality healthcare services.	Applying the intelligence available to us from inspections, the sector, patient feedback, and analysis of our data to make more targeted and responsive interventions.	Ability to make earlier and more responsive regulatory interventions, without the need to wait for the next inspection point. Regulatory performance is more consistent across the inspection cycle.	March 2019
	Reviewing our risk tool, to improve clinics' access to feedback about their own performance.	Risk tool brought up to date with latest benchmarks and available clinic data (entered through the HFEA's data submission system). More clinic data published for clinics' own use, using the clinic portal.	March 2019
Maintaining the Register of Treatments and Outcomes and working with clinics to ensure they are accurately reporting their data. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 2: creating the safest, highest quality healthcare services.	Register data and forms continue to be processed and quality assured, through liaison with clinics on errors and omissions and through validation and verification of Register entries.	High quality data available to develop patient information and respond to information requests. Risk-based regulation and evidence-based policy-making.	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
Publishing and supplying the information we hold, for the benefit of stakeholders. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 7: enabling people and communities to make decisions about own health and care; and objective 9: improving services through the use of digital technology, information and transparency.	Regularly updating Choose a Fertility Clinic (CaFC) information to assist patient choice.	Provide more up-to-date, and accurate, information to patients.	Throughout year
	Continued publication of inspection reports on CaFC.	Inspection reports continue to be published via CaFC, providing patients with an independent assessment of the quality of services offered by each clinic.	Throughout year
	Further develop and improve the presentation of clinic comparison information and user experience scores on CaFC, guided by patient feedback.	Published outcome data is more useful and easier to understand and sets up positive incentives for improvements. Patient feedback enables us to evaluate the effectiveness and usability of the new presentation, and to plan future improvements.	Throughout year
	Continuing to facilitate timely access to information from the Register for those who are entitled to it.	Opening the Register requests continue to be met in a sensitive manner and within required time limits (20 working days, excluding time for counselling).	Throughout year
	Facilitating access to information under various statutory regimes and fulfilling Government requirements such as quarterly disclosure of information on procurement.	Legal and Parliamentary requirements continue to be met within time limits.	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
	To continue to publish statistical and other reports.	'Fertility trends report. - Provides the public, patients, clinic staff and others with up-to-date, high quality information about treatment outcomes. - Provides important information to those affected by donor conception, to patients seeking treatment and to us, to help us to enhance the quality of care that patients and donors receive in clinics, through our regulatory work. - Report carries 'official statistics' status.	March 2019
		'State of the fertility sector' report -2017-18 - Provides the public and the sector with the most up-to-date information about the performance of clinics. - Contributes to a culture of openness and information sharing where clinic staff are empowered to report mistakes and learn from each other. - Increases transparency and maximises opportunities for learning from incidents to improve quality of care for patients.	November 2018
Responding effectively to specific enquiries from individuals. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 7: enabling people and communities to make decisions about own health and care.	Continuing to respond to the many individual patient and public enquiries we receive each year.	Individual patients and members of the public are able to ask specific, sometimes complex, questions and receive a tailored and meaningful response. We remain responsive, and continue to be able to handle the range of one-off enquiries raised by individuals, providing a considered and informed response within a reasonable timescale. We are able to identify any trends and common themes in the enquiries we receive, informing the	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
		development of additional information which could be placed (for example) on our website.	
Maintaining our role as the UK's competent authority for ART in the European Union[1]. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 2: creating the safest, highest quality healthcare services.	Gain intelligence through participation in competent authority events and implementation of associated EU decisions.	We participate in approximately two meetings per year. Up-to-date intelligence gained about the perspective of other EU member states, helping to inform UK approach to patient safety and care. Free movement of gametes and embryos enabled within the UK and standards upheld in the UK that are consistent with the rest of the EU.	[Dates tbc] Throughout year
Gaining insight into the patient experience in clinics and encouraging good practice based on feedback. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 7: enabling people and communities to make decisions about own health and care.	Collecting more patient feedback through various channels, including our website and social media. Establish additional channels and methods for obtaining patient experience information. Analysing and using this intelligence to inform our activities and our messaging to clinics, sharing the information with professional stakeholders.	Improvement in the quality of services and patient/donor support as a result of patient ratings and other feedback. Quantifiable increase in the amount and frequency of patient feedback available to the HFEA and our professional stakeholders. Patient feedback loop in place to ensure a regular flow of fresh feedback which can be incorporated into our stakeholder interactions and regulatory approach.	Throughout year
	Surveying stakeholders about our performance as a regulator.	Stakeholder input obtained to inform future developments and improvements.	March 2019

[1] For as long as the UK remains in the EU.

Aims	Methods and channels	Benefits and outcomes	Timescale
Ensuring the HFEA is a good value organisation and makes best use of its limited resources. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 3: maintaining and improving performance against core standards while achieving financial balance.	Working smartly with our limited resources, capitalising on improvements in our information systems and ensuring that our infrastructure and central systems are efficient and responsive.	Resources are deployed in the interests of high quality care for everyone affected by fertility treatment. Achieving measurable 'added value' and internal efficiency. Our infrastructure is effective and contributes to the delivery of the strategic vision. Central systems, processes and tools are efficiently run, giving good value and service. Updated staff intranet.	Throughout year
	Ensuring that we retain the staff we need in order to operate a good quality service, and implement our People Strategy for 2017-2020.	We are able to maintain the staff capacity and capability to deliver our strategy and our core statutory duties. Continuing to develop our staff to ensure they have the skills they need, through Civil Service Learning and other means.	Throughout year
	Reviewing our internal records management and information governance arrangements.	HFEA's records management system updated and reviewed to ensure that records are securely held and that good practice is followed. Information governance arrangements comply with latest requirements and roles and responsbilities and are clearly set out for staff.	January 2019

Aims	Methods and channels	Benefits and outcomes	Timescale
Ensuring the HFEA is easy to deal with and offers a professional service. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 3: maintaining and improving performance against core standards while achieving financial balance.	Full realisation of the benefits of HFEA's improved Register function and processes (including the data submission system and the Clinic Portal).	System fully bedded in with Clinics and EPRS providers. Reduced transactional costs for clinics and increased satisfaction. 'Right first time' data quality and reduction in unnecessary effort by clinics submitting the data.	April-October 2018
	Continuation of engagement arrangements with clinics on fees charged.	Accountability and transparency in respect of the fees we charge clinics. Fees Group continues to be run effectively, and annual review of fees takes place.	Throughout year
Responding as appropriate to government requirements on transparency, better regulation and the new General Data Protection Regulation (from May 2018 onwards). Outcomes in this area of work will contribute to the Department of Health's SDP – objective 3: maintaining and improving performance against core standards while achieving financial balance, and objective 6: supporting research, innovation and growth.	Ongoing compliance with government requirements, including: Reporting in our Annual Report on the growth duty and compliance with the Regulators' Code . Complying with the Business Impact Target by identifying and reporting any 'in-scope activity'. Complying with the new General Data Protection Regulation.	The HFEA responds to government requirements and new initiatives in a manner consistent with its legal status, and proportionately within our small resource envelope, carefully recognising our duties. Annual Report publication including additional required information. Compliance with the Business Impact Target for any activities that may be in scope.	Throughout year June 2018 Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
Ensuring the HFEA is an effective collaborator and partner in the interests of the efficiency of the wider Department of Health group of ALBs and other health organisations. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 4: improving efficiency and productivity of the health and care system.	Continued participation in the collaborative regulatory advice service for regenerative medicine, to provide advice to those working in the life sciences industry.	Continued constructive joint working between the HFEA, the Human Tissue Authority (HTA), the Health Research Authority (HRA) and the Medicines and Healthcare products Regulatory Authority (MHRA). Businesses and other organisations in the life sciences industry can quickly and easily navigate the different regulators and allow them to access the right advice more quickly.	Throughout year
	Sharing services and infrastructure with other organisations as practicable: Maximising benefit of finance resources shared with HTA. Continuing with service level agreements (SLAs) with relevant other organisations for certain HR services and using Civil Service Learning as a key learning and development provider. Continuing to receive facilities services from the landlord of our office premises, via an SLA.	We continue to operate in as efficient a way as possible, extracting maximum value from shared arrangements and seeking other opportunities.	Throughout year
	Collaborative and partnership working with other ALBs and health regulators UK wide, such as the CQC, NHS England, MHRA, UKAS, HRA, GMC and the devolved nations, maintaining the close positive working relationships that have been developed over the past several years.	Ability to capitalise on previously established relationships, eg, to address issues that require joint working in an efficient and coordinated way, or to establish the best approach if any new areas of regulatory overlap should arise (as was done previously with the CQC, removing overlap in relation to the regulation of medicines management and surgical procedures in clinics). Continued savings and avoidance of unnecessary administrative or regulatory burden, by avoiding duplication of effort or uncoordinated approaches between regulators.	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
Maintaining our previously established collaborative information management relationships. Outcomes in this area of work will contribute to the Department of Health's SDP – objective 4: improving efficiency and productivity of the health and care system.	Maintaining our good working relationships with relevant other information management bodies, such as the Government Digital Service (GDS), NHS Digital and being an active member of the National Information Board (NIB).	We contribute to the objectives of the wider health system, with respect to information management. Learning from best practice and sharing expertise, so that we can make use of each other's strengths and knowledge in data management, systems integrity and security.	Throughout year

Measuring our performance

[Section to be added in March/April]

Financial picture

[Section to be added in Jan/Feb]

Other required information

Introduction

A sound delivery framework and a well-maintained organisational infrastructure are prerequisites for the successful delivery of any strategy or business plan. It is also important that we remain compliant with Government rules that apply across the whole family of arm's length bodies (ALBs).

The HFEA's governance structure includes corporate governance tools, a people plan (currently being revised to reflect our new strategy and organisational structure) and HR policies, and a business continuity plan. These enable us to manage our work effectively and meet external and internal requirements such as information requests, compliance with the Equality Act 2010, the production and laying in Parliament of our annual report, and the management of organisational risks and performance.

The information below is provided to explain those aspects of our organisation that are structural or which help us to meet particular Department of Health or cross-Government requirements.

Better regulation and innovation

The objective of the Business Impact Target (BIT) is to reduce unnecessary regulatory burdens on business and ensure that regulatory decisions are made in the light of high quality, robust evidence about the likely impact on business.

Reporting against the BIT became a statutory duty for the HFEA in 2016, when statutory regulators were brought into scope of the Small Business, Enterprise and Employment (SBEE) Act 2015. We must produce BIT assessments of all regulatory provisions that are in scope and obtain independent verification of the economic impact of these regulatory decisions by submitting assessments to the Regulatory Policy Committee. We must publish our assessments, which are used by the government to report on progress against its deregulation targets. On 3 March 2016 the Government announced its overall target is to save business £10 billion of regulatory costs from qualifying measures that come into force or cease to be in force during this Parliament. The Government also announced an interim target of £5 billion of savings in the first three years of this Parliament.

In 2016 when the requirement began, we produced retrospective assessments for our initial reporting period 2015 – 2017. This work is now handled as part of our usual processes. We plan to continue to work closely with our external stakeholders as well as the Department of Health Better Regulation Unit, the Better Regulation Executive (who have the responsibility for implementing the BIT framework) and the Regulatory Policy Committee to ensure that our assessments are fit for purpose. We will satisfy the statutory requirements that are relevant to us in a proportionate manner, that assists our continued implementation of effective regulation across the whole of the IVF sector, and our strategy objective of high quality care.

Organisational structure and establishment

Since 2010/11, the HFEA has significantly reduced its staffing, in keeping with overall pressures on the public sector and Government expectations. Our staff complement is now 67 (compared to 86 in 2010/11). We have put in place shared services arrangements with other bodies, where feasible. For example, we share part of our finance and resources team staffing with the HTA, and our facilities management service is provided by NICE (since we occupy the same premises). We also have a shared services agreement with the Care Quality Commission (CQC) for recruitment.

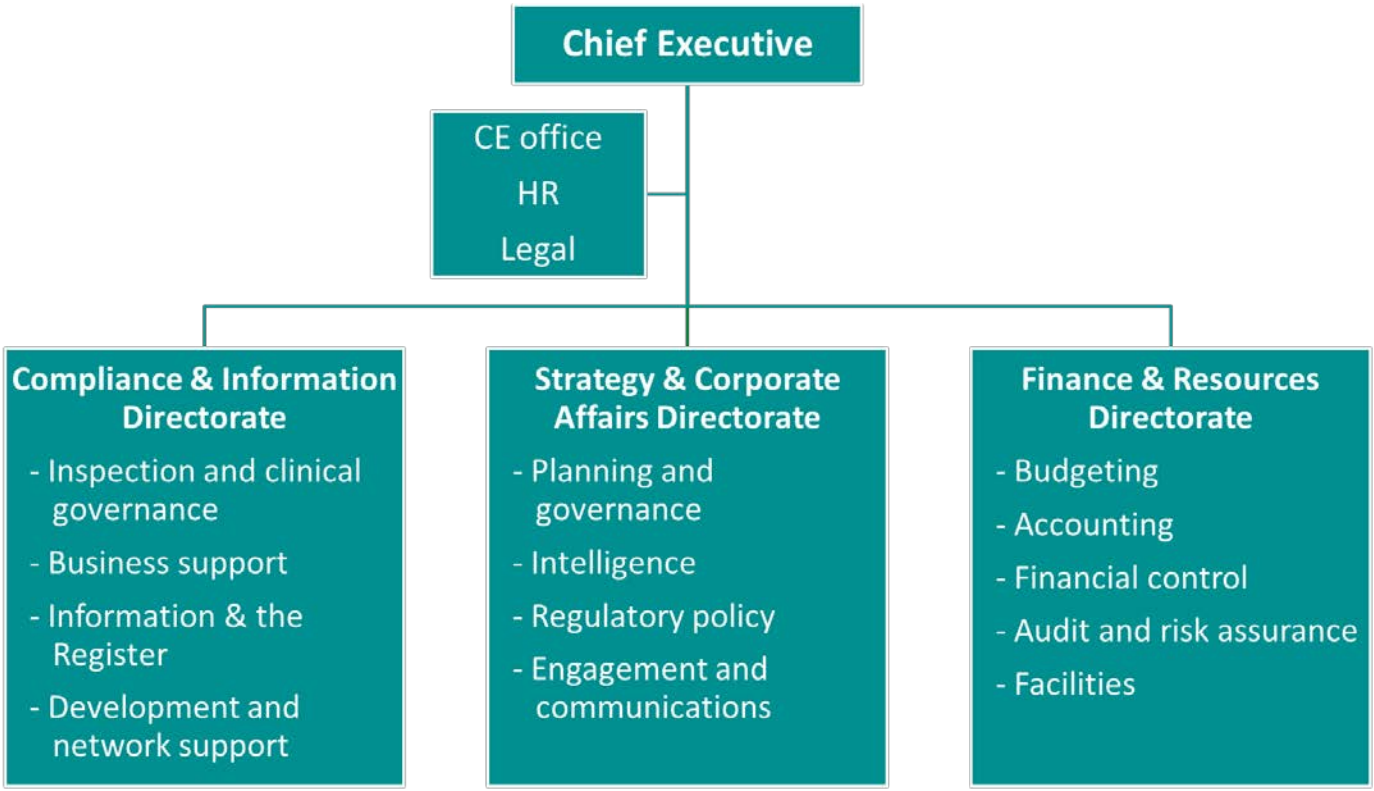
Having made considerable savings, our size will now need to remain stable for the foreseeable future. We need to ensure we retain the capability and capacity to deliver our overall strategy for 2017-2020.

Our learning and development activities continue to equip our staff with the skills they need. Services are procured in accordance with continuing Government requirements to ensure value for money, using Civil Service Learning, and their associated suppliers, or other ALB provision, as appropriate.

Together with other ALBs, we continue to participate in a talent management consortium which aims to provide cost effective leadership development programmes and other development opportunities.

All staff pay is determined in line with HM Treasury annual guidance. We adhere to the formal pay remit when it is announced.

In 2017/18 we revised our organisational structure so as to allow us to capitalise on the improvements to our information systems, achieved through our Information for Quality Programme. The current structure is illustrated below.



Financial management systems

We continue to maintain sound financial governance and business planning processes. We manage our processes efficiently and continue to develop and deepen our various collaborative relationships and shared services with other bodies, which provide increased value as well as some economies of scale.

Internal audit

We continue to be part of the Department of Health group assurance framework and to work with the co-sourcing provider on delivering the annual internal audit plan for each year. The programme of internal

audits has been streamlined to meet the HFEA's needs and to make best use of the group audit arrangement, which helps to improve the overall levels of assurance for the group.

Assurance framework

A framework agreement with the Department of Health (in 2014) sets out the critical elements of the relationship between the HFEA and the department, and other ALBs where relevant. As an ALB, the HFEA will continue to manage its assurance and risk management independently and report this to the Authority. The HFEA recognises that, on rare occasions, its risks or assurance may have a significant impact or interdependency with the Department of Health or other ALBs and understands the correct dialogue and escalation mechanisms for communicating the issues and relevant mitigations.

Equality Act 2010

The HFEA remains compliant with the requirements of the Equality Act 2010. There is an equality champion on the Authority. We will collectively continue to ensure, throughout the year, that the HFEA fulfils its obligations under the Equality Act.

Whistleblowing policy

We value staff who raise concerns over potential wrongdoing and are committed to ensuring that our staff have access to, and a clear understanding of, public interest disclosure (whistleblowing). Our policy is reviewed each year to ensure that the details are up to date and reflect latest legislation and guidance. Should any individual raise a concern through this route, we are committed to ensuring that their confidentiality is appropriately protected and that they will not suffer any detriment as a result of whistleblowing.

Transparency requirements

We will continue to comply with the various data requests and requirements for the publication of data on our own website and on data.gov.uk, arising from the transparency agenda that was first introduced in 2010. We regularly publish all required spending data openly, in the required file format, via data.gov.uk.

All of our Authority meetings are held in public and the papers and audio recordings are published on our website. Committee papers and a wealth of other information are also routinely published on our website.

Information technology (IT) and data security

The HFEA maintains an information asset register identifying our key IT systems and their owners. Our IT systems ensure we comply with the data management requirements of legislation, including the HFE Act 1990 (as amended) and help us to manage the significant databases we hold.

HFEA databases are currently held on highly secure servers within the premises. While we occupy premises shared with another ALB, this necessarily entails sharing a communications room on-site to house the servers. Security measures are in place so as to ensure that 'section 33A patient-identifying data' is appropriately protected.

The HFEA remains fully compliant with Cabinet Office rules regarding data security and with its own legislative requirements regarding confidentiality of information under the HFE Act 1990 (as amended).

Our IT strategy includes secure arrangements for our servers, while adhering to all applicable central Government requirements. We have also moved into a cloud-based Office 365 arrangement for our desktop systems, which is more cost-effective and increases our resilience in the event of any business continuity issues with our physical premises.

The robust information security arrangements the HFEA has in place, in line with the information governance toolkit, include a security policy for staff, secure and confidential storage of and limited access to Register information and stringent data encryption standards for systems and IT hardware. A programme of information security and cyber security training is conducted, and this is regularly reviewed.

We operate a clear desk policy and have on-site shredders and confidential material disposal arrangements in place.

Business continuity

We reviewed our business continuity plan in 2017/18, to ensure it remains fit for purpose. The plan is regularly updated and periodically tested. There is an operational disaster recovery site available if needed.

Estates strategy

The HFEA has no estate. Our office strategy remains to be a tenant or co-tenant of a larger Department of Health organisation. In April 2016 we moved into NICE's office space in Spring Gardens, taking up 269 square metres.

The HFEA works with NICE on health and safety and general facilities services. We have access to an online system for individual workplace assessment and meet with the NICE lead on fire evacuation procedures and fire warden liaison.

Sustainable development

We recycle paper, card, glass, plastic cups, containers and bottles, metal cans and toner cartridges.

We have two multi-function devices (for secure printing, scanning and photocopying), pre-set to print on both sides of the paper. Our IT equipment is re-used and working lives extended where possible and is switched off when not in use. Surplus equipment is either sold or donated. A proportion of our staff are able to work from home, allowing reduced travel impacts, and this proportion has increased slightly over the past two years, since we moved into smaller premises.

We do not procure energy or other items with significant environmental impacts.

Procurement

The HFEA complies with all relevant Department of Health and Cabinet Office efficiency controls. These cover advertising, marketing and communications, IT, digital, professional services and learning and development. Business case approval from the Department is required in most cases.

We are aware of the green agenda in relation to procurement. However, we rarely set our own contract terms or purchase directly and are dependent on CCS and other framework holders for integrating sustainability features in their contract letting.

Nearly all of our procurement is done through CCS. So, as far as we are able, we aim to meet the Department of Health target for public sector procurement of 23% of procurement spend going to SMEs but we are dependent (as with sustainability) on CCS ensuring that SME suppliers are present on the relevant frameworks in the first place. Where we have a choice of supplier, our criteria do include both sustainability and SME usage.

We are too small to have a procurement pipeline. Any necessary procurement will be conducted using CCS frameworks and with close CCS oversight. There will be no procurements over £100,000 in 2018/19. We provide the Department of Health with quarterly reporting on procurement.

There is no significant non-pay spend that is not via CCS, NICE or Department of Health frameworks or contracts.

We remain committed to the principles of the voluntary sector compact and work with the voluntary sector where applicable. For example we have worked successfully for some years with other organisations to reduce the prevalence of multiple births in the fertility sector and we routinely open developments to our policies and processes to a wide range of inputs and influences, including voluntary organisations.

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Fertility sector report: 2016-17

Strategic delivery:	☒ Setting standards	☐ Increasing and informing choice	☐ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	8		
Paper number	HFEA (15/11/17) 857		
Meeting date	15 November 2017		
Author	Nick Jones, Director of Compliance and Information		
Output:			
For information or decision?	For decision		
Recommendation	The Authority is invited to: • Provide any final comments on the report • Approve the publication of this report • Agree that the report be embargoed until publication later this month.		
Resource implications	None		
Implementation date	November 2017		
Communication(s)	National publication, with press release		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes:	Annex 1 Near-final report – State of the fertility sector 2016-17		

1. Background

1.1. At the September 2017 meeting the Authority reviewed an early draft of a new style report designed to reflect the performance of the fertility sector. The report built on previous reports to Authority on the level of non-compliance with requirements identified at licensed clinics by HFEA inspectors in the year; and the publication of a report on the number and type of incidents reported in the same period.

1.2. We proposed facilitating a broader and more even-handed discussion of the fertility sector, focussing not just on the performance of licensed clinics, but also on essential characteristics of the sector itself; its size, public private split, geographical concentration and much else.

1.3. The draft report *State of the fertility sector: 2016-2017* was warmly received by Members. In discussion, several suggestions for improvement were also made and, on that basis, it was agreed that the report would be revised further. The near final version is presented to this meeting of the Authority for final approval.

2. Revised version

2.1. The designed report is attached at annex 1. The revised report contains most of the material in the first draft, although it has been shortened where possible to make it a clearer and more accessible read. In addition, some sections have been renamed and re-ordered. The main changes and new features of the report are as follows

- There is a new section at the beginning setting out how we regulate (this now includes brief reference to research regulation as well).
- The context section has been expanded and renamed: 'About the UK fertility sector'
- This is then followed by the 'regulatory compliance' section which has been redrafted to further emphasise what is done well and renamed: 'Quality of service and compliance'
- Members were keen to see examples of good practice to prompt readers to think about adopting – and some examples from what inspectors found are included in this section and later
- The final three sections are entitled 'areas of focus' and build on the draft version – relate to minimising multiple births, learning from incidents and patient experience

2.2. The executive summary has been deliberately left blank at this stage. We plan to draft this following the Authority discussion and would be grateful for members views on the key issues you think should be highlighted.

3. Publication

3.1. The draft report is not published as part of the Authority papers set on the basis it is a future publication.

3.2. Our ambition is to publish the report in the week commencing 27 Noember 2017.

3.3. In the future, we expect to publish an annual report each Autumn which will complement our annual fertility trends report.

4. Recommendation

4.1. The Authority is asked to:

- Provide any final comments on the report (including in particular the executive summary)
- Approve the publication of this report
- Agree that the report be embargoed until publication later this month.

Strategic risk register

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value

Details:	
Meeting	Authority
Agenda item	9
Paper number	HFEA (15/11/17) 858
Meeting date	15 November 2017
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 edition of the strategic risk register.
Resource implications	In budget
Implementation date	Ongoing
Communication(s)	The risk register is reviewed quarterly by the Corporate Management Group (CMG), and presented at every Audit and Governance Committee (AGC) meeting. AGC last reviewed the risk register at its meeting on 3 October, and will review it again at its meeting on 5 December.
Organisational risk	☐ Low ☒ Medium ☐ High
Annexes	Annex A: Strategic risk register

1. Latest reviews

1.1. CMG reviewed the risk register at its meeting on 6 September. CMG reviewed all risks, controls and scores. Two of the seven risks were above tolerance.

1.2. The risk register was discussed at AGC on 3 October. No changes were proposed to the risk scores at that time. Any comments from the Authority will be fed into the Committee's next review on 5 December.

1.3. CMG and AGC's comments are summarised on page 22 of the risk register, at Annex A.

1.4. Since the AGC meeting, the executive has reviewed the register and considered comments made at AGC about controlling above tolerance risks. During this review, we have reduced the residual risk rating of the organisational change risk in light of the current position. This now brings this risk to within tolerance.

2. Recommendation

2.1. The Authority is asked to note and comment on the latest edition of the strategic risk register.

Strategic risk register 2017/18

Risk summary: high to low residual risks

Risk area	Strategy link*	Residual risk	Status	Trend**
C1: Capability	Generic risk – whole strategy	**16 – High**	Above tolerance	⇔⇔⇧⇔
LC1: Legal challenge	Generic risk – whole strategy	**12 – High**	At tolerance	⇧⇔⇩⇔
OC1: Organisational change	Generic risk – whole strategy	**12 – High**	Above tolerance	⇧⇔⇔⇔
FV1: Financial viability	Generic risk – whole strategy	**9 – Medium**	At tolerance	⇔⇔⇔⇔
CS1: Cyber security	Generic risk – whole strategy	**6 – Medium**	At tolerance	-⇔⇔⇔
RE1: Regulatory effectiveness	Improving standards through intelligence	**6 – Medium**	At tolerance	-⇔⇔⇔
ME1: Effective communications	Safe, ethical effective treatment Consistent outcomes and support	**6 – Medium**	At tolerance	-⇔⇔⇔

* Strategic objectives 2017-2020:

- Safe, ethical effective treatment: Ensure that all clinics provide consistently high quality and safe treatment
- Safe, ethical effective treatment: Publish clear information so that patients understand treatments and treatment add ons and feel prepared
- Safe, ethical effective treatment: Engender high quality research and responsible innovation in clinics
- Consistent outcomes and support: Improve access to treatment
- Consistent outcomes and support: Increase consistency in treatment standards, outcomes, value for money and support for donors and patients
- Improving standards through intelligence: use our data and feedback from patients to provide a sharper focus in our regulatory work and improve the information we produce

** This column tracks the four most recent reviews by AGC, CMG, or the Authority (eg,⇧⇔⇩⇔). Recent review points are:

- Risk register 2017-2020: CMG 17 May 2017⇨ AGC 7 June ⇨ CMG 6 September ⇨ AGC 3 October
- (Some risks are new or recent, as at May 2017, and therefore do not yet show four trend points.)

FV1: There is a risk that the HFEA has insufficient financial resources to fund its regulatory activity and strategic aims.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	4	16 - High	**3**	**3**	**9 - Medium**
Tolerance threshold:					**9 - Medium**

Risk area	Risk owner	Links to which strategic objectives?	Trend
Financial viability FV1: Income and expenditure	Richard Sydee, Director of Finance and Resources	Whole strategy	⇔⇔⇔⇔

Commentary
At tolerance. As of Q2, we are showing a surplus against budget which is due to the steady increase in our treatment fee income and the slow expenditure activity of which unfilled vacancies are a major part. Our forecast for the year is likely to be a surplus subject to any new legal issues and assuming spend on the data submission and migration projects is maintained.

Causes / sources	Mitigations	Timescale / owner
Our annual income can vary significantly as: - Our income is linked directly to level of treatment activity in licensed establishments - Forecasting treatment numbers is complex - We rely on our data submission system to notify us of billable cycles.	Activity levels are tracked and significant changes are discussed at CMG, who would consider what work to deprioritise and reduce expenditure.	Monthly (on-going) – Richard Sydee
	Fees Group enables dialogue with sector about appropriate fee levels.	Ongoing – Richard Sydee
	We have sufficient reserves to function normally for a period if there was a steep drop-off in activity, or clinics were not able to submit data and could not be invoiced. If this happened, resolving it would be high priority, and the roll-out of the new data submission system will be planned carefully.	In place – Richard Sydee/Nick Jones
	Work on the drivers of treatment fees to better understand the likely future trends in treatment cycle activity.	Begun in Q2. Ongoing – Richard Sydee
Annual budget setting process lacks information from directorates on variable/additional activity that will impact on planned spend.	Annual budgets are agreed in detail between Finance and Directorates with all planning assumptions noted. Quarterly meetings with Directorates flags any shortfall or further funding requirements.	Quarterly meetings (on-going) – Morounke Akingbola

Project scope creep.	Senior Finance staff present at Programme Board. Periodic review of actual and budgeted spend by Digital Projects Board (formerly IfQ) and monthly budget meetings with finance.	Ongoing – Richard Sydee or Morounke Akingbola
	Cash flow forecast updated.	Monthly (on-going) – Morounke Akingbola
Risk interdependencies (ALBs / DH)	**Control arrangements**	**Owner**
DH: Legal costs materially exceed annual budget because of unforeseen litigation.	Use of reserves, up to contingency level available. DH kept abreast of current situation and are a final source of additional funding if required.	Monthly – Morounke Akingbola
DH: GIA funding could be reduced due to changes in Government/policy.	A good relationship with DH Sponsors, who are well informed about our work and our funding model.	Accountability quarterly meetings (on-going) – Richard Sydee
	Annual budget agreed with DH Finance team alongside draft business plan submission. GIA funding has been provisionally agreed through to 2020.	December annually – Richard Sydee
	Detailed budgets for 2017/18 have been agreed with Directors. DH has previously agreed our resource envelope.	In place – Morounke Akingbola

C1: There is a risk that the HFEA experiences unforeseen knowledge and capability gaps, threatening delivery of the strategy.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
5	4	20 – Very high	**4**	**4**	**16 - High**
Tolerance threshold:					**12 - High**

Risk area	Risk owner	Links to which strategic objectives?	Trend
Capability C1: Knowledge and capability	Peter Thompson, Chief Executive	Whole strategy	⇔⇔⇧⇔

Commentary
Above tolerance. This risk and the controls are focused on business as usual capability, rather than capacity, though there are obviously some linkages between capability and capacity. Since we are a small organisation, with little intrinsic resilience, it seems prudent to retain a low tolerance level. We are currently in a period of turnover and internal churn, with some knowledge gaps, and data submission and migration work ongoing. As a result, the tolerance level for this risk was raised from 6 to 12 at CMG in May. And in September, CMG raised the risk level in recognition of the additional impact of organisational change. **Action plan** Heads and managers are proactively treating this risk by ensuring that handovers are as full and thorough as possible and ensuring that recruitment happens as quickly as possible. Now that an Interim Head of HR (Yvonne Akinmodun) has been appointed, we will be able to go further to mitigate this risk and bring it back within tolerance. The new people strategy will be key.

Causes / sources	Mitigations	Timescale / owner
High turnover, sick leave etc., leading to temporary knowledge loss and capability gaps.	Staff have access to Civil Service Learning (CSL); expectation is five working days per year of learning and development for each member of staff. Staff are encouraged to identify personal development opportunities with their manager, through the PDP process, making good use of CSL.	In place – Yvonne Akinmodun (Interim Head of HR)/Peter Thompson
	Organisational knowledge captured via documentation, handovers and induction notes, and manager engagement.	In place – Yvonne Akinmodun

	Vacancies are addressed speedily, and any needed changes to ways of working or backfill arrangements receive immediate attention.	In place – Peter Thompson
Poor morale leading to decreased effectiveness and performance failures.	Engagement with the issue by managers through team and one-to-one meetings to obtain feedback and identify actions to be taken.	In place – Peter Thompson
	Implementation of staff survey outcomes, followed up after December 2016 staff conference (follow-up staff conference held on 10 July 2017). Task and Finish Groups submitted ideas for improvements, which are being included in the people strategy for 2017-2020.	Survey and staff conferences 2016 done – Rachel Hopkins Follow-up plan and communications in place – Peter Thompson
Particular staff changes could lead to specific knowledge loss and low performance.	CMG and managers prioritise work appropriately when workload peaks arise.	In place – Peter Thompson
	Policies and processes to treat staff fairly and consistently, particularly in scenarios where people are or could be 'at risk'.	In place – Peter Thompson
Insufficient Register team resource to deal properly with OTR enquiries.	The team is now at full capacity (headcount) and this risk is reducing over time as the new member of staff gets up to speed.	In place – Nick Jones
Increased workload either because work takes longer than expected or reactive diversions arise.	Careful planning and prioritisation of both business plan work and business flow through our Committees. Regular oversight by CMG – standing item on planning and resources.	In place – Paula Robinson
	Oversight of projects by both Programme Board and CMG, to ensure that projects end through due process (or closed, if necessary).	In place – Paula Robinson
	Learning from Agile methodology to ensure we always have a clear 'definition of done' in place, and that we record when products/outputs have met the 'done' criteria and are deemed complete.	Partially in place – agile approach to be brought into project processes under new project governance framework – Paula Robinson

	Early emphasis on team-level service delivery planning for the next business year, with active involvement of team members. CMG will continue to review planning and delivery.	In place – Paula Robinson
	Planning and prioritising data submission project delivery, and therefore strategy delivery, within our limited resources.	In place until project ends (Autumn 2017) – Paula Robinson
Possible future increase in capacity and capability needed to process mitochondrial donation applications.	Starting to be considered now, but will not be known for sure until later, so no controls can yet be put in place. Only one clinic licensed to provide these treatments, applications unlikely to be many at first. New licensing processes for mitochondrial donation are in place (decision trees etc). One Licence Committee variation agreed, with first Statutory Approvals Committee decision at August 2017 meeting.	Issue for further consideration – Juliet Tizzard
Technical issues with our communications systems since our office move in 2016. This leads to poor service (missed calls, poor quality Skype meetings), reputational impacts, additional costs (meetings having to be held externally), and potentially to complaints.	IT team working to identify and resolve the issues, with staff encouraged to continue to send support tickets. External expert commissioned to assist and the system has subsequently displayed improvements. Continued use of external venues with appropriate facilities. A project is underway to implement a new switchboard, this will be in place from November 2017 and may prevent some of the Skype issues. The Director cannot be assured that the mitigations in place have been comprehensively effective. The newly appointed CIO will give this day to day attention and will therefore be proactively managing this risk ongoing, from September 2017.	In progress – Nick Jones
Risk interdependencies (ALBs / DH)	**Control arrangements**	**Owner**
Government/DH: The government may implement further cuts across all ALBs, resulting in further staffing reductions. This would lead to the HFEA having to reduce its workload in some way.	We were proactive in reducing headcount and other costs to minimal levels over a number of years. We have also been reviewed extensively (including the McCracken review and Triennial Review).	In place – Peter Thompson

OC1: There is a risk that the implementation of organisational changes results in instability, loss of capability and capacity, and delays in the delivery of the strategy.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	4	16 – High	**3**	**3**	**9 - Medium**
Tolerance threshold:					**9 - Medium**

Risk area	**Risk owner**	**Links to which strategic objectives?**	**Trend**
Organisational change OC1: Change-related instability	Peter Thompson, Chief Executive	Whole strategy	⇧⇔⇔⇔ (Added in February 2017)

Commentary
At tolerance. For some months, this risk was above tolerance and its impact was closely related to the C1, Capability risk. However, as at November, almost all of the agreed voluntary redundancies have taken place and most of the recruitment is complete. Taken together, we are now of the view that the organisational change programme has largely been completed and that the associated risk is now at tolerance. We will retain the risk until the remaining organisational changes are in place.

Causes / sources	**Mitigations**	**Timescale / owner**
The change period may lead to dips in morale, commitment, discretionary effort and goodwill. There are likely to be differential impacts as different changes affect different groups of staff at different times. Risks are to the delivery of current work, including IfQ, and possibly technical or business continuity risks.	Clear published process, with documentation.	In place – Peter Thompson
	Consultation, discussion and communication, with opportunity to comment, and being responsive and empathetic about staff concerns. Staff informed of likely developments and next steps and, when applicable, of personal role impacts and choices.	Completed – Peter Thompson
	Relatively short timeline for decision making, so that uncertainty does not linger.	In place – Peter Thompson
	HR policies and processes are in place to enable us to manage any individual situations that arise.	In place – Yvonne Akinmodun
	Employee assistance programme (EAP) support accessible by all.	In place – Peter Thompson

Organisational change combined with other pressures for particular teams could lead to specific areas of knowledge loss lasting some months (pending recruitment to fill any gaps).	Policies and processes to ensure we treat staff fairly and consistently, particularly those 'at risk'. We will seek to slot staff who are at risk into other roles (suitable alternative employment).	In place – Peter Thompson
	Well established recruitment processes, which can be followed quickly in the event of unplanned establishment leavers.	In place – Rachel Hopkins
	Good decision-making and risk management mechanisms in place. Knowledge retention via good records management practice, SOPs and documentation.	In place – Peter Thompson
Potential impact on our ability to complete IfQ on time.	Ability to use more contract staff if need be.	In place – Peter Thompson
Implementing the new structure involves significant additional work across several teams to embed it so that the benefits are realised. There will also be result in some internal churn.	Business plan discussions acknowledging that work in teams doing IfQ or organisational change should not be overloaded.	In place – Paula Robinson
	CMG able to change priorities or timescales if necessary, to ensure that change is managed well.	In place – Paula Robinson
	Organisational development activity will continue, including summer awayday (took place 10 July), to support new ways of working development. A leadership awayday is planned in November and another all staff day in January.	In place for 2017 – Yvonne Akinmodun
Additional pressure on SMT, HR and Heads, arising from the need to manage different impacts and responses in a sensitive way, while also implementing formal processes and continuing to ensure that work is delivered throughout the change period.	Recognition that change management requires extra attention and work, which can have knock-on effects on other planned work and on capacity overall. Ability to reprioritise other work if necessary.	In place – Peter Thompson
	Time being set aside by managers to discuss the changes with staff as needed, with messaging about change repeated via different channels to ensure that communications are received and understood.	In place – Peter Thompson
	SMT/CMG additional informal meetings arranged to enable mutual support of managers, to help people retain personal resilience and be better able to support their teams.	In place – Paula Robinson
Level of service to Authority members may suffer while the changes are implemented, negatively impacting on the relationship between staff and members.	Communicate the changes clearly to Authority members so that they understand when staff are particularly under pressure, and that they will have reduced capacity. Inform Members when staff are new in post, to understand that those staff need the opportunity to learn and to get up to speed.	In place, with some implementation ongoing – Peter Thompson

Once the changes have been implemented, a number of staff will simultaneously be new in post. This carries a higher than normal risk of internal incidents and timeline slippages while people learn and teams adapt.	Recognition that a settling in period where staff are inducted and learn, and teams develop new ways of working is necessary. Formal training and development provided where required. Knowledge management via records management and documentation.	To be implemented, Yvonne Akinmodun will review onboarding methods – Peter Thompson
Bedding down the new structure will necessarily involve some team building time, developing new processes, staff away days to discuss new ways of working, etc. This will be challenging given small organisational capacity and ongoing delivery of business as usual.	Change management will be prioritised, where possible, so that bedding down occurs and is effective, and does not take an unduly long time.	To be implemented – Peter Thompson
	Continuing programme of leadership development for Heads and SMT.	Development day planned in November – Yvonne Akinmodun
The new model may not achieve the desired benefits, or transition to the new model could take too long, with staff losing faith in the model.	The model will be kept under review following implementation to ensure it yields the intended benefits.	Being planned – to occur beginning of 2018/19 business year – Peter Thompson
Risk interdependencies (ALBs / DH)	**Control arrangements**	**Owner**
-		

CS1: There is a risk that the HFEA has unsuspected system vulnerabilities that could be exploited, jeopardising sensitive information and involving significant cost to resolve.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
5	4	20 – Very high	**3**	**2**	**6 - Medium**
Tolerance threshold:					**6 - Medium**

Risk area	Risk owner	Links to which strategic objectives?	Trend
Cyber security CS1: Security and infrastructure weaknesses	Nick Jones, Director of Compliance and Information	Whole strategy	-⇔⇔⇔ (added in April 2017)

Commentary
At tolerance. The cyber-security event earlier in 2017, affecting the NHS and other organisations demonstrates that there is no room for complacency. However recent audits and our own assessments indicate that the HFEA is well protected. We were not affected by the 2017 incident.

Causes / sources	Mitigations	Timescale / owner
Insufficient governance or board oversight of cyber security risks (relating to awareness of exposure, capability and resource, independent review and testing, incident preparedness, external linkages to learn from others).	AGC receives regular information on cyber-security and associated internal audit reports. Internal audit report (2017) gave a 'moderate' rating, and recommendations are being actioned. Detailed information on our security arrangements is available in other documents. A business continuity plan is in place.	In place - Nick Jones/Dan Howard
Recent system infrastructure changes open up potential attack surfaces or new vulnerabilities. Our relationship with clinics is now more digital than ever before, and patient data or clinic information could therefore be exposed to attack.	All key IfQ products were subject to external expert advice and penetration testing, with recommendations implemented.	In place - Nick Jones/Dan Howard
	A security consultant provided advice throughout IfQ. At the end of the programme, we have received documented assurance of security and the steps necessary to maintain that security at a high level. Penetration testing for the portal and website (completed and passed).	In place – Dan Howard

	Ongoing security advice is in place for the development of the new data submission systems.	
We could become more dependent on external advice and support, with the risk that we cannot identify or fix problems quickly.	Budget available to commission external support when needed.	In place – Nick Jones
Confidentiality breach of Register data.	Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality. We know we need to refresh this obligation. Secure working arrangements for Register team, including when working at home.	In place, but corporate oversight of completion of security training is needed, this is being reviewed – Peter Thompson
Loss of Register or other data by staff or through lack of encryption.	Robust information security arrangements, in line with the Information Governance Toolkit, including a security policy for staff, secure and confidential storage of and limited access to Register information, and stringent data encryption standards. CIO will review these arrangements and can do so alongside a review of the arrangements for implementing the new GDPR requirements.	In place – Dan Howard
Register or other data (electronic or paper) becomes corrupted or lost.	Back-ups and warehouse in place to ensure data cannot be lost. Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality. As above, this needs refreshing.	In place but needs review – Nick Jones/ Dan Howard
Infrastructure turns out to be insecure, or we lose connection and cannot access our data.	IT strategy agreed, including a thorough investigation prior to the move to the Cloud, with security and reliability factors considered.	In place – Dan Howard
	Deliberate internal damage to infrastructure, or data, is controlled for through off-site back-ups and the fact that any malicious tampering would be a criminal act.	In place – Nick Jones
Business continuity issue (whether caused by cyber-attack or an event affecting access to Spring Gardens).	Business continuity plan and staff site in place. Improved testing of the BCP information cascade to all staff was undertaken in September 2017 as well as a tabletop test and testing with Authority members. New technology options need to be further explored, to enable us to restore critical on premise systems into a cloud environment if our premises become unavailable for a period.	In place and ongoing – Nick Jones Update done Dave Moysen (former Head of IT) – September 2016

	Records management systems to be reviewed in 2017/18. During an outage, staff cannot access TRIM, our current records management system. As above, we need to consider this in relation to GDPR project.	A revised BCP will be considered by CMG in November.
Poor records management or failure of the document management system.	A comprehensive review of our records management practices and document management system (TRIM) will be conducted in 2018/19, following planned organisational changes and the conclusion of IfQ.	To follow in 2018/19 business year – Peter Thompson
Cloud-related risks.	Detailed controls set out in 2017 internal audit report on this area. We have in place remote access for users, appropriate security controls, supply chain security measures, appropriate terms and conditions with Microsoft Azure, Microsoft ISO 27018 certification for cloud privacy, GCloud certification compliance by Azure, a permission matrix and password policy, a web configuration limiting the service to 20 requests at any one time, good physical and logical security in Azure, good back-up options for SQL databases on Azure, and other measures.	In place – Nick Jones
Risk interdependencies (ALBs / DH)	**Control arrangements**	**Owner**
None. Cyber-security is an 'in-common' risk across the Department and its ALBs.		

LC1: There is a risk that the HFEA is legally challenged in such a way that resources are significantly diverted from strategic delivery.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
5	5	25 – Very high	**3**	**4**	**12 - High**
Tolerance threshold:					**12 - High**

Risk area	Risk owner	Links to which strategic objectives?	Trend
Legal challenge LC 1: Resource diversion	Peter Thompson, Chief Executive	Safe, ethical effective treatment: Ensure that all clinics provide consistently high quality and safe treatment	⇧⇔⇩⇔

Commentary
At tolerance. The judgment on consent to legal parenthood in 2015 and subsequent cases, which include cases where errors have been made as recently as 2016/17, have administrative and policy consequences for the HFEA, and potentially reputational consequences too if we are criticised in judgments. The number of new and upcoming cases has reduced, however, recent cases suggest that learning has not been embedded in every clinic. This raises the question of whether further guidance or training is required in clinics. The most recent judgment is somewhat critical of how the HFEA chose to address certain issues and the guidance it provided to clinics. A judicial review hearing of one discrete element of the IfQ CaFC project was held in December 2016 and January 2017. The HFEA won this case. A decision by the Court of Appeal on whether permission to appeal will be granted is still awaited. This is entirely in the hands of the Court as far as timescales go. A licensing matter was considered by the Appeals Committee in October. The matter was settled by way of consent and having disposed of the appeal the judicial review claim which had been launched concurrently with the appeal became redundant and will be withdrawn. Following the consent order, the executive will be undertaking a piece of work looking at options for the regulation and inspection of groups of clinics.

Causes / sources	Mitigations	Timescale / owner
Assisted reproduction is complex and controversial and the Act and regulations are not beyond interpretation, leading to a need for court decisions.	Panel of legal advisors at our disposal for advice, as well as in-house Head of Legal.	In place – Peter Thompson
	Evidence-based and transparent policy-making and horizon scanning processes.	In place – Hannah Verdin

	Case by case decisions regarding what to argue in court cases, so as to clarify the position.	In place – Peter Thompson
Decisions or our decision-making processes may be contested. Policy changes may also be used as a basis for challenge (Licensing appeals and/or JRs). Note: New guide to licensing and inspection rating on CaFC may mean that more clinics make representations against licensing decisions.	Panel of legal advisors in place, as above.	In place – Peter Thompson
	Maintaining, keeping up to date and publishing licensing SOPs, committee decision trees etc. to ensure we take decisions well. Consistent decision making at licence committees supported by effective tools for committees. Standard licensing pack distributed to members/advisers (refreshed in April 2015).	In place, further work underway on licensing SOPs – Paula Robinson
	Well-evidenced recommendations in inspection reports.	In place – Sharon Fensome-Rimmer
Moving to a bolder strategic stance, eg on add ons or value for money, could result in claims that we are adversely affecting some clinics' business model or acting beyond our powers. Any changes could be perceived as a threat – not necessarily ultimately resulting in legal action, but still entailing diversion of effort.	Risks considered whenever a new approach or policy is being developed. Business impact target assessments carried out whenever a regulatory change is likely to have a cost consequence for clinics. Stakeholder involvement and communications in place to ensure that clinics can feed in views before decisions are taken, and that there is awareness and buy-in in advance of any changes. Major changes are consulted on widely.	In place – Juliet Tizzard
Subjectivity of judgments means we often cannot know which way a ruling will go, and the extent to which costs and other resource demands may result from a case.	Scenario planning is undertaken at the initiation of any likely action.	In place – Peter Thompson
Legal proceedings can be lengthy and resource draining.	Panel in place, as above, enabling us to outsource some elements of the work.	In place – Peter Thompson
	Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise work should this become necessary.	In place – Peter Thompson
Adverse judgments requiring us to alter or intensify our processes, sometimes more than once.	Licensing SOPs being improved and updated, committee decision trees in place.	In progress and in place – Paula Robinson
HFEA process failings could create or contribute to legal	Licensing SOPs being improved and updated, committee decision trees in place.	In progress and in place –

challenges, or weaken cases that are otherwise sound, or generate additional regulatory sanctions activity (eg, legal parenthood consent).		Paula Robinson
	Up to date compliance and enforcement policy and related procedures.	In place – Nick Jones / Sharon Fensome-Rimmer
	Seeking robust assurance from the sector regarding parenthood consent issues, and detailed plan to address identified cases and anomalies.	In progress and ongoing – Nick Jones
Risk interdependencies (ALBs / DH)	**Control arrangements**	**Owner**
DH: HFEA could face unexpected high legal costs or damages which it could not fund.	If this risk was to become an issue then discussion with the Department of Health would need to take place regarding possible cover for any extraordinary costs, since it is not possible for the HFEA to insure itself against such an eventuality, and not reasonable for the HFEA's small budget to include a large legal contingency. This is therefore an accepted, rather than mitigated risk. It is also an interdependent risk because DH would be involved in resolving it.	In place – Peter Thompson
DH: Legislative interdependency.	Our regular communications channels with the Department would ensure we were aware of any planned change at the earliest stage. Joint working arrangements would then be put in place as needed, depending on the scale of the change. If necessary, this would include agreeing any associated implementation budget. The Department are aware of the complexity of our Act and the fact that aspects of it are open to interpretation, sometimes leading to challenge. Sign-off for key documents such as the Code of Practice in place.	In place – Peter Thompson

RE1: There is a risk that planned enhancements to our regulatory effectiveness are not realised, in the event that we are unable to make use of our improved data and intelligence to ensure high quality care.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	4	16	**2**	**3**	**6 – Medium**
Tolerance threshold:					**6 - Medium**

Risk area	**Risk owner**	**Links to which strategic objectives?**	**Trend**
Regulatory effective-ness RE 1: Inability to translate data into quality	Nick Jones, Director of Compliance and Information	Improving standards through intelligence: use our data and feedback from patients to provide a sharper focus in our regulatory work and improve the information we produce	-⇔⇔⇔ (added in May 2017)

Commentary
At tolerance. Resource strains, reflected elsewhere in this risk register, have at times affected our ability to progress the data submission project and migration activities.

Causes / sources	**Mitigations**	**Timescale / owner**
IfQ has taken longer than planned, and there will be some ongoing development work needed.	The data submission project is well planned and under way after initial delays. Data cleansing is being done to improve the quality of the data in the Register. The new Register has been designed to be easier to extract data from for analytical purposes.	Completion of data submission project March 2018 – Nick Jones
Risks associated with data migration to new structure, together with records accuracy and data integrity issues.	IfQ programme groundwork focused on current state of Register. Extensive planning in place, including detailed research and migration strategy.	In place – Nick Jones/Dan Howard
We could later discover a barrier to meeting a new reporting need, or find that an unanticipated level of accuracy is required, involving data or fields which we do not currently focus on or deem critical for accuracy.	IfQ planning work incorporated consideration of fields and reporting needs were agreed. Decisions about the required data quality for each field were 'future proofed' as much as possible through engagement with stakeholders to anticipate future needs and build these into the design.	In place – Nick Jones

Reliability of existing infrastructure systems – (eg, Register, EDI, network, backups).	Maintenance of desktop, network, backups, etc. core part of IT business as usual delivery. Though there has been a reduction in desktop support, there are mitigations in place to ensure day to day support, however, we are running a risk due to lack of resilience.	In place – Dan Howard
The new Intelligence team is critical to the new model, and needs to draft an information strategy before it will be possible to use the data for regulatory and other purposes.	Head of Intelligence started in September. The development of the team, and the information strategy, will follow. An Information Strategy will be produced by the new Intelligence team, to ensure that data analysis and associated internal mechanisms are in place.	In place – Juliet Tizzard To be developed – Caylin Joski-Jethi
Benefits of IfQ not maximised and internalised into ways of working.	During IfQ delivery, product owners were in place, and a communications plan. The changes were developed involving the right staff expertise (as well as contractors) and part of the purpose of this was to ensure that the changes are culturally embraced and embedded into new ways of working. The data submission project has been delayed but is now making good progress. Inevitably, this will impact the timeframe of benefit realisation delivery on a range of fronts.	In place (from June 2015) – Nick Jones
Insufficient capability and capacity in the Compliance team to enable them to act promptly in response to the additional data that will be available.	Largely experienced inspection team. Business support is now at full complement. Recruitment process underway for final additions to inspection team. Although not all systems are in place in relation to providing data to inspectors eg, patient feedback, workarounds are in place which are working.	In place – Nick Jones
Organisational change could take too much time to embed, the necessary culture shift may not be achieved, or new structure not accepted, with an accompanying risk to our ability to make full use of our data and intelligence as intended by the new organisational model.	Organisational re-shaping in progress, to set the right staffing structure and capabilities in place to ensure we can realise IfQ's benefits. This includes the establishment of an Intelligence team.	New organisational model in place – Peter Thompson
Regulatory monitoring may be disrupted if Electronic Patient Record System (EPRS) providers are not able to submit data to the new register structure until their software has been updated.	Earlier agreements to extend part of 'IfQ' delivery help to address this risk by extending the release date for the EDI replacement (Data submission project). Mitigation plans for this risk have been agreed as part of planning.	Mitigation in place - Nick Jones
Monitoring failure.	Outstanding recommendations from inspection reports are tracked and followed up by the team.	In place – Sharon

		Fensome-Rimmer
Data accuracy in Register submissions.	Data migration efforts are being privileged over data quality currently (Aug 2017) this is an accepted risk. The Register team has introduced a triage system to deal with clinic queries systematically. Completion of verification processes, steps in the OTR process, regular audit alongside inspections.	In place – Nick Jones
	Audit programme to check information provision and accuracy.	In place – Nick Jones
	There are data accuracy requirements for different fields as part of migration planning, and will put in place more efficient processes.	In place – Nick Jones
	If subsequent work or data submissions reveal an unpreventable earlier inaccuracy (or an error), we explain this transparently to the recipient of the information, so it is clear to them what the position is and why this differs from the earlier provided data.	In place – Nick Jones
	Data verification work (February 2017) in preparation for Register migration has improved overall data accuracy, and the exercise included tailored support for individual clinics that were struggling.	In place – Nick Jones
Excessive demand on systems and over-reliance on a few key expert individuals – request overload – leading to errors	PQs, FOIs and OTRs have dedicated expert staff/teams to deal with them. We have systems for checking consistency of answers and the flexibility to push PQ deadlines if necessary. FOI requests are refused when there are grounds for this. PQ SOP revised and log created, to be maintained by Committee and Information Officer/Scientific Policy Manager.	In place – Juliet Tizzard / Caylin Joski-Jethi
Insufficient understanding of our data and/or of the topic or question, leading to misinterpretation or error.	As above – expert staff with the appropriate knowledge and understanding in place.	In place – Juliet Tizzard / Caylin Joski-Jethi
Risk that we do not get enough patient feedback to be useful / usable as soft intelligence for use in regulatory and other processes, or to give feedback of value to clinics.	Communications strategy in place, including more patient feedback. Part of the information strategy will focus on making best use of the information gleaned from patients, and converting our mix of soft and hard data into real outcomes and improvements.	In place and to be developed – Juliet Tizzard
Risk interdependencies (ALBs / DH)	**Control arrangements**	**Owner**

None	-	-

ME1: There is a risk that patients and our other stakeholders do not receive the right information and guidance, so we miss opportunities to bring about positive change.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
3	4	12 High	**2**	**3**	**6 - Medium**
Tolerance threshold:					**6 - Medium**

Risk area	Risk owner	Links to which strategic objectives?	Trend
Effective communications ME1: Messaging, engagement and information provision	Juliet Tizzard Director of Strategy and Corporate Affairs	Safe, ethical effective treatment: Publish clear information so that patients understand treatments and treatment add ons and feel prepared Safe, ethical effective treatment: Engender high quality research and responsible innovation in clinics. Consistent outcomes and support: Increase consistency in treatment standards, outcomes, value for money and support for donors and patients.	-⇔⇔⇔ (added May 2017)

Commentary
At tolerance.

Causes / sources	Mitigations	Timescale / owner
Our ability to provide patient information via the website or CaFC could be compromised by a website failure.	We have good cyber-security measures to prevent website attacks, and the new content management system is more reliable than the old one.	In place – Juliet Tizzard
Some of our strategy relies on persuading clinics to do things better. This is harder to put across effectively, or to achieve firm outcomes from.	Communications strategy in place, including social media and other channels as well as making full use of our new website. Stakeholder meetings with the sector in place to help us to underline key campaign messages.	In place – Juliet Tizzard
Our information does not meet the needs or expectations of our audience.	Ongoing user testing and feedback about the information on the website allows us to properly understand user needs. We have internal processes in place which meet the Information Standard.	In place – Juliet Tizzard
We are not able to reach the right people with the right message at the right time.	Partnering with NHS Choices to get information to patients early in their fertility journey. Planning for campaigns and projects includes consideration of communications channels.	In place and developing – Jo Triggs

	Extended use of social media to get to the right audiences.	
Some information will be derived from data, so depends on risk above being controlled.	See controls listed in RE1, above.	
Risk interdependencies (ALBs / DH)	**Control arrangements**	**Owner**
NHS Choices site and our site contain links to one another.	We maintain a relationship with the NHS Choices team.	

Reviews and revisions

CMG – September 2017 meeting (06/09/2017)

CMG reviewed the new risk register and made the following points in discussion:

- CMG discussed the Capability risk (C1) in detail and acknowledged that the main source of risk relating to knowledge and capability is the current period of turnover. The organisational change programme has had an impact on the Compliance and Information directorate in particular and on top of this, non-organisational change related turnover is affecting teams across the organisation. CMG acknowledged that knowledge and capacity gaps because of turnover were not straightforward to deal with. If internal promotion and maternity leave are included, one third of staff have spent less than 12 months in their current posts. CMG acknowledged the need to manage the bedding in of new staff effectively and agreed to look at how to manage this to mitigate the risk, including staff development and induction. CMG agreed that in the light of the changes to this risk and the period of organisational change and bedding in, the inherent rating for C1 had risen. The residual risk was also raised to a high score of 16 which is above tolerance.
- CMG discussed the organisational change risk and acknowledged that though it relates to the capability risk, the organisational change was planned for so it was integrally less risky. Members discussed when the review of the new organisational model would be done and agreed that this should be towards the beginning of the 2018/19 business year, when the effectiveness of the model could be properly assessed. An Authority paper will be required, probably to the May Authority.
- CMG discussed the cyber security risk and acknowledged the need to provide further assurance about the effectiveness of the business continuity plan. A further test is needed and this will be done in September. CMG also acknowledged that following the departure of the Head of IT, the responsibility for ensuring staff have undertaken mandatory information security training will lie with line managers, to ensure through the PDP process that all staff complete this training annually on Civil Service Learning.
- CMG agreed to amend the wording of the regulatory effectiveness (RE1) and effective communications (ME1) risks so that they better capture that they are opportunity risks.
- CMG acknowledged the concerns of AGC at its last meeting in relation to ongoing technical issues affecting communications. CMG noted that this was continuing to be investigated and external committee meetings will not be returned in house until all technical issues have been satisfactorily resolved. CMG acknowledged that issues relating to Skype will be managed day to day by the newly appointed Chief Information Officer. A review of the switchboard system (in progress) should also have a positive effect on telephone issues.

AGC feedback – October 2017 meeting (03/010/2017)

AGC made the following points when reviewing the Register:

- The Committee discussed risk tolerances and heard how the desired tolerance level is reached for the individual risks. The Committee commended the quality of the Strategic Risk Register, noting that it would be useful for further explanation of the tolerance levels to be added. The concepts of risk tolerance and risk appetite should also be explained in the HFEA's risk policy.
- The Committee felt there is currently insufficient governance with regards to cyber security. It asked the executive to ensure that the Authority member responsible for cyber security is informed of any issues and that all staff receive cyber security training.

Following the AGC meeting, we have commenced a review of the risk policy and this will be reconsidered at CMG risk meeting on 22 November. We have also ensured that there is more discussion about how above tolerance risks are being managed in the summary of each risk.

In relation to AGC's comments regarding cyber security, the CIO is ensuring that all staff have completed their cyber security training by end December 2017. The executive will raise any cyber security issues to the Authority member responsible and ensure that she is updated on developments in this area.

Criteria for inclusion of risks

- Whether the risk results in a potentially serious impact on delivery of the HFEA's strategy or purpose.
- Whether it is possible for the HFEA to do anything to control the risk (so external risks such as weather events are not included).

Rank

The risk summary is arranged in rank order according to the severity of the current residual risk score.

Risk trend

The risk trend shows whether the threat has increased or decreased recently. The direction of the arrow indicates whether the risk is: Stable ⇔ , Rising ⇧ or Reducing ⇩.

Risk scoring system

We use the five-point rating system when assigning a rating to the likelihood and impact of individual risks:

Likelihood:	1=Very unlikely	2=Unlikely	3=Possible	4=Likely	5=Almost certain
Impact:	1=Insignificant	2=Minor	3=Moderate	4=Major	5=Catastrophic

Risk scoring matrix

Impact	1. Rare (≤10%)	2. Unlikely (11%-33%)	3. Possible (34%-67%)	4. Likely (68%-89%)	5. Almost Certain (≥90%)
5.Very high	5 Medium	10 Medium	15 High	20 Very High	25 Very High
4. High	4 Low	8 Medium	12 High	16 High	20 Very High
3. Medium	3 Low	6 Medium	9 Medium	12 High	15 High
2. Low	2 Very Low	4 Low	6 Medium	8 Medium	10 Medium
1. Very Low	1 Very Low	2 Very Low	3 Low	4 Low	5 Medium
	Likelihood				

Risk Score = Impact x Likelihood

Assessing inherent risk

Inherent risk is usually defined as ‘the exposure arising from a specific risk before any action has been taken to manage it’. This can be taken to mean ‘if no controls at all are in place’. However, in reality the very existence of an organisational infrastructure and associated general functions, systems and processes introduces some element of control, even if no other mitigating action were ever taken, and even with no particular risks in mind. Therefore, for our estimation of inherent risk to be meaningful, we define inherent risk as:

‘the exposure arising from a specific risk before any additional action has been taken to manage it, over and above pre-existing ongoing organisational systems and processes.’

System-wide risk interdependencies

As of April 2017, we explicitly consider whether any HFEA strategic risks or controls have a potential impact for, or interdependency with, the Department or any other ALBs. A distinct section to record any such interdependencies beneath each risk has been added to the risk register, so as to be sure we identify and manage risk interdepencies in collaboration with relevant other bodies, and so that we can report easily and transparently on such interdependencies to DH or auditors as required.

Report on the activity of the Register Research Panel

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

Details:

Meeting	Authority
Agenda item	12
Paper number	HFEA (15/11/17) 860
Meeting date	15 November 2017
Author	Caylin Joski-Jethi (Head of Intelligence)

Output:

For information or decision?	For information
Recommendation	The Authority is asked to: • Note the report of the Register Research Panel activities since January 2016. • Approve the suggested ways in which the profile of the Register Research Panel can be increased to extract greater value from the data we hold
Resource implications	None
Implementation date	
Communication(s)	
Organisational risk	☒ Low ☐ Medium ☐ High
Annexes	Annex 1: Register Research Panel applications since January 2016 Annex 2: All papers published using Register Research Panel authorisations Annex 3: Papers published using anonymised Register data since January 2016

1. Introduction

1.1. The HFEA holds the largest register of fertility treatment data in the world. Since 2010, world class research has been carried out using our data, either alone or by linking to other datasets. There are two main types of data which can be used:

- Anonymised data, where no identifiers are present and some of the information is banded, or obscured, to protect patient privacy, and
- Patient-identifying data, where the data may be very detailed, or contain actual identifiers (such as name, and date of birth) allowing the records to be linked to another database.

1.2. Prior to October 2009, the HFEA was not able to disclose identifying information for research as patient consent was not sought. Since October 2009, patients who register for fertility treatment are asked whether they consent to their information being included in studies that need patient identifiers.

1.3. To ensure that information collected and held by the HFEA prior to 2009 could be made available for high quality research, Parliament introduced the Human Fertilisation and Embryology (disclosure of information for research purposes) regulations 2010 ('the 2010 regulations'), allowing the release of this data in some circumstances under strict ethical oversight.

1.4. The HFEA Standing Orders April 2016 set out that Authority is the Oversight Committee to fulfil the functions set out in the 2010 regulations, and delegates to the Register Research Panel the power to:

- authorise access to Register data for the purposes of medical or non-medical research, and
- deny, suspend, revoke, vary or impose conditions upon authorisation to access Register data

1.5. To enable the Authority ('the Oversight Committee') to discharge its functions, it considers an overview report submitted by the Register Research Panel.

1.6. This paper has two related aims. First it provides an overview of the approvals made by the Register Research Panel since the last paper to the Authority in January 2016, the progress of all authorised research studies, and the results of studies conducted using our anonymised dataset. Second, it suggests ways in which the profile of the Register Research Panel can be increased in the context of wider changes we are making to how we use the data we hold.

2. The impact of Register research

2.1. This paper details all studies which have been published from Register Research Panel authorisations, or those using our anonymised Register data, published on our archived website. All published studies resulting from Register

Research Panel authorisations were deemed high quality and published in peer-reviewed journals, demonstrating that they have potential to influence society (such as creating a greater awareness of the safety of IVF treatment) or shaping academic progress (such as identifying potential factors which might influence the effectiveness of fertility treatment). One recently approved study seeks to determine the economic impact of IVF treatment which will help inform the scope and direction of current debates around the commissioning, and provision of, fertility treatment in the UK.

2.2. These studies contribute to our, the public, and the research community's understanding of fertility treatment through:

- Influencing the development of policy, practice and service provision and informing ways to change behaviour (e.g. informing CCG commissioning discussions based on cumulative success rates)
- Reframing our conceptual perspective on issues and debates (e.g. exploring the long-term impact on live birth rates for women who have a miscarriage during their first cycle)
- Building capacity and technical expertise in the research and innovation sectors by creating new knowledge and identifying future areas of research.

2.3. All studies contribute to ensuring patients can make informed and ethnical decisions about treatment and associated risks, as long as we communicate these effectively with patients and the public.

2.4. Annex 1 contains details of applications made since the last Register Research Panel report to the Oversight Committee (in January 2016).

2.5. Due to the broader strategic aim of this report of Register Research Panel activity, Annex 2 contains details of all publications which have resulted from Register Research Panel authorisations (regardless of previous reports to the Oversight Committee), and highlights newly published studies for the Committee.

2.6. Annex 3 contains details of studies published using the anonymised Register since the last report to the Oversight Committee. These provide valuable insights using HFEA data that has been made available for research.

2.7. The studies detailed within Annex 2 and Annex 3 of this report have been summarised below and include all studies using Register Research Panel authorisations (studies 4 to 6 were released since the last report to Authority) and studies published using anonymised Register data since the last report to Authority.

No.	Study	Finding
1	Cancer risk in children born after IVF/ICSI	No overall increased cancer risk
2	Cancer risk and mortality in women after IVF	Possible increased risk of ovarian cancer
3	Effect of ethnicity on the success of assisted reproduction technologies	Lower birth rate for ethnic groups
4	Predicting the chances of a live birth after one or more complete cycles of in vitro fertilisation: population based study of linked cycle data from 113 873 women	Predictors of live birth include: women's age, duration of infertility, number of eggs collected, cryopreservation of embryos and stage of embryos transferred
5	Cumulative live birth rates after one or more complete cycles of IVF: a population-based study of linked cycle data from 178 898 women	Chance of a live birth after three complete cycles of IVF was 42.3%
6	Cumulative live birth rates following miscarriage in an initial complete cycle of IVF: a retrospective cohort study of 112 549 women	Women who had miscarried or had a live birth in their first complete cycle had a higher chance of live birth than those who had no pregnancies
7	Pre-term birth and low birth weight following preimplantation genetic diagnosis: analysis of 88 010 singleton live births following PGD and IVF cycles (anonymised register project)	No increased risk of adverse perinatal outcomes for PGD
8	Reproductive outcome following pre-implantation genetic diagnosis (PGD) in the UK (anonymised register project)	The declining rate of congenital abnormalities suggests PGD is a safe alternative to pre-natal diagnosis
9	Perinatal outcomes after gestational surrogacy versus autologous IVF: analysis of national data (anonymised register project)	The incidence of high birth weight was significantly higher after gestational surrogacy compared with fresh autologous IVF; no difference for frozen
10	High-risk of preterm birth and low birth weight after oocyte donation IVF: analysis of 133,785 live births (anonymised register project)	Higher risk of low birth weight (LBW) for donated embryos compared to IVF singletons; significantly higher risk of pre-term birth (PTB) for donated embryos compared with autologous IVF multiple births

3. Using intelligence to improve standards

3.1. In our strategy for 2017-2020, we have committed to deliver high quality care for everyone affected by fertility treatment.

3.2. The Intelligence Team was created to improve standards through intelligence and the Head of Intelligence has worked closely with colleagues to develop early thoughts on the direction of this team's strategy, including its scope and principles.

3.3. As a department, the Intelligence team aims to provide:

- Data services: facilitating availability of and access to information through a range of tools and services

- Analytical services: support to analyse information effectively
- Statistical services: develop and publish national and official statistics, and release additional data and publications

3.4. The Intelligence team will work with colleagues across the HFEA under the following principles:

- Innovation for impact: we will pursue new creative ideas that have the potential to generate real impact for society and the sector
- 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 society as a whole
- Targeted and accessible: we will ensure the information and services we provide are evidence-based, ensure more people receive high quality care and receive the information they need
- Collaborative: we will build strategic partnerships within, and external to, the HFEA to achieve our aim and share good practice promoting sector-wide improvement

3.5. The work of the Register Research Panel will be one feature of how we deliver these aims and values in the future because it can ensure research activity extracts more value from our data, maximises the impact of information within the Register, drives quality improvements for patients, and capitalises on recent system developments.

To do this, the Intelligence team will support dissemination, engagement and impact across a range of areas:

Fostering excellent research

3.6. We will give advice and guidance to researchers seeking to use out data for excellent research, using our website and responding to enquiries. We will make best use of our assets to ensure social researchers are aware of the information held in the Register and can access the anonymised Register for research, or have a clear process to follow for Register Research Panel authorisations.

Publication, dissemination and promotion

3.7. We will publish the outcomes of high quality research using the HFEA register through reports to the Authority, easy-to-read summaries on our website, and through social media updates. This will help us to connect with patients, researchers, the media, and the public to support knowledge exchange and promote innovation and developments that lead to safe, efficient and effective treatment for patients.

Reaching the public, patients and policymakers by working across disciplines

3.8. We will help researchers, patients, patient-advocate groups, policy makers and other stakeholders engage and interact on key policy questions, sharing

information across the organisation and through external publication, dissemination and promotion, and provide support and guidance to translate research into policy-focused output, such as working with the policy team to ensure any relevant information that should be provided to patients is included in the Code of Practice updates. This already happens to a large extent through the work of the Scientific and Clinical Advances Advisory Committee (SCAAC), but more could be done to join up the work between the Register Research Panel, SCAAC and external communications. We will seek to find solutions to complex problems through collaboration across internal HFEA departments and external stakeholders groups such as SCAAC and research organisations by ensuring knowledge is shared appropriately.

Research impact support

3.9. We will monitor and, where appropriate, support any impact emerging from HFEA register research. The core vehicles for this will be through annual reports using Register research data, annual reports on the work of the Register Research panel, and the work of SCAAC.

4. Scientific and Clinical Advances Advisory Committee

4.1. The Scientific and Clinical Advances Advisory Committee (SCAAC) is a subcommittee of the Authority. It meets three times a year to consider advances in science and clinical practice which are relevant to our work. We are seeking to improve the links between the Register Research Panel and SCAAC because there is scope for shared benefits, including:

- Joined up approaches to similar issues and more cost-effective solutions (e.g. the horizon scanning process)
- More effective policy decisions as more knowledge and expertise can be shared
- Having a role in supporting and championing the work of both areas of the organisation and help us to disseminate and report on findings.
- Some Members of SCAAC have made applications through the Register Research Panel and can provide valuable first hand feedback to improve the process

4.2. The results of all studies detailed in this document were presented to SCAAC in October 2017 and members discussed the value and means of engaging researchers in epidemiological research and the best way to facilitate this process without creating excessive administrative burdens upon the HFEA's resources.

4.3. Discussions included:

- An acknowledgement that this in an important stream of work and that SCAAC would like to be involved.

- SCAAC felt they could have more impact if there was a wider recognition and publication of the work that they do.
- Researchers who do not already work in the fertility sector, often have limited knowledge of the potential and availability of the HFEA's data that could be available for research.
- There is no area of the website for researchers or clinicians, which limits our ability to share information not primarily aimed at patients.
- The anonymised Register is a valuable tool which needs to be prioritised as a value-for-money way to deliver high quality research.
- Members of SCAAC reported that there are challenges in the register research process which include:
  - Low consent rates for some years (but also a lack of awareness that consent rates had significantly improved and were now around 70%).
  - Complicated, long, and expensive linkage processes.
  - A lack of clarity around the Register application and authorisation process.
- Research should be reviewed by SCAAC prior to publication on the website to ensure only high quality research is published (including both Register Research Panel authorised publications, and those making use of the anonymised Register).

5. Next steps

5.1. We hold the largest register of fertility treatment data in the world and have invested in IT infrastructure and a new organisational structure so that we can release the value held within this and achieve the aims set out in our 2017-2020 strategy. Register research holds a vital role in improving the quality of services and helping patients make informed decisions about their care.

5.2. The first year of the new structure will be focused on building up the function and developing our Intelligence strategy, whilst ensuring that the Register Research Panel continues to run smoothly, and building relationships with SCAAC and other stakeholders.

5.3. We have specific plans relating to increasing the impact of the Register Research Panel, which include to:

- Generating greater visibility around the publication of the Annual Register Research Panel update report on the HFEA website.
- Create a statistics area on the website to meet the needs of researchers and clinicians, which will include:
  - Anonymised Register
  - Clear information on the data and quality of information in the register (including consent rates post-2009)

  - Working with researchers to establish a clear process for Register research applicants
  - Information on how Register research informs policy through SCAAC
- Liaise with SCAAC about producing easy-to-read summaries of research outcomes for patients, clinics and the public for publication on our website.
- Develop an Intelligence Strategy which responds to the opportunities offered by Register research.

6. Summary and recommendations

6.1. It is recommended that the Authority in its role as the Oversight Committee:

- Notes the report of the Register Research Panel activities since January 2016.
- Approves the suggested ways in which the profile of the Register Research Panel can be increased to extract greater value from the data we hold.

7. Annex 1: Register research panel applications since January 2016

Prolonged effects of assisted reproductive technologies on the health of women and their children: a record linkage study for England (PEARL)1

7.1. The Panel received a new application from researchers at the National Perinatal Epidemiology Unit (NPEU) at the University of Oxford.

In general, most children born after the use of fertility treatment (such as IVF) are healthy. However, there is a slight increase in the number of children who are born early, have a low birthweight, and who have health or developmental problems. Less is known about the health of children born after fertility treatment as they grow up, as long-term follow-up studies are costly and time consuming. As a result, many studies are not big enough to detect small differences between the groups – which is important because the effects of fertility treatment on health may be subtle. More evidence is also needed about the long-term wellbeing of women who have had fertility treatment.

7.2. The study aims to:

- Find out the effect of fertility problems and fertility treatment on the health and development of ART children through to adolescence
- Look at the impact of successful fertility treatment on the health and wellbeing of women who underwent treatment
- Estimate the additional costs to the NHS (if any) of caring for women and their children after successful fertility treatment
- Explore how changes in the number of patients agreeing to allow information about their fertility treatment to be used in research affects the results of studies that use this information.

7.3. This study will link data from the HFEA Register, health records from GP practices across England held by the Clinical Practice Research Datalink (CPRD); and records of hospital care, from Hospital Episode Statistics already linked to CPRD data. The study already has provisional Research Ethics Committee (REC) and Confidentiality Advisory Group (CAG) approval.

7.4. The Panel was satisfied to give a provisional indication that it would grant access to the data and authorise the research proposal for two years from the date of submission of the full Research Ethics Committee and Confidentiality Group approval letters (received on 31/7/2017).

7.5. Proposed Impact: patients and public considering ART can receive appropriate and reliable information, explore the impact of consent rates on research validity and understand the long-term economic costs/benefits of ART.

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[1] Carson, C (2016). Prolonged Effects of ART: A Record Linkage study (PEARL). http://www.hra.nhs.uk/news/research-summaries/prolonged-effects-of-art-a-record-linkage-study-pearl/

Educational outcomes in children born after ART2

7.6. The panel received an application by Dr Alastair Sutcliffe of the Institute of Child Health of University College London Hospital.

The number of children born through ART is increasing year on year. One major concern for parents is whether their children are at higher risk of developing learning or behavioural problems. To date this question has not been adequately answered because existing studies have been small, and have not included adequate comparison groups.

7.7. The study aims to compare educational and behavioural outcomes in children born following ART with two comparison groups of naturally conceived children.

7.8. This study will link data from the HFEA Register and the National Pupil Database (NPD). The application has been reviewed recently by the HRA CAG who has given a provisionally positive opinion and approval has been given under regulations made under section 251 of the NHS Act. the data is already held by the applicant as a database, with data from the ONS linked to HFEA data.

7.9. The Panel was satisfied and gave provisional indication that it would grant access to the data and authorise the research proposal for the period to 31/05/2019.

7.10. Proposed Impact: patients and public considering ART can receive appropriate and reliable information, and any problems in children can be identified and managed early.

[2] Sutcliffe, A. G. (2017). Educational Outcomes in Children Born after ART. http://www.hra.nhs.uk/news/research-summaries/educational-outcomes-in-children-born-after-art/

8. Annex 2: All papers published using Register Research Panel authorisations

8.1. Due to the wider strategic role of this report, this Annex details all publications relating to Register Research Panel authorisations so that the context, challenges and potential value of changes to the way the Register Research Panel operates can be understood.

8.2. The approval of these studies was previously reported to the Authority; this is an update on their progress. The studies detailed in sections 8.10 to 8.17 have been published since the last report to the Oversight Committee.

Cancer risk in children born after IVF/ICSI (approved 2010)[3]

8.3. The results of this study were published in the New England Journal of Medicine in November 2013. The study found that there was no increase in the overall risk of cancer among children born after assisted conception. While there were increased risks of two rare types of cancer (hepatoblastoma and rhabdomyosarcoma) the absolute risks were small and these types of cancer have been linked to low birth weight.

8.4. Impact: This study won the Clinical Science Award at ESHRE 2013. It allows patients to make informed choices about embarking upon treatment.

Cancer risk and mortality in women after IVF (approved 2010)[4]

8.5. The results of this study were published in Fertility and Sterility in September 2015. The study found that the rates of breast and uterine cancer were no different to UK women as a whole, however an increased risk of ovarian cancer was observed in women who had ART. Most analyses of the dataset suggest that this increased risk was principally because of the nature of women needing these treatments in the first place not due to the hormone drug treatments themselves, however other findings (including the risk being highest in the first three years after receiving treatment and in younger women) leave open the possibility that ART might affect risk.

8.6. Although the lead researcher said there was a 'small possibility' that IVF could raise the risk of cancer, some British health experts said the new findings were serious enough to consider screening IVF patients at regular intervals and called for infertile women to be informed that their risk of ovarian cancer was higher than that of women who conceive naturally.

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[3] Williams, C. L., Bunch, K. J., Stiller, C. A., Murphy, M. F., Botting, B. J., Wallace, W. H., ... & Sutcliffe, A. G. (2013). Cancer risk among children born after assisted conception. N Engl J Med, 2013(369), 1819-1827, http://www.nejm.org/doi/full/10.1056/NEJMoa1301675

[4] Sutcliffe, Alastair & Williams, C.L. & Jones, M.E. & Swerdlow, A.J. & Davies, Melanie & Jacobs, I & Botting, B.J.. (2015). Ovarian tumor risk in women after Assisted Reproductive Therapy (ART); 2.2 million person years of observation in Great Britain. Fertility and Sterility. 104. e37. 10.1016/j.fertnstert.2015.07.112.

8.7. Impact: This study allows patients to make informed choices about embarking upon treatment, and could be used to inform post-treatment interventions to maintain patient safety.

Mortality and general health in children born after IVF (approved 2012)

8.8. The study, merged from two separate applications, has full approval from the Register Research Panel but is awaiting internal approval from NHS Digital (who are performing the matching, and have had a backlog recently) before matching can start.

Effect of ethnicity on the success of assisted reproduction technologies (approved 2012)[5]

8.9. The researchers published a paper based on this study in the British Journal of Obstetrics and Gynaecology in November 2013. The study shows that live birth rates, clinical pregnancy rates, and implantation rates following IVF treatment are significantly reduced in ethnic groups compared with white European women, which suggests that ethnicity is a major determinant of live birth following IVF treatment.

8.10. Impact: This study allows patients to be well informed about their realistic probabilities of a positive outcome with fertility treatment. Further studies and analysis for each ethnic group could help provide appropriate counselling to women from ethnic minority groups promoting safe and ethnical treatment.

Development and validation of statistical models to predict pregnancy outcomes following in-vitro fertilization (IVF) treatment (approved 2013)

8.11. This project has resulted in multiple publications, detailed below.

Predicting the chances of a live birth after one or more complete cycles of in vitro fertilisation: population based study of linked cycle data from 113 873 women[6]

8.12. This study was published in the BMJ in November 2016. The study developed a prediction model to estimate the chances of a live birth over multiple complete cycles of in vitro fertilisation (IVF) based on a couple's specific characteristics and treatment information. Key pre-treatment predictors of live birth were the woman's age and duration of infertility. Post-treatment predictors included number of eggs collected, cryopreservation of embryos, the woman's age, and stage of embryos transferred. This study provides an individualised estimate of a couple's cumulative chances of having a baby over a complete package of IVF both before treatment and after the first fresh embryo transfer.

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[5] Jayaprakasan, K., Pandian, D., Hopkisson, J., Campbell, B. K., & Maalouf, W. E. (2014). Effect of ethnicity on live birth rates after in vitro fertilisation or intracytoplasmic sperm injection treatment. BJOG: An International Journal of Obstetrics & Gynaecology, 121(3), 300-307, http://onlinelibrary.wiley.com/doi/10.1111/1471-0528.12504/pdf

[6] McLernon, D. J., Steyerberg, E. W., Te Velde, E. R., Lee, A. J., & Bhattacharya, S. (2016). Predicting the chances of a live birth after one or more complete cycles of in vitro fertilisation: population based study of linked cycle data from 113 873 women. bmj, 355, i5735., http://www.bmj.com/content/355/bmj.i5735

8.13. Impact: This resource may help couples plan their treatment and prepare emotionally and financially for their IVF journey, ensuring ethical and informed decision making.

Cumulative live birth rates after one or more complete cycles of IVF: a population-based study of linked cycle data from 178 898 women[7]

8.14. This study was published in Human Reproduction in March 2016. The study calculates the chance of a live birth following one or more linked complete cycles of IVF (including ICSI). The study showed that the chance of a live birth after three complete cycles of IVF was 42.3% for treatment commencing from 1999 to 2007.

8.15. The results demonstrate, at a national level, the chances of live birth in couples undergoing a number of complete (fresh and frozen) IVF cycles. Although most couples in the UK still do not receive three complete IVF cycles; assuming no barriers to continuation of IVF treatment, around 83% of women receiving IVF would achieve a live birth by the eighth complete cycle, similar to the natural live birth rate in a non-contraception practising population. The results support the call from NICE to develop consistent IVF policies based on three complete cycles.

8.16. Impact: The results provide additional insight on national policy and commissioning decisions, and help inform patient choice and expectations around undergoing treatment.

Cumulative live birth rates following miscarriage in an initial complete cycle of IVF: a retrospective cohort study of 112 549 women[8]

8.17. This study was published in Human Reproduction in September 2017, and shows that after two further complete cycles of IVF/ICSI, women who had miscarried or had a live birth in their first complete cycle had a higher chance of live birth (40.9% and 49.0%, respectively) than those who had no pregnancies (30.1%).

8.18. Impact: The findings provide reassurance to these couples who have a miscarriage in their first cycle as they consider their options for continuing treatment allowing them to make safe, ethical and informed decisions.

EpiHealth Outcomes Project: The effect of maternal age, embryo cryopreservation and culture on perinatal outcomes and child health (approved 2013)

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[7] McLernon, D. J., Maheshwari, A., Lee, A. J., & Bhattacharya, S. (2016). Cumulative live birth rates after one or more complete cycles of IVF: a population-based study of linked cycle data from 178 898 women. Human Reproduction, 31(3), 572-581, https://academic.oup.com/humrep/article/31/3/572/2384747/Cumulative-live-birth-rates-after-one-or-more

[8] Cameron, N. J., Bhattacharya, S., Bhattacharya, S., & McLernon, D. J. (2017). Cumulative live birth rates following miscarriage in an initial complete cycle of IVF: a retrospective cohort study of 112 549 women. Human Reproduction, 1-11, https://academic.oup.com/humrep/article-abstract/doi/10.1093/humrep/dex293/4157548/Cumulative-live-birth-rates-following-miscarriage?redirectedFrom=fulltext

8.19. The researchers have received the linked data (HFEA data linked with Scottish Morbidity and Birth Records) but findings have not yet been published.

9. Annex 3: Papers published using anonymised Register data since January 2016

9.1. Pre-term birth and low birth weight following preimplantation genetic diagnosis: analysis of 88 010 singleton live births following PGD and IVF cycles[9]

This study was published in Human Reproduction in January 2017. Pregnancies resulting from ART are associated with a higher risk of pregnancy complications compared with spontaneously conceived pregnancies, and it is of interest whether interventions such as embryo biopsy as performed in PGD affect perinatal outcomes. The study showed there was no increase in the risk of adverse perinatal outcomes of pre-term birth (PTB), and low birth weight (LBW) following PGD compared with autologous IVF.

Impact: the demonstration that PGD is not associated with higher risk of PTB and LBW provides reassurance towards its current expanding application (patient safety) and informs patient choice about treatment options.

9.2. Reproductive outcome following pre-implantation genetic diagnosis (PGD) in the UK[10]

The study, published in Human Fertility in June 2017, showed the incidence of PGD in UK has risen 127-fold over the past 20 years, but remained static over the last 7 years. Although the live birth rate has risen over years in PGD cycles, the rate is not significantly different between PGD and non-PGD cycles. 1 in 4 cycles do not reach embryo transfer. The declining rate of congenital abnormalities suggests PGD is a safe alternative to pre-natal diagnosis.

Impact: PGD has emerged as a safe and effective alternative to prenatal diagnosis providing reassurance towards its current expanding application and informs patient choice about treatment options.

9.3. Perinatal outcomes after gestational surrogacy versus autologous IVF: analysis of national data[11]

[9] Sunkara, S. K., Antonisamy, B., Selliah, H. Y., & Kamath, M. S. (2017). Pre-term birth and low birth weight following preimplantation genetic diagnosis: analysis of 88 010 singleton live births following PGD and IVF cycles. Human Reproduction, 32(2), 432-438, https://academic.oup.com/humrep/article-abstract/32/2/432/2691435/Pre-term-birth-and-low-birth-weight-following?redirectedFrom=fulltext

[10] Sharpe, A., Avery, P., & Choudhary, M. (2017). Reproductive outcome following pre-implantation genetic diagnosis (PGD) in the UK. Human Fertility, 1-8, http://www.tandfonline.com/doi/full/10.1080/14647273.2017.1336259?src=recsys

[11] Sunkara, S. K., Antonisamy, B., Selliah, H. Y., & Kamath, M. S. (2017). Perinatal outcomes after gestational surrogacy versus autologous IVF: analysis of national data. Reproductive BioMedicine Online, http://www.sciencedirect.com/science/article/pii/S1472648317304157

This study was published in Reproductive BioMedicine Online in September 2017 and looked at whether gestational surrogacy influences perinatal outcomes compared with pregnancies after autologous IVF.

No difference was found in the risk of pre-term birth (PTB) and low birth weight (LBW) after gestational surrogacy compared with autologous fresh IVF–ICSI and gestational surrogacy compared with autologous frozen embryo transfers.

The incidence of high birth weight (HBW) was significantly higher after gestational surrogacy compared with fresh IVF–ICSI; no difference was found in HBW between gestational surrogacy and autologous frozen embryo transfers.

Impact: This study enables patients to make informed choices about their treatment options with regards to surrogacy decisions.

9.4. High-risk of preterm birth and low birth weight after oocyte donation IVF: analysis of 133,785 live births[12]

This study, published in Reproductive BioMedicine Online in September 2017, looked at whether use of donor oocytes affects perinatal outcomes compared with pregnancies after autologous IVF. The risk of adverse perinatal outcomes after oocyte donation was increased with a higher risk of low birth weight (LBW) observed with oocyte donation compared with autologous IVF singletons. There was a significantly higher risk of pre-term birth (PTB) after oocyte donation compared with autologous IVF multiple births.

Impact: This study enables patients to make informed choices about their treatment options with regards to donated embryos.

[12] Kamath, M. S., Antonisamy, B., Mascarenhas, M., & Sunkara, S. K. (2017). High-risk of preterm birth and low birth weight after oocyte donation IVF: analysis of 133,785 live births. Reproductive BioMedicine Online, 35(3), 318-324, http://www.sciencedirect.com/science/article/pii/S1472648317302663

NHS commissioning of IVF

Strategic delivery	☒ Safe, ethical, effective treatment	☐ Consistent outcomes and support	☐ Improving standards through intelligence
Details			
Meeting	Authority		
Agenda item	13		
Paper number	HFEA (15/11/17) 861		
Meeting date	15 November 2017		
Author	Juliet Tizzard, Director of Strategy and Corporate Affairs Caylin Joski-Jethi, Head of Intelligence (data and analysis)		
Output			
For information or decision?	For information		
Recommendation	Members are asked to comment on the progress made on improvements to commissioning in England		
Resource implications	De minimis		
Implementation date	Detailed in the paper		
Communication(s)			
Organisational risk	☐ Low	☒ Medium	☐ High

1. Background

1.1. Our 2017-2020 strategy sets out our ambition to improve access to fertility treatment and to ensure that services have consistent standards, outcomes, value for money and support. Specifically, we want to see less variation in the price of treatment, both for private and NHS services, and we want NHS commissioners to be able to give their local population access to good quality fertility services.

1.2. Although regulation of fertility services is UK-wide, commissioning is devolved to the national level.

England

- Fertility services are commissioned locally, through 208 clinical commissioning groups (CCGs) (with the exception of fertility services for those in the armed services) from both NHS and private sector providers
- NICE has a clinical guideline (last reviewed in August 2016) which English CCGs should follow, though this is not mandatory. The NICE guideline does not include social eligibility criteria.
- Access is variable across the country, with only 12% of CCGs offering three full cycles of IVF, 23% offering two, 61% offering one and 4% offering no NHS service at all.
- There is no tariff for IVF and CCGs pay different prices for the same service, depending upon local negotiation.

Scotland

- Fertility services are commissioned by the 14 regional health boards, using a £12million central fund, from four NHS providers
- Clinical and social eligibility criteria are set centrally
- Patients are entitled to three full cycles of IVF
- The average cost per IVF cycle is £4500

Wales

- Fertility services are commissioned centrally, according to a specialised commissioning policy
- Clinical and social eligibility criteria are set centrally
- Patients are entitled to two full cycles of IVF

Northern Ireland

- NHS services are offered at one provider in Belfast
- Patients are entitled to one cycle of IVF, with only the fresh and one frozen embryo transfer included
- The waiting time to start treatment is currently 18 months

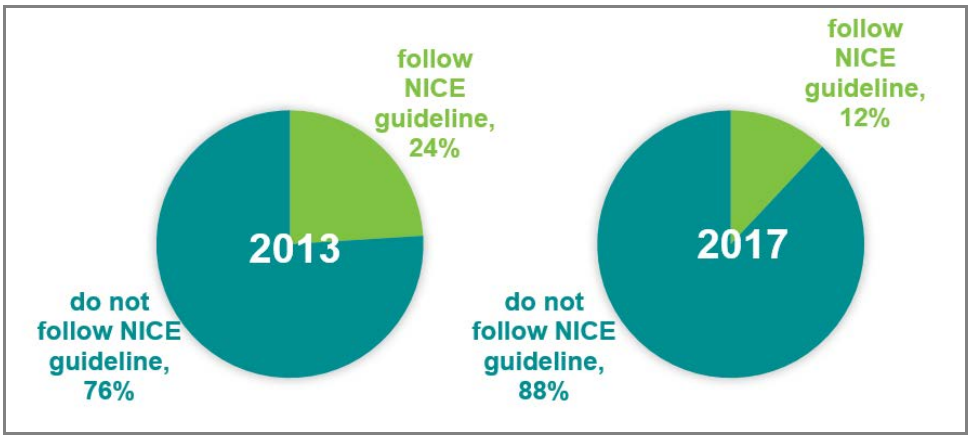
1.3. Although there is inconsistent access to NHS fertility services across the UK, the greatest variation in access is within England, where 87% of fertility treatment is carried out. We have therefore decided to focus our efforts on improving access to NHS fertility services in England.

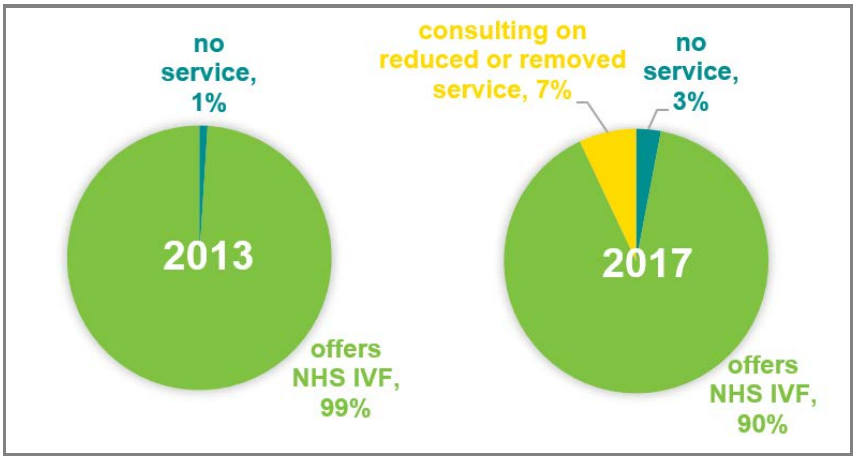
1.4. Although pricing and NHS commissioning do not fall under our regulatory control, both our Chair and Chief Executive have stated publicly that we would like to see full implementation of the NICE fertility guideline in England, for reasons of social equity and because it is the most effective and efficient wayto commission services. We can't force change, but we can use our position as the UK's specialist fertility regulator to influence and support commissioning and to inform patients going through treatment. This paper is designed to update the board on our progress in this area of strategic importance.

2. NHS commissioning in England

2.1. The NICE clinical guideline states that the most cost-effective use of IVF is that women under the age of 40 and who meet certain criteria, should be offered three full cycles of IVF. A cycle is defined as 'one episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s)'.

2.2. The trend over the past few years has been for CCGs to reduce their fertility service. In 2013, 24% of CCGs followed the NICE guideline; in 2017, it is 12%. Some have cut the service altogether. In 2013, 1% of CCGs offered no service; in 2017, it is 3%, with a further 7% consulting on a reduced or removed service. The result is a patchy service across England, with neighbouring CCGs in the same region offering differing levels of access to fertility patients.





2.3. Beyond the number of cycles offered, the criteria for accessing the service is also variable across England. Nearly half (49%) of CCGs use their own definition of an IVF cycle, mostly by limiting the number of frozen embryo transfers to one or two, regardless of how many embryos are available. From our own data, we know that the birth rate per full cycle is higher than the birth rate following one fresh and one frozen transfer. Other CCGs change the age criteria, with 10% offering treatment only to women under 35 years (the NICE guideline says 40).

2.4. Finally, CGGs have their own, variable social eligibility criteria (which do not feature in the NICE guideline). These relate to whether the couple has any existing children living with them and whether they have any children from previous relationships, whether they live with them or not.

2.5. Looking at the current commissioning picture in England in more detail, there are a number of underlying issues and problem areas:

- Duplication of effort: although there are pockets of collaboration between CCGs and within newly formed sustainability and transformation plans (STPs), most of the 208 CCGs have their own fertility policy
- Limited local expertise or time: IVF is a complex treatment but the patient population is comparatively small. Commissioners, understandably, therefore invest few resources in getting this area of commissioning right.
- Variation in service specification and in price: in the absence of a national tariff or standard service specification for IVF, CCGs are commissioning different services at non-standard prices. Local negotiation means that commissioners and providers agree their own price and there have been examples of private providers undercutting NHS providers.
- Inefficient use of resources: in an attempt to cut costs, many CCGs ‘salami slice’ the service, either by reducing the number of cycles available or redefining a cycle, as described above. This departure from the NICE guideline may seem cheaper but creates inefficiencies. Patients having fewer cycles or non-full cycles are less likely to conceive and, in some cases, are exposed to additional, unnecessary clinical risk (for

example, by being forced to move to a second stimulated cycle without using up frozen embryos first).

2.6. Besides the impact that all this has on the efficacy of treatment, the psychological toll on patients - before the emotional strain of treatment itself has even begun - is significant.

3. Work to improve commissioning in England

3.1. Patients and professionals have raised concerns about the poor availability of IVF on the NHS in the political sphere and Fertility Fairness has run an active public campaign. Successive Ministers of Public Health have pushed for improvements in NHS commissioning of fertility services. At the request of the previous Minister, Jane Ellison, NHS England started a project in November 2016 to work collaboratively with us, NHS Improvement, fertility sector stakeholders and commissioning representatives to address some of the problems described in section 2. The project has three planned outputs:

1. Guidance for CCGs on commissioning an IVF service, including standardised social eligibility criteria – by April 2018
2. A benchmark price for IVF – by April 2018
3. A national tariff, with a performance incentive built in – by April 2019

Benchmark price

3.2. Currently, CCGs pay between £3000 and £11,000 for a cycle of IVF treatment. The aim of this element of the project is to develop a non-mandatory benchmark price for a standard set of treatment pathways (currencies), with normal regional adjustments. This will give commissioners greater clarity, less need to negotiate price locally and will give providers great financial predictability. The agreed currencies are:

IVF cycle (including ovarian stimulation)	ICSI cycle (including ovarian stimulation)
Abandoned IVF/ICSI cycle (including ovarian stimulation)	Genetic screening (where required for ICSI)
Frozen cycle stimulated	Frozen cycle unstimulated
IVF cycle (including ovarian stimulation) using donor eggs	ICSI cycle (including ovarian stimulation) using donor eggs
Semen analysis	Consultation
Follow-up appointment	Surgical sperm removal
IVF cycle (including ovarian stimulation) using donor sperm	

3.3. In the absence of reliable cost data collected centrally, it was agreed that it would be better to base the benchmark price on cost data from a sample of NHS providers, rather than from CCGs. The next step is discussion with commissioners and providers to agree the price, ready for implementation in April 2018.

Commissioning guidance

3.4. Work on commissioning guidance began in the summer of 2017 and is planned for delivery, alongside the benchmark price, by April 2018. It is likely to include:

- A standard specification for the different types of IVF described above and advice on what falls outside of that (add on treatments, for example)
- Reiteration of the NICE guideline, particularly the definition of a full cycle
- Standardised social eligibility criteria
- A description of the HFEA's role and responsibilities so that CCGs do not seek duplicate effort regarding performance and quality control

3.5. The commissioning guidance will be crucial to improving commissioning decisions locally and in moving towards more consistent provision across England.

National tariff

3.6. The national tariff is a longer-term output, to be implemented once the benchmark price and commissioning guidance are in place. The current agreement is that:

- The tariff will have a performance element: 95% of the price will be paid to the CCG in year, with 5% held back and awarded later if a certain level of performance (the 'outcome standard') is reached.
- The outcome measure will be the birth rate per embryo transferred for all NHS-funded cycles performance at the provider (regardless of whether that particular CCG commissioned all the cycles), separated into women under 38 and 38 and over

3.7. The performance target is yet to be agreed. There are many complicating factors to bear in mind, both in determining the performance target and, crucially, in determining whether or not the provider has met the target. The latter is difficult because the number of NHS cycles being measured in any year at each provider is relatively low and determining performance with any degree of statistical significance may be difficult.

3.8. In 2015-16, there were 54 providers in England carrying out NHS treatment. For women under 38 alone, 53% of those carried out fewer than 250 NHS cycles.

4. Data collection

4.1. Another area of inefficiency in the current system in England is data collection. CCGs collect data from each provider about outcomes, as well as other information such as around safeguarding and equalities. Some providers measure performance, though this is more often done through KPIs in the contract, rather than linked to prices. Each CCG collects slightly different data in different time periods. This approach also means that providers – who often have contracts with multiple CCGs – are sending similar data to multiple places.

4.2. CCGs legitimately want to understand the performance of their providers. But what data should they use to do so? Given we collect most (though not all) of the data CCGs need, it makes sense for the HFEA to play a part. This would remove the need for each CCG to collect data for each provider. It would also iron out any variation.

4.3. Some commissioners refer to Choose a Fertility Clinic to assess their providers, though we don't know of any using it as a tool for deciding whether or not to use a new provider or to monitor performance of an existing contract. Given Choose a Fertility Clinic is designed for patients, this may be a good thing.

4.4. However, we could use the underlying data from Choose a Fertility Clinic and supply it to CCGs in a way that is easier for them to use and more helpful. We have agreed to do this in principle, though are some way off agreeing how this would work. We will need to agree:

- how often we supply data
- whether we do it as an annual report, some kind of bespoke tool or as data extracts for individual CCGs on request
- whether we use verified or unverified data
- how we measure providers' performance against the target specific in the performance-based tariff and how we supply data to support that

5. Recommendations

5.1. Members are asked to comment on the progress made on improvements to commissioning in England.