

Authority meeting - agenda

14 November 2018, Church House, Deans Yard Westminster, London SW1P 3NZ

Agenda item	Time
1. Welcome, apologies and declaration of interests	12.45pm
2. Minutes of 12 September 2018 Authority meeting HFEA (14/11/18) 893 For decision	12.50pm
3. Chair's report (verbal)	12.55pm
4. Chief Executive's report (verbal)	1.05pm
5. Committee chairs' reports (verbal)	1.15pm
6. Performance report HFEA (14/11/18) 894 For information	1.25pm
7. National patient survey HFEA (14/11/18) 895 For information	1:35pm
8. Draft business plan 2019-2020 HFEA (14/11/18) 896 For decision	2:20pm
Break	2:40pm
9. Donor conceived register HFEA (14/11/18) 897 For decision	2:50pm
10. Strategic risk register HFEA (14/11/18) 898 For decision	3.25pm
11. Consensus statement on treatment add-ons HFEA (14/11/18) 899 For Information	3.40pm
12. Any other business	3:55pm
13. Close	4:00pm

Minutes of Authority meeting 12 September 2018

Strategic delivery:

Safe, ethical
effective
treatment

Consistent
outcomes and
support

Improving standards
through intelligence

Details:

Meeting

Authority

Agenda item

2

Paper number

HFEA (14/11/18) 893

Meeting date

14 November 2018

Author

Catherine Burwood, 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 12 September 2018 held at 10 Spring Gardens, London, SW1A 2BU

Members present	Sally Cheshire (from item 8) Margaret Gilmore Andy Greenfield Anita Bharucha Anne Lampe Anthony Rutherford	Gudrun Moore Jonathan Herring Kate Brian Rachel Cutting Ruth Wilde Yacoub Khalaf
Apologies	Bobbie Farsides Richard Sydee	
Observers	Samantha Hayhurst (Department of Health and Social Care) Steve Pugh (Department of Health and Social Care)	
Staff in attendance	Peter Thompson Clare Ettinghausen Nick Jones Anna Quinn Catherine Drennan Caylin Joski-Jethi	Helen Crutcher Laura Riley Paula Robinson Sharon Fensome-Rimmer Sumrah Chohan

Members

There were 12 members at the meeting; seven lay and five professional. The Deputy Chair led the meeting until the end of item 7, at which point the Chair arrived and took over.

Agenda

An item on the egg freezing report was not brought to this meeting, as indicated in the minutes of the 27 June 2018 meeting. The report was published on the morning of 12 September 2018 and a copy was sent to the members.

1. Welcome, apologies and declarations of interest

- 1.1. The Deputy Chair opened the meeting by welcoming Authority members and members of the public to the fifth meeting of 2018. As with previous meetings, it was audio-recorded, and the recording would be made available on our website to enable interested members of the public who could not attend the meeting to listen to our deliberations.
- 1.2. Apologies were received from Bobbie Farsides and Richard Sydee, the Director of Finance and Resources.
- 1.3. Declarations of interest were made by:
 - Anthony Rutherford (Clinician at a licensed centre)
 - Rachel Cutting (Clinician at a licensed centre)
 - Yacoub Khalaf (Clinician at a licensed centre)

2. Minutes of Authority meeting held on 27 June 2018

- 2.1. Members agreed the minutes of the meeting held on 27 June 2018 for signature by the Chair of the meeting.
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3. Chair's report

- 3.1. The Deputy Chair welcomed three new Authority members: Jonathan Herring, Gudrun Moore and Rachel Cutting. The new members introduced themselves to the rest of the Authority. The Deputy Chair also confirmed that a fourth new member, Emma Cave, would join the Authority at a later date this year.
- 3.2. On 5 July the Chair opened the Science Museum exhibition marking the 40th anniversary of IVF. The Deputy Chair also attended this event. On the same day the Chair attended the NHS 70th birthday celebrations at Westminster.
- 3.3. The Deputy Chair also delivered a speech to the Society for Reproduction and Fertility, in relation to the anniversary, on 25 July 2018.
- 3.4. On 7 August the Chair led an Appointments Committee meeting with Margaret Gilmore and Anita Bharucha.
- 3.5. On 8 August the Chair appeared on the Victoria Derbyshire programme on BBC 2 to discuss egg freezing. The Chair sat on a panel with other professionals from the sector and a patient. The Deputy Chair advised that the Director of Strategy and Corporate Affairs would provide information about the newly published egg freezing report later in the meeting.
- 3.6. On 29 August the Chair gave an interview to the Health Service Journal regarding a report on the economic cost of multiple births. The HFEA jointly commissioned the report with the Multiple Births Foundation, the British Fertility Society (BFS) and the Royal College of Obstetricians and Gynaecologists (RCOG).
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4. Chief Executive's report

- 4.1. On 28 June the Chief Executive attended the opening of the new Digital Catapult Centre in Stevenage. The centre provides much needed manufacturing capacity for companies developing therapeutic medicines from stem cells. The new centre is a key element of the government's industrial strategy for bio-sciences.
- 4.2. Along with Authority member Yacoub Khalaf, the Chief Executive met Siobhain McDonagh MP on 4 July to discuss Ovarian Hyperstimulation Syndrome (OHSS).
- 4.3. On 5 July the Chief Executive attended the NHS 70th birthday celebrations with the Chair.
- 4.4. On 10 July the Chief Executive participated in the Health and Care Leaders Scheme quarterly senior talent board. This is a board made up of leaders from the Department of Health and Social Care (DHSC) and its arm's length bodies (ALBs) to identify and manage talented individuals.

- 4.5.** On 21 August Laura Riley, Head of Regulatory Policy, Anna Quinn, Scientific Policy Manager, and the Chief Executive met staff from the Royal Society of Biology to discuss areas of mutual interest such as genome editing.

Press Coverage

40th anniversary of IVF

- 4.6.** As well as opening the Science Museum exhibition as mentioned earlier, the Chair also gave various interviews at the event.
- 4.7.** Authority member Yacoub Khalaf also gave a number of interviews at another Science Museum event, including to Sky News, Channel 5 News and Al Jazeera.
- 4.8.** The Chief Executive noted that our social media output around these events proved very popular making us part of the wider conversation about fertility and the 40th anniversary.

Egg freezing/National Patient Survey

- 4.9.** The Chief Executive advised that these were areas which had also gained press interest recently.

OHSS/welfare of the woman and storage limit campaigns

- 4.10.** Two campaigns about OHSS/women's welfare and the ten-year gamete storage limit have begun recently.
- 4.11.** Siobhain McDonagh MP is leading a campaign seeking to have the law changed to strengthen protections for women's safety, especially in relation to OHSS. We responded to a number of press enquiries regarding OHSS, setting out the facts underlying this issue, and reassuring people that severe OHSS is thankfully very rare. Yacoub Khalaf represented the HFEA on BBC London in August reiterating this.
- 4.12.** The other campaign is seeking to have the ten-year gamete storage limit increased so that gametes can be stored for longer. The issue of ten-year storage is for Parliament as it requires a change in the law.

5. Committee Chairs' reports

Licence Committee

- 5.1.** The Chair of the Licence Committee advised members that the Committee met on 12 July and 6 September. Six items were considered at each meeting.
- 5.2.** In July the committee considered one initial storage application; two research renewals; one treatment (including embryo testing) and storage renewal; one investigation report; and one additional inspection report. Three applications were approved and one adjourned. The committee noted the interim inspection report/investigation.
- 5.3.** In September the committee considered two research renewal applications; one treatment and storage renewal; one treatment and storage renewal including a Grade A incident; and two executive updates. The minutes were yet to be finalised so the Chair of the Licence Committee was unable to provide details about the decisions made.

Statutory Approvals Committee

- 5.4.** The Chair of the Statutory Approvals Committee (SAC) advised members that the Committee met on 28 June, 26 July, 13 August and 30 August.
- 5.5.** In June the committee considered six pre-implantation genetic diagnosis (PGD) applications and one application for special directions. The PGD applications were approved and the special directions application was adjourned.
- 5.6.** In July the committee considered three mitochondrial donation applications; five PGD applications; and one application for special directions. All applications were approved.
- 5.7.** The Chair of SAC explained that the 13 August meeting was an extraordinary meeting arranged at short notice due to a delayed application caused by an issue with the HFEA's portal and the patient potentially losing funding for her treatment. The application was approved.
- 5.8.** At the second meeting in August the committee considered two mitochondrial donation applications; five PGD applications; and one application for special directions. The minutes for these items were yet to be signed so the outcomes could not be given.
- 5.9.** The Chair of SAC noted that most recent PGD applications have featured multiple conditions to be considered.

Executive Licensing Panel

- 5.10.** The Chair of the Executive Licensing Panel advised members that the Panel had met six times since the last Authority meeting, on 6 July, 20 July, 1 August, 16 August, 29 August and 11 September. 24 items were considered in total: one initial licence application; ten renewal applications; ten interim inspection reports; one variation of licence application; one executive update; and one human leukocyte antigen (HLA) testing application. 22 applications were approved. The panel deferred decisions in relation to one renewal application and one interim inspection report.
- 5.11.** The Licensing Officer considered 12 applications, which were all approved: eight EU import certificate applications; three change of licence holder applications; and one voluntary revocation.

Appointments Committee

- 5.12.** The Deputy Chair advised members that the Committee had met on 7 August. The committee considered the renewal of three members of the independent Appeals Committee whose first terms were ending shortly. All three reappointments were approved.
- 5.13.** The committee also appointed three new members to the Licence Committee that considers representations, leading up to three current members' final terms ending shortly.

6. Performance report

- 6.1.** The Chief Executive introduced this item and covered several areas, including the upcoming PR leadership events in November; Brexit and the prospect 'no-deal' would

have on guidance and standards in the sector; staffing and the higher than expected levels of 'unplanned' leavers; and a planned office move, which will likely see the HFEA moving to a new base in Stratford in 2020. The Chief Executive advised that progress updates on the office move would be given at future Audit and Governance Committee (AGC) and Authority meetings.

- 6.2.** The Chief Executive also provided the members with information about the finance performance data, including confirmation that the DHSC had given permission for the HFEA to increase our capital budget.
- 6.3.** The Chief Executive explained that the data given in the finance commentary section of the performance scorecard presented in the papers was incorrect. The commentary indicated that we were below our budget position, when in fact we were forecasting a year end surplus.
- 6.4.** In relation to information given about increasing income from IVF and DI cycles, the members enquired about differences between the levels of treatments at private and NHS clinics, and whether there are differences across the UK nations. The Chief Executive advised that information such as this could be found in the Fertility Trends report.
- 6.5.** The Director of Compliance and Information provided information about: delays in PGD application processing; how the counselling provider used by the HFEA to support opening the register (OTR) work had withdrawn their services; and the new EU directive and the higher than expected number of applications received for clinics to become Importing Tissue Establishments (ITEs).
- 6.6.** The Director of Compliance and Information also provided an update on the data submission programme, advising members that work was in the final stages.
- 6.7.** The Director of Compliance and Information reported that overall performance was good with three indicators classified as red and three amber.
- 6.8.** Three indicators relating to SAC were classified as red. We have seen the knock-on effects of the technical issues with our information systems in April and May, reported to Authority previously and now resolved, which caused a backlog of applications. This will impact Key Performance Indicators (KPIs) for the next month or so.
- 6.9.** Additionally, as the PGD conditions being applied for become more complex and obscure, the consideration of them also becomes more complex and time consuming. The position in relation to SAC indicators has been also exacerbated by the need to implement mitochondrial donation application processing effectively.
- 6.10.** The amber indicators related to: 'unplanned' leavers; outstanding errors; and average number of working days from day of inspection to the day the draft report is sent to the PR.
- 6.11.** The Director of Strategy and Corporate Affairs provided the members with information about: the 40th anniversary of IVF celebrations and events, including a debate in the House of Lords; the publication of new report about the cost of multiple births with the Multiple Births Foundation, Fertility Network UK (FNUK) and the RCOG; the launch of the egg freezing report today; the new version of the Code of Practice, which was with

the Secretary of State for Health and Social Care for approval; work on the consensus statement on treatment add-ons; and planned events for PRs taking place in November.

Decision

- 6.12. The members noted the performance report.
- 6.13. The members noted that proposals on the operation of the Donor Conceived Register would be brought to the November 2018 meeting of the Authority.
- 6.14. The members congratulated the small team involved in the data submissions programme. The members also agreed that it was important to ensure that the sector has time and support to respond to these changes when they go live.

7. Business plan 2019/20

- 7.1. The Head of Planning and Governance and the Risk and Business Planning Manager presented an outline of the proposed business plan for 2019/20, the full draft of which would be presented to the Authority in November before being given to the DHSC for sign off by March.
- 7.2. The Head of Planning and Governance explained that the HFEA was in the last year of our current strategy, and the business plan will indicate what actions we would take in the coming year to ensure delivery of the strategy.
- 7.3. The Risk and Business Planning Manager advised the members of work completed to meet the strategy to date, and went through the outline of the proposed 2019/20 business plan:
 - Safe, ethical, effective, treatment**
 - 7.4. Work would be completed in relation to leadership; embedding patient feedback into our processes; recognising excellent patient care; and benchmarking the performance of clinics.
 - Consistent outcomes and support**
 - 7.5. Work would be completed in relation to ensuring compliance with the new Code of Practice requirements regarding patient support; embryo research; defining factors that lead to successful outcomes; benchmarking treatment prices; and counselling support services for those applying for Register information.
 - Improving standards through intelligence**
 - 7.6. Work would be completed in relation to the national patient survey findings; analysing Register data on success rates; and patient engagement.

Decision

- 7.7. The members discussed the outline business plan, and in particular treatment add-ons and the HFEA's use of social media to engage with patients and the sector.
- 7.8. One member asked what had been done to increase consent for research and the Chief Executive advised that the Executive would look into evaluating measures taken to date.
- 7.9. Following the discussion, members approved the outline business plan for 2019/20.

8. State of the fertility sector

- 8.1.** The Director of Compliance and Information introduced this presentation which provided data about the current state of the fertility sector. He explained that this information would enable the Executive to decide which areas to focus on during inspections and enable us to collaborate with clinics to improve performance.
- 8.2.** The Head of Intelligence provided the members with details about the size and shape of the sector. There had been a 61% growth in activity since 2007/08. The members heard that 84055 treatments and cycles were undertaken in 2017/18, in 130 licenced fertility clinics. The value of the market was estimated as £320m in 2016.
- 8.3.** The members were also presented with information about regional variations in the number and type of clinics licenced, with London having the most, and greatest range of, clinics.
- 8.4.** The members heard how more private clinics are now operating in groups, such as CARE and the Fertility Partnership. These groups control 39% of the market.
- 8.5.** The Chief Inspector reported that there were 101 inspections in 2017/18. When critical or major non-compliances were found, 45% of clinics had improved by the next inspection. Considering all non-compliances, 61% of clinics were identified as being improved by the next inspection; this indicated that the inspection regime was effective.
- 8.6.** The Chief Inspector explained that it is difficult to compare non-compliances at a sector level and presented the reasons for this.
- 8.7.** The members heard that the main three areas of non-compliance at renewal inspections in 2015/16 related to Quality Management Systems (QMS); equipment and materials; and data submission. The main three areas of non-compliance at interim inspections related to QMS; equipment and materials; and procuring, processing and transporting of gametes and embryos. Members heard that whilst the reasons for non-compliance were reasonably stable, overall numbers of non-compliances were increasing.
- 8.8.** Areas that were not meeting the standards expected and that needed development were identified from renewal and interim inspections combined: consent; equipment and materials, including medical devices; and QMS. The members heard that several areas had also improved: witnessing; Third Party Agreements (TPAs); multiple births; and medicines management.
- 8.9.** The members heard that the incident rate in clinics had remained broadly stable, with reported incidents representing less than 1% of all cycles. There had been a decrease in communication and laboratory equipment incidents, but an increase in clinical incidents.
- 8.10.** Complaints had increased with most being about clinical and communication issues. General complaints had increased for the third consecutive year.
- 8.11.** The Head of Intelligence went on to present the members with information about Choose a Fertility Clinic (CaFC) ratings. 1500 patients had given feedback about their clinic, but the Head of Intelligence advised that we would hope for more. The feedback received was predominantly positive.

Decision

- 8.12.** The members discussed the findings and agreed that, although the sector is generally performing well it was important to learn from this information and focus our regulatory work over the coming year.

9. Donor anonymity and direct-to-consumer genetic testing

- 9.1.** The Chief Executive introduced this item explaining that direct-to-consumer genetic testing will have wide ranging impacts, including direct impacts to the HFEA's services.
- 9.2.** The Donor Information Manager explained that the HFE Act 1990 assumes gamete and embryo donor anonymity as a default position. Donor-conceived people and donors have a statutory right of access to certain information held on the Register. However, people discovering donation information without the Act's provisions do not have these rights.
- 9.3.** The Head of Regulatory Policy provided the members with background information about direct-to-consumer genetic testing and advised that there were millions of users of websites providing these services worldwide.
- 9.4.** The Head of Regulatory Policy also provided details about how such websites operate, with genetically 'matched' users often being identified to each other by name. Contact can be made without any mediation or support.
- 9.5.** The members heard how, from the information users received, it was reasonably simple to infer relatedness and go on to find other relatives through social media.
- 9.6.** The Donor Information Manager explained that the possibility of relatedness inference affected all sperm, egg and embryo donors; all donor conceived people of any age; the genetic relatives of donor-conceived people or donors; and recipient parents and families. Other groups affected include people coming into donation; people coming into fertility treatment using donation; and groups on social media who offer advice and share information on using DNA matching to find out a donor's identity.
- 9.7.** The members heard that there is a lack of understanding around the complexities of direct-to-consumer genetic testing, including the potential for unexpected genetic information on relatedness or health issues, and that the HFEA had found that many websites do not offer specific emotional support, information relating to donor conception issues, or signpost users to other support services.
- 9.8.** The Head of Regulatory Policy explained that while we have no regulatory powers in relation to this area, there were several possible responses to direct-to-consumer genetic testing. These included raising patient and donor awareness through the HFEA website, HFEA consent forms and at clinics, and setting out new expectations in the Code of Practice. We could also seek dialogue with UK based genetic matching services in regard to their information giving and signposting to support.
- 9.9.** The Authority was asked to note:
- the rapidly growing number of people using DNA testing and matching websites.

- the implications of discovering a donor or donor conceived person's identity through such websites, including unexpectedly.
- the changing context of HFEA's managed (Donor Conceived Register) DCR and (Opening the Register) OTR services including the offer of emotional support.
- that information is freely available on how to use DNA matching websites to seek donors' or donor-conceived peoples' identifiable information.
- that there is little support available around responding to 'matching' information, or contacting others in relation to matches.
- the summary of possible responses outlined above.

Decision

- 9.10.** The members noted the points above and were encouraged that this topic was being explored in a timely way.
- 9.11.** In discussion the members expressed differing opinions about the level of responsibility the HFEA should or could have towards people who are not covered by the provisions of the Act.
- 9.12.** It was agreed that this could be a potential topic for the next Annual Conference.
- 9.13.** The Chief Executive advised the members that the Executive would continue to explore the responses available for the HFEA and report back to the Authority.

10. Standard licence condition T53 - screening

- 10.1.** The Scientific Policy Manager and Head of Planning and Governance presented a paper about amendments made to standard licence condition T53.
- 10.2.** The Scientific Policy Manager set out the purpose of condition T53 and its requirements, including that 'donor sperm must be quarantined for a minimum of 180 days, after which repeat testing is required. If the blood donation sample is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, quarantining of the gametes and re-testing of a repeat blood sample is not required. Quarantine and re-testing is also not required if the processing includes an inactivation step that has been validated for the viruses concerned'.
- 10.3.** The members heard that there were discrepancies between our guidance regarding best practice in relation to quarantining and guidance provided by professional bodies.
- 10.4.** The Scientific Policy Manager also explained that there was a potential for varying practice within the sector, along with a risk that centres do not necessarily complete serological testing alongside NAT testing, or do not quarantine samples after any NAT testing has been done.
- 10.5.** The members heard that the HFEA had engaged with the relevant professional bodies, including the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO), the Association of Clinical Embryologists (ACE), the BFS, and the Association of Biomedical Andrologists (ABA), to agree recommendations relating to NAT testing and quarantine requirements.

- 10.6.** Additionally, SaBTO had agreed to consider the evidence in this area and publish an addendum to their donor selection criteria report 2017, a document which was included in the paper.
- 10.7.** The members heard that the Executive had drafted an improved, up to date and clear articulation of standard licence condition T53.
- 10.8.** The Head of Planning and Governance outlined proposals to update the centrally held list of standard licence conditions on 1 October 2018, to coincide with the implementation of the new Code of Practice. The revised wording would be included on all new or renewed licences issued to clinics after this date. The Executive would manage any risk of misinterpretation of T53 through guidance and the inspection regime.
- 10.9.** The members also heard about plans to highlight the issue through Clinic Focus.
- 10.10.** The Authority was asked to:
- Note and approve the proposed revision of standard licence condition T53.
 - Note the intended implementation and communication plan.

Decision

- 10.11.** The members noted and approved the proposed revision of standard licence condition T53. They also noted the intended implementation and communication plan.

11. Any other business

- 11.1.** There was no any other business discussed.

12. Chair's signature

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

Signature

Chair

Date

Performance report

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

Details:

Meeting	Authority
Agenda item	6
Paper number	HFEA (14/11/18) 894
Meeting date	14 November 2018
Author	Helen Crutcher, Risk and Business Planning Manager

Output:

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

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 2018.
- 1.2. Further updates on performance and trends since this point will be provided verbally in the meeting.

2. Reviewing performance

- 2.1. SMT reviewed the September performance data at its October 29 meeting.
- 2.2. Overall performance is good. Five indicators are currently classified as red. There is a full discussion of these in the performance report, provided in the annex to this paper.

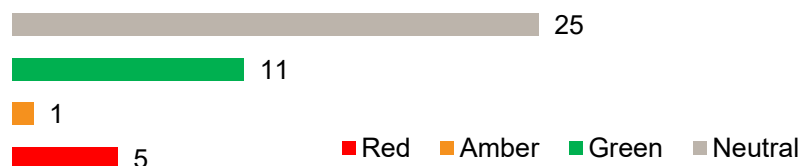
3. Recommendation

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

Annex 1 - HFEA performance scorecard

Dashboard – September data

Overall performance – RAG status (all indicators)



People – capacity

Establishment leavers per month
(% turnover for the year).

KPI: 5 - 15% establishment turnover

↔
Leavers: 1
(22.1%)

Engagement – Website traffic

Website sessions this month

Arrow tracks performance since last month



45,305

Licensing end-to-end

Length of the whole inspection and licensing process

KPI: ≤ 70 working days

★
50 working
days

Money – budget

Summary Financial Position - September 2018

	Year to Date			Full Year		
	Actual £'000	Budget £'000	Variance £'000	Forecast £'000	Budget £'000	Variance £'000
Income	3,266	3,271	5	6,497	6,490	(6)
Expenditure	3,003	3,082	79	6,242	6,270	28
TOTAL Surplus / (Deficit)	263	189	74	255	221	34

Commentary

The position at the end of Q2 is a small surplus against budget of £74k, a result of a small drop in income of £5k offset by minor underspends in revenue expenditure.

The full year forecast is a surplus of £255k, an increase of £34k against out budgeted position of £221K. This position has been arrived at after a detailed review of directorate plans and expenditure for the remaining six months of the year. We will look to utilise this emerging position and will undertake a further review at Quarter 3.

Overall performance – September 2018

SMT reviewed the overall performance picture on 29 October. There were 5 red indicators related to performance in three areas; staff turnover, minuting times and PGD processing. Overall, September performance was generally good. A particularly positive story is the end to end licensing indicator, which tracks our performance from inspection through to the sign off of minutes. On average in September the whole process took 50 working days, well within our 70 working day target.

Turnover is higher than we would want. However, we have carried out a useful analysis of turnover and exit interviews which has shown that leavers over the past year have an average of 6 years of service. Given that we are a small organisation where there are few opportunities for promotion, it is understandable that staff may leave after a period of time. However, we are also working hard to ensure the HFEA is an attractive employer, both in terms of our benefits package, and the culture and values of the organisation. We have made some progress during 2018 but have a way to go to achieve this.

Following an external review of our internal licensing capacity, we are making a number of changes to ensure this core function of the HFEA is as well supported as possible. As part of ensuring adequate capability and capacity for the increasing number and complexity of licensing papers and decisions, (especially to SAC) we are recruiting a further committee officer and a senior governance manager to the governance team. We are also looking at widening the membership pool of licensing committees, to ensure that the workload is shared more broadly over the year, which will hopefully alleviate pressure on the sign off of minutes etc. We hope these changes, together with others relating to processes and procedures will ensure we are able to meet the growing demands in this area.

The low rate of PGD completion within three months was due to unusually high volumes of applications received between March and May, exacerbated by Clinic Portal submission issues in April which caused a backlog of applications. The number due to be processed in the three months to September was 60% higher than the same period last year. Such high volumes have been hard to schedule for consideration, owing to full agendas. The handling of SAC business, including PGD applications, is also being considered during the aforementioned implementation of the licensing review.

Red indicators

The 5 red key performance indicators (KPIs) shown in the 'overall status - performance indicators' bar chart on the dashboard are as follows:

Turnover

- Establishment ('unplanned') leavers per month. Our target is to remain within 5 - 15% headcount turnover for the year. Performance in September was 22.1%. The overall planned and unplanned leavers for the year is 26.9%.

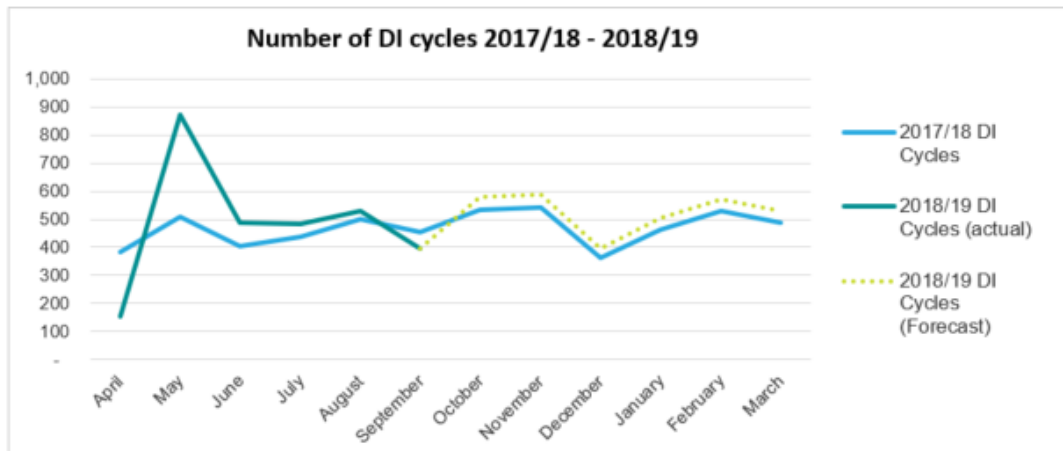
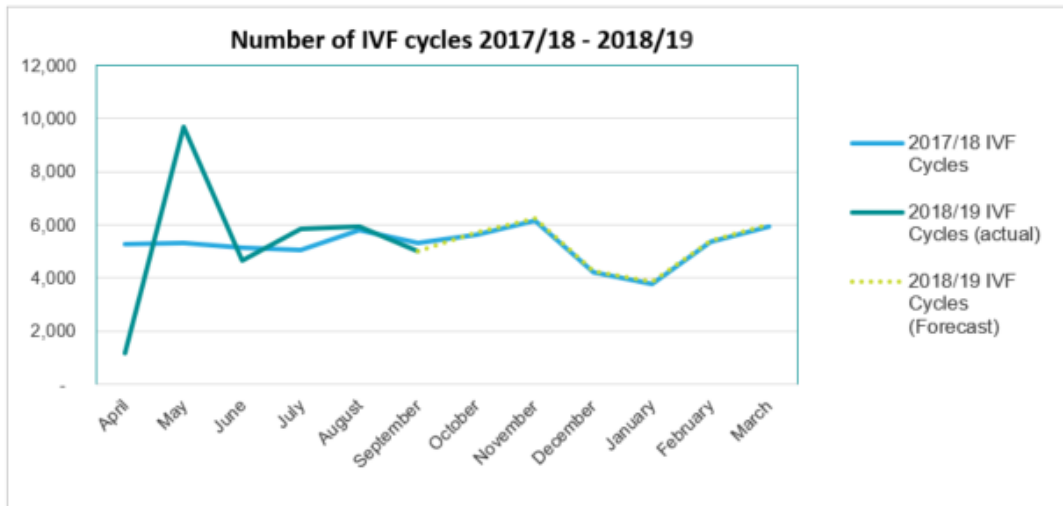
Licensing decisions approved and finalised

- Average number of working days between Licence Committee (LC) date and minutes being finalised (signed by the Chair). The target for LC minutes is 100% in 15 working days but in September they were completed on average in 17 working days with one of the 3 due to be completed delivered within the target. These delays were due to the availability of members and legal advisor to approve them, in addition to several complex applications.
- Average number of working days between SAC date and minutes being finalised (signed by the Chair). The target for SAC minutes is 100% in 20 working days but in September average performance was 21 working days with 50% finalised within the 20 working day target. Increasingly complex SAC items are adding to delays in finalising these minutes

PGD processing

- Percentage of PGD applications processed within three months. Our target is 100%, but in September only 33%, one of the three applications due to be completed, was in this timeframe.
- 3 month rolling average figure – Percentage of all PGD applications processed within 3 months for the three months to date. Our target is 100% within 66 working days, but in the three months to September this dropped to 21% (5/24) with an average processing time for those that had been completed of 80 working days.

2018/19 Income



IVF Cycles

	YTD		YE / Forecast	
	Volume	£	Volume	£
2017/18 IVF Cycles	31,876	2,550,080	62,969	5,037,520
2018/19 IVF Cycles	32,332	2,586,560	63,870	5,109,584
Variance	456	36,480	901	72,064

The year to date position shows an increase of 1.4% in IVF activity over the same period last year. 2018/19 budgets were predicated on a 2% increase on 2017/18 volumes, although volumes are slightly lower to the mid point we are of the view that the year end position will be broadly in line with our budget.

We review our income forecast monthly and will make amendments to the outturn position should we see material variances to our forecast profile.

DI Cycles

	YTD		YE / Forecast	
	Volume	£	Volume	£
2017/18 DI Cycles	2,688	100,800	5,607	210,263
2018/19 DI Cycles	2,918	109,425	6,087	228,254
Variance	230	8,625	480	17,991

Year to date, the volume of DI treatment cycles reported is 9% higher than the same period in 2017/18. Although we have seen a fall in September volumes compared to the same period in 2017/18 we remain significantly above our budgeted position, should the current trend continue we would see an increase over last years' DI volumes by c500 cycles.

HFEA Income & Expenditure

Sep-2018

	Year to Date			Full Year		
	Actual £'000	Budget £'000	Variance £'000	Forecast £'000	Budget £'000	Variance £'000
Income						
Grant-in-aid	467	467	-	934	934	-
Licence Fees	2,723	2,734	11	5,416	5,416	-
Other Income	6	-	(6)	6	-	(6)
Seconded Salary reimbursed	70	70	(0)	141	141	-
Total Income	3,266	3,271	5	6,497	6,490	(6)
Revenue Costs						
Salaries (excluding Authority)	2,003	1,955	(48)	3,817	3,911	94
Staff Travel & Subsistence	77	87	10	159	162	3
Other Staff Costs	49	63	13	131	126	(5)
Authority & Other Committees costs	119	137	18	302	280	(21)
Facilities Costs incl non-cash	364	327	(37)	715	710	(5)
IT Costs	119	110	(9)	249	211	(38)
Legal / Professional Fees	172	280	108	585	585	-
Other Costs	99	123	24	284	285	1
Total Revenue Costs	3,003	3,082	79	6,242	6,270	28
TOTAL Surplus / (Deficit)	263	189	74	255	221	34

Management commentary

Income.

At the end of Q2, total income recovered is 5k below the budgeted figure. Our treatment cycle volumes are in line with budget expectations, Although we have seen a small drop in volumes in September compared to the same period in 2017/18 (6%) .

Expenditure.

Year to date expenditure is below our budget by **£79k** (2.5%). Below are the details of our material variances:

Staff costs including Temporary staff - £48k above budget - a result of overspends on agency staff (£163k) offset by underspends from unfilled posts across the first half of the year.

Facilities - £37k above budget - additional desks space was rented for the first half of the year to provide space for IT contractors.

IT Costs - £9k over budget - due to overspend in Photocopy (£4k), IT Subscriptions (£6k) and Consumable costs (£13k), offset by underspend within Telecoms (£2k), IT Consultancy (£6k), Internet and Low value assets (£1k).

Legal/Professional fees - £108k under budget- the core legal budget is underspent by **£4k**, due to the write back of an accrued costs award from a current case (£40k). The balance of the underspend relates to the litigation contingency funds (now not required) being held to meet pending Court of Appeal hearing

Other Costs £24k under budget - net underspends within the Strategy directorate totalling (£25k) offset by net overspend with Compliance. The most significant area we are currently under budget is our Stakeholder events (£18k).

Forecast Outturn.

We are forecasting a small increase in our income of **£6k** and a small underspend on expenditure of **£28k** resulting in a surplus against budget of **£34k**. This position assumes that we will utilise all of our contingency budget against either legal and/or IT and Telecoms spend. Progress on any legal issues are monitored by the senior management team. The proposals for further investment in our IT infrastructure are currently at Business Case stage and are awaiting consideration by CMG.

People – key performance and volume indicators

Indicator	Score	RAG	Recent trend ¹	Notes
Current headcount by month Staff in post/headcount	61/66	↔	<p>Headcount vs establishment</p>	Overall volume (capacity) indicator.
Turnover: Establishment ('unplanned') leavers (% establishment turnover for the year). This is done monthly for the rolling year to date.	22.1%	↑	<p>Turnover vs target range (5-15%)</p>	KPI range: 5-15% turnover for the rolling year The public-sector average is 10.9% (Xpert HR 2017) on which we base our target.
Staff sickness absence rate (%) per month.	1.1%	★	<p>Sickness absence</p>	KPI: Absence rate of ≤ 2.5%. Average rate of public sector sickness absence is 2.9% versus 1.7% for the private sector. (Source: ONS data 2016)

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

Information – key performance and volume indicators

Indicator	Score	RAG	Recent trend	Notes																		
Number of emailed public enquiries received (compared with same month last year)	146	↓	<table border="1"> <caption>Number of emailed public enquiries received</caption> <thead> <tr> <th>Month</th> <th>This year</th> <th>Last year</th> </tr> </thead> <tbody> <tr> <td>May</td> <td>159</td> <td>196</td> </tr> <tr> <td>June</td> <td>138</td> <td>186</td> </tr> <tr> <td>July</td> <td>143</td> <td>156</td> </tr> <tr> <td>August</td> <td>143</td> <td>169</td> </tr> <tr> <td>September</td> <td>146</td> <td>165</td> </tr> </tbody> </table>	Month	This year	Last year	May	159	196	June	138	186	July	143	156	August	143	169	September	146	165	Volume indicator.
Month	This year	Last year																				
May	159	196																				
June	138	186																				
July	143	156																				
August	143	169																				
September	146	165																				
Percentage of Opening the Register requests responded to within 20 working days	100%	★	<table border="1"> <caption>Percentage of Opening the Register requests responded to within 20 working days</caption> <thead> <tr> <th>Month</th> <th>Number of requests</th> <th>% within 20 days</th> </tr> </thead> <tbody> <tr> <td>May</td> <td>33</td> <td>97%</td> </tr> <tr> <td>June</td> <td>31</td> <td>100%</td> </tr> <tr> <td>July</td> <td>31</td> <td>100%</td> </tr> <tr> <td>August</td> <td>26</td> <td>100%</td> </tr> <tr> <td>September</td> <td>36</td> <td>100%</td> </tr> </tbody> </table>	Month	Number of requests	% within 20 days	May	33	97%	June	31	100%	July	31	100%	August	26	100%	September	36	100%	KPI: 100% of complete OTR requests to be responded to within 20 working days (excluding counselling time)
Month	Number of requests	% within 20 days																				
May	33	97%																				
June	31	100%																				
July	31	100%																				
August	26	100%																				
September	36	100%																				
Number of requests for contributions to Parliamentary questions	0	↔	<table border="1"> <caption>Number of requests for contributions to Parliamentary questions</caption> <thead> <tr> <th>Month</th> <th>PQs answered</th> <th>Same month last year</th> </tr> </thead> <tbody> <tr> <td>May</td> <td>1</td> <td>0</td> </tr> <tr> <td>June</td> <td>15</td> <td>0</td> </tr> <tr> <td>July</td> <td>2</td> <td>0</td> </tr> <tr> <td>August</td> <td>0</td> <td>0</td> </tr> <tr> <td>September</td> <td>0</td> <td>0</td> </tr> </tbody> </table>	Month	PQs answered	Same month last year	May	1	0	June	15	0	July	2	0	August	0	0	September	0	0	Volume indicator. We received no PQs in August and September due to the parliamentary recess. We have since received a spike of applications in October.
Month	PQs answered	Same month last year																				
May	1	0																				
June	15	0																				
July	2	0																				
August	0	0																				
September	0	0																				

Indicator	Score	RAG	Recent trend	Notes																		
Number of Freedom of Information (FOI) requests	8	↑	<table border="1"> <caption>FOI Data</caption> <thead> <tr> <th>Month</th> <th>FOIs answered</th> <th>Same month last year</th> </tr> </thead> <tbody> <tr> <td>May</td> <td>11</td> <td>8</td> </tr> <tr> <td>Jun</td> <td>3</td> <td>7</td> </tr> <tr> <td>Jul</td> <td>6</td> <td>5</td> </tr> <tr> <td>Aug</td> <td>5</td> <td>13</td> </tr> <tr> <td>Sep</td> <td>8</td> <td>2</td> </tr> </tbody> </table>	Month	FOIs answered	Same month last year	May	11	8	Jun	3	7	Jul	6	5	Aug	5	13	Sep	8	2	Volume indicator.
Month	FOIs answered	Same month last year																				
May	11	8																				
Jun	3	7																				
Jul	6	5																				
Aug	5	13																				
Sep	8	2																				

Inspection and licensing process – key performance and volume indicators

Indicator	Score	RAG	Recent trend ²	Notes																		
Average number of working days taken for the whole licensing process, from the day of inspection to the decision being finalised (signed off by the chair)	50	★	<table border="1"> <caption>Working Days Data</caption> <thead> <tr> <th>Month</th> <th>Working days</th> <th>KPI</th> </tr> </thead> <tbody> <tr> <td>May</td> <td>49</td> <td>70</td> </tr> <tr> <td>Jun</td> <td>46</td> <td>70</td> </tr> <tr> <td>Jul</td> <td>69</td> <td>70</td> </tr> <tr> <td>Aug</td> <td>62</td> <td>70</td> </tr> <tr> <td>Sep</td> <td>50</td> <td>70</td> </tr> </tbody> </table>	Month	Working days	KPI	May	49	70	Jun	46	70	Jul	69	70	Aug	62	70	Sep	50	70	KPI: Less than or equal to 70 working days.
Month	Working days	KPI																				
May	49	70																				
Jun	46	70																				
Jul	69	70																				
Aug	62	70																				
Sep	50	70																				

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

Indicator	Score	RAG	Recent trend ²	Notes																		
Monthly percentage of PGD applications processed within three months (66 working days).	33% (1/3)	↑	<table border="1"> <caption>Monthly Performance Percentage</caption> <thead> <tr> <th>Month</th> <th>Performance (%)</th> <th>KPI (%)</th> </tr> </thead> <tbody> <tr> <td>May</td> <td>100%</td> <td>100%</td> </tr> <tr> <td>Jun</td> <td>100%</td> <td>100%</td> </tr> <tr> <td>Jul</td> <td>29%</td> <td>100%</td> </tr> <tr> <td>Aug</td> <td>0%</td> <td>100%</td> </tr> <tr> <td>Sep</td> <td>33%</td> <td>100%</td> </tr> </tbody> </table>	Month	Performance (%)	KPI (%)	May	100%	100%	Jun	100%	100%	Jul	29%	100%	Aug	0%	100%	Sep	33%	100%	KPI: 100% processed (i.e. considered by SAC) within three months (66 working days) of receipt of completed application.
Month	Performance (%)	KPI (%)																				
May	100%	100%																				
Jun	100%	100%																				
Jul	29%	100%																				
Aug	0%	100%																				
Sep	33%	100%																				
Average number of working days taken (in the month).	34 (1 application)	★	<table border="1"> <caption>Monthly Working Days</caption> <thead> <tr> <th>Month</th> <th>Working Days</th> <th>KPI</th> </tr> </thead> <tbody> <tr> <td>May</td> <td>42</td> <td>66</td> </tr> <tr> <td>Jun</td> <td>51</td> <td>66</td> </tr> <tr> <td>Jul</td> <td>70</td> <td>66</td> </tr> <tr> <td>Aug</td> <td>79</td> <td>66</td> </tr> <tr> <td>Sep</td> <td>34</td> <td>66</td> </tr> </tbody> </table>	Month	Working Days	KPI	May	42	66	Jun	51	66	Jul	70	66	Aug	79	66	Sep	34	66	
Month	Working Days	KPI																				
May	42	66																				
Jun	51	66																				
Jul	70	66																				
Aug	79	66																				
Sep	34	66																				
Cumulative 3 month (rolling average) percentage of PGD applications processed within three month KPI (66 working days)	21% (5/24)	↓	<table border="1"> <caption>Cumulative 3-month Performance Percentage</caption> <thead> <tr> <th>Month</th> <th>Performance (%)</th> <th>KPI (%)</th> </tr> </thead> <tbody> <tr> <td>May</td> <td>100%</td> <td>100%</td> </tr> <tr> <td>Jun</td> <td>100%</td> <td>100%</td> </tr> <tr> <td>Jul</td> <td>50%</td> <td>100%</td> </tr> <tr> <td>Aug</td> <td>35%</td> <td>100%</td> </tr> <tr> <td>Sep</td> <td>21%</td> <td>100%</td> </tr> </tbody> </table>	Month	Performance (%)	KPI (%)	May	100%	100%	Jun	100%	100%	Jul	50%	100%	Aug	35%	100%	Sep	21%	100%	KPI: As above.
Month	Performance (%)	KPI (%)																				
May	100%	100%																				
Jun	100%	100%																				
Jul	50%	100%																				
Aug	35%	100%																				
Sep	21%	100%																				
Average number of working days taken (cumulative 3 month picture).	80	↑	<table border="1"> <caption>Cumulative 3-month Working Days</caption> <thead> <tr> <th>Month</th> <th>Working Days</th> <th>KPI</th> </tr> </thead> <tbody> <tr> <td>May</td> <td>53</td> <td>66</td> </tr> <tr> <td>Jun</td> <td>52</td> <td>66</td> </tr> <tr> <td>Jul</td> <td>69</td> <td>66</td> </tr> <tr> <td>Aug</td> <td>70</td> <td>66</td> </tr> <tr> <td>Sep</td> <td>80</td> <td>66</td> </tr> </tbody> </table>	Month	Working Days	KPI	May	53	66	Jun	52	66	Jul	69	66	Aug	70	66	Sep	80	66	
Month	Working Days	KPI																				
May	53	66																				
Jun	52	66																				
Jul	69	66																				
Aug	70	66																				
Sep	80	66																				

National Patient Survey

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

Details:

Meeting Authority

Agenda item 7

Paper number HFEA (14/11/2018) 895

Meeting date 14 November 2018

Author Lisa Whiting, Research Manager

Output:

For information or decision? For information

Recommendation The Authority are asked to:

- note the summary results of the national patient survey
- comment on the strategic implications for the Authority

Resource implications None

Implementation date N/A

Communication(s) Publication shortly

Organisational risk Low Medium High

1. Introduction

- 1.1. Our 2017-2020 strategy firmly places patients at the centre of high quality care. Currently we have limited means of evaluating whether this ambition is reflected in every day practice within clinics.
- 1.2. The Intelligence strategy, which was approved by Authority in January 2018, introduced a focus on patient experience, responding to the principles introduced by the Darzi review (2012) which stated, “If quality is to be at the heart of everything we do, it must be understood from the perspective of patients”.
- 1.3. A key part of putting patients at the heart of care, is creating a culture where feedback is actively sought and acted upon. By asking patients in a rigorous, systematic fashion about their experiences of care and treatment, patient experience can be accurately measured, interventions and best practice developed and shared, improvements made, and progress towards reaching our strategy vision evaluated and celebrated.
- 1.4. The national patient survey provides an opportunity to understand the experiences of patients and their partners in fertility clinics, to understand what matters most, and to understand what changes could have the greatest impact on their experiences at a difficult point in their lives.
- 1.5. Currently the YouGov report on the survey findings is embargoed and will be published shortly. It should be noted that there will be additional opportunities to discuss the findings of the survey so the purpose of today’s presentation is to provide an overview and discuss the findings with YouGov.

2. Approach

- 2.1. We put the project out to tender specifying a qualitative and a quantitative phase to explore patient experience of care in clinics. This ensured that patients and partner views informed the quantitative survey design. We received four applications and found the strongest proposal to be YouGov’s due to their detailed methodology and access to patients through their online panel.
- 2.2. We set up an internal working group which included two Authority members to provide oversight and give direction to YouGov as they planned the initial stages.
- 2.3. The qualitative phase included eight focus groups based in London, Manchester and online, and eight in-depth one to one interviews. This work generated a wide range of insights which helped feed into the development of the survey.
- 2.4. The survey was carried out between 3rd September and 2nd October 2018. The total number of responses was 1,017 patients or partners and the data was weighted to be representative by treatment type, age, region and partner status.

To the best of our knowledge, this is the largest and most representative survey of fertility patients in the UK, certainly in recent years.

3. Summary of results

- 3.1. Overall, most (75%) patients are satisfied with their treatment experience. There are no significant differences in satisfaction levels among private / NHS clinic users, between patients and partners, nor between those that had undergone more or less cycles.

- 3.2.** Just over three quarters (78%) of those who have visited a fertility clinic in the past two years spoke to a GP about their options when they first started thinking about fertility treatment. Just over half (54%) of patients are satisfied with the advice their GP provided, a sizable minority (26%) were not.
- 3.3.** The majority (73%) are satisfied with the coordination and administration of treatment and this is significantly higher for those whose most recent treatment was in a private clinic (78%), than for those who most recently used an NHS clinic (65%). This difference may reflect the resources available to the private sector. Private clinics in general are perceived to be more flexible, with their users more likely to be satisfied than NHS clinic users. An element of service provision comes through quite strongly – when people are paying, they expect better standards.
- 3.4.** Patients were more likely than partners to say that they felt involved and treated with respect and dignity in certain aspects of the fertility treatment process; those participating in the focus groups suggested that female partners are likely to feel more involved than male partners.
- 3.5.** Although three quarters (75%) remember receiving information about how to access counselling, one in five (20%) report not receiving any information. Patients welcome friendly and personable staff making an effort to learn their (and their partners’) names. Seemingly small changes, such as where staff talk to patients and their partners while they’re waiting for their appointments, has a positive impact.
- 3.6.** On the topic of feedback, 63% of respondents said that they felt able to provide feedback at any time. Very few can recall being told about formal feedback channels upfront and, perhaps as a result of this, few see this as an official part of the treatment process.
- 3.7.** Just over three fifths (62%) of those whose most recent treatment was at a private clinic said they paid more than they expected to, compared to less than a quarter (23%) of those who visited an NHS clinic. Just over three quarters (77%) of fertility clinic users who had additional treatments used a treatment add-on were satisfied with how open and transparent the costs of these were.
- 3.8.** Private clinic users are more likely to say they are aware of the HFEA than those who most recently used an NHS clinic (76% vs. 64%). A fifth (20%) of those that had treatment in the past two years considered the HFEA ‘Choose a Fertility Clinic’ website an important tool in choosing a particular clinic, particularly the information it provides on location and success rates.

4. Next steps

- 4.1.** We intend to publish the YouGov report shortly on our website alongside the data tables and highlight areas of interest for possible future work. We are currently exploring ways to best communicate the results, both internally and externally. This may involve breaking the report into briefings relating to specific themes.
- 4.2.** Due to the wide scope of the research, there is a large amount to digest and we believe the results will form a fundamental evidence base for our future work, for example, our 2020-23 strategy will be informed by this evidence. Following the discussion at Authority, we will look at ways to ensure the results are fed into future strategic planning and consider additional opportunities to explore key themes in greater detail. This may include presentations, workshops, articles and speeches at relevant conferences.

-
- 4.3.** We will also be considering how the survey could run in the future should we wish to replicate it and monitor progress over time.
-

5. Recommendation

- 5.1.** This is primarily an opportunity for Authority members to explore the findings with YouGov. There will be subsequent opportunities to discuss the operational delivery of areas considered significant.
- 5.2.** Therefore, the Authority are asked to:
- Note the results of the national patient survey
 - Comment on the strategic implications for the Authority.

Draft business plan 2019- 2020

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

Details:

Meeting Authority

Agenda item 8

Paper number HFEA (14/11/18) 896

Meeting date 14 November 2018

Author Paula Robinson, Head of Planning and Governance and Helen Crutcher, Risk and Business Planning Manager

Output:

For information or decision? For decision

Recommendation The Authority is asked to approve the draft business plan at its current stage of development, and to note that a draft will be submitted to the Department of Health and Social Care according to their timetable.

Resource implications In budget (to be agreed with DHSC in the usual way).

Implementation date 1 April 2019 – 31 March 2020

Communication(s) The business plan is published on our website.

Organisational risk Low Medium High

Annexes Annex A: Draft business plan for 2019/20

1. Introduction

- 1.1.** Our current strategy sets out our aims for 2017-2020. Our next business plan, for 2019-2020, will take us to the end of that strategy.
- 1.2.** In September, the Authority approved an outline of the business plan for 2019-2020. 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 Social Care (DHSC) in the next two months.
- 1.3.** Our business plans are designed to help us deliver our overall strategy, year by year. This business plan will deliver the third phase of our three-year strategy.
- 1.4.** As a reminder, the business planning cycle consists of the following main steps:

Date	Item
August 2018	Initial CMG discussion (done)
October 2018	First draft of 2018/19 business plan produced (done)
November 2018	Draft approved by Authority (this meeting)
January 2019	Draft submitted to DHSC; budget discussions
February 2019	DHSC comments on draft; budget near-final
March 2019	Finalisation of budget with Authority and DHSC
April 2019	Formal DHSC approval and publication on website.

2. Draft business plan

- 2.1.** The outline business plan (attached at Annex A), flows from the CMG discussion in August, and earlier discussions. As well as capturing our delivery plan for the third and final year of our current strategy, it also sets out our usual range of statutory work and other 'business as usual'.
- 2.2.** As agreed in September, the focus in our final year of the 2017 - 2020 strategy will be to embed changes and build on the work done in years one and two, while at the same time encouraging clinics to strive for excellence in leadership and patient support and provide the best possible outcomes for patients. Key pieces of strategic work will include:

Safe ethical effective treatment

- Work to define quality criteria to recognise excellent patient care in clinics.
- Work on encouraging and supporting leadership in clinics.
- Investigating ways that HFEA can support and encourage research.

Consistent outcomes and support

- Considering what more could be done to improve the availability of donor sperm and eggs.
- Exploring with professionals the key factors behind success at the clinic level.
- Improving the emotional experience of care in clinics, by continuing to encourage best practice, and focusing on support at inspection.

Improving standards through intelligence

- Review of the risk tool, to improve clinics' access to feedback about their own performance.
- Review our patient engagement channels and pilot a new patient forum to ensure we have access to feedback to inform our activities.

2.3. The current draft sets out our key activities for 2019/20. We can return to specific issues as this year progresses. 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 2018/19
- measuring our performance
- financial picture.

3. Recommendation

3.1. The Authority is asked to approve the draft business plan for 2019/20, for submission to the Department of Health and Social Care on request, and for further development.

3.2. A near-final version of the business plan will come to March 2019 Authority for sign-off, prior to publication.

Business plan (draft) 2019/20

Contents

Our role and strategic aims	3
What we did in 2018/19	4
Delivering our strategy in 2019/20	6
Measuring our performance	26
Financial picture	27
Other required information	28

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.

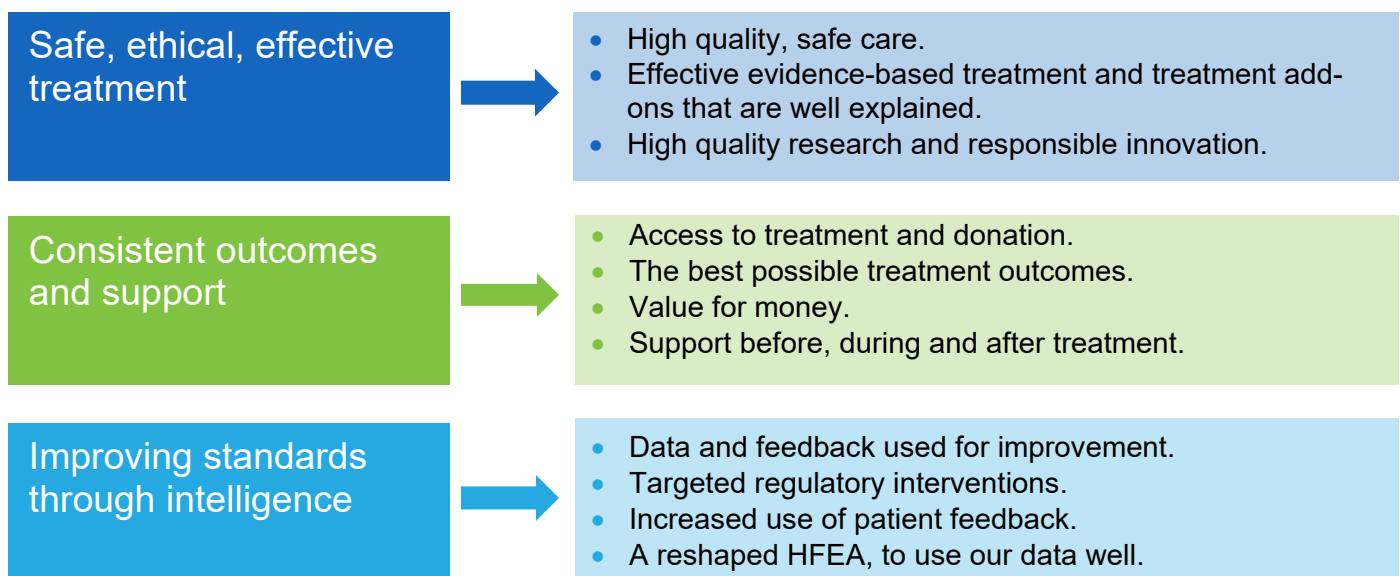
Patients, donors and donor-conceived people are at the heart of our strategy, and our work. We want them all to receive high quality care and support, at every stage in their journey through fertility services.

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 sperm or eggs, 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:



This business plan sets out how we will work towards our vision in 2019/20.

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
- license and inspect centres undertaking human embryo research
- license and inspect the storage of gametes (eggs and sperm) and embryos
- publish a Code of Practice, giving guidance to clinics and research establishments about the proper conduct of licensed activities
- keep a Register of information about donors, treatments and children born as a result of those treatments
- keep a register of licences granted
- keep a register of certain serious adverse events or reactions
- 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.

[DN: We will consider how we might update this in the light of Brexit]

What we did in 2018/19

Overview

[Section to follow in March/ April 2019]

Delivering our strategy in 2019/20

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 our 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: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Improve the quality of treatment, by encouraging world class research and clinical trials.
Consistent outcomes and support	4. Improve access to treatment. Our aim: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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.

Our people plan sits alongside the organisational strategy and in the final year we will continue to work to attract and retain talented and capable staff to support the whole of our strategic delivery.

The activities set out over the next few pages describe how we will meet these strategic objectives in 2019/20.

Although we are a specialist regulator, there are broad priorities that will be important across the health and care system which are relevant to us, and our programme of work is well aligned to these.

Activities for 2019/20

[We will review this summary once the following section is final, to sum up the year's work]

The focus of delivery in 2018/19 was on making full use of the tools and data resulting from the Information for Quality programme, to provide an enhanced range of information for patients and clinics on a range of topics.

The 2019/20 business plan represents the third and final year of our 2017 - 2020 strategy. As such, it includes all the remaining work we believe is needed in order to complete our strategy in 2020, and deliver the Authority's vision of high quality care for everyone affected by fertility treatment.

Our focus will be to embed changes and build on the work done in years one and two, while at the same time encouraging clinics to strive for excellence in leadership and patient support and provide the best possible outcomes for patients.

During the year we will be composing our next strategy and will aim to publish this in the first few months of 2020.

The activities set out over the next few pages will help us to deliver our strategic objectives in 2019/20, in the interests of high quality care for everyone affected by fertility treatment.

Activities for 2019/20

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.			
<p>Ensure that clinics are well regulated and provide a high quality, consistent service.</p>	<p>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.</p>	<ul style="list-style-type: none"> • All clinics and research establishments in the sector are: <ul style="list-style-type: none"> – 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 publish (eg, on their websites) and provide to us. • Patients know that all clinics are safe and appropriately licensed. • Reduction in the number of critical, major and other non-compliances. 	<p>Throughout year</p> <p>October 2019</p>

Aims	Methods and channels	Benefits and outcomes	Timescale
		<ul style="list-style-type: none"> Reduction in the number of clinic incidents, owing to learning from own and others' mistakes. 	
	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 the publication of our annual review of clinical incidents.	<ul style="list-style-type: none"> Publication of 'State of the sector' report for 2018/19, 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 events. 	November 2019 Throughout year
	Proactively encouraging and supporting leadership in clinics, on inspection and through wider engagement with the sector and professional bodies.	<ul style="list-style-type: none"> 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
	Updates to the Code of Practice including further guidance on electronic consent.	<ul style="list-style-type: none"> Guidance for clinics is up to date and reflects latest scientific developments, legal advice and policy decisions. 	October 2019
	Project to review HFEA consent forms and guidance around electronic consent.	<ul style="list-style-type: none"> Consent forms remain fit for purpose and accessible and reflect GDPR requirements. 	October 2019
Ensure that licensing decisions and other approvals are well governed.	Ensuring governance tools underpinning licensing and other decisions are in place and effective.	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> • Growing area of work dealt with effectively and efficiently, with applications processed according to performance indicator timelines. • Public confidence assured in mitochondrial donation and PGD approvals. • 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
	Implementing recommendations from a review of our licensing function to ensure it remains fit for purpose.	<ul style="list-style-type: none"> • Quality improvements to processes and licensing 'products' and the resulting decision making. • Revisions to Standing Orders, particularly Committee terms of reference and membership options. • Development of licensing reporting to Authority. 	March 2020

Strategic objective 2:

Publish clear information so that patients understand treatments and treatment add-ons and feel prepared for treatment.

Maintain up to date information on our website to increase patients' understanding about the science and evidence base behind treatments and added extras known as 'add-ons', and their safety and effectiveness.	<p>Inclusion of up-to-date scientific content on our website to maintain our expanded range of information about current and future treatment options and the scientific evidence base for these.</p> <p>In response to recommendations from SCAAC we will review our information for patients on treatment add-ons to ensure it reflects the most up to date advice.</p>	<ul style="list-style-type: none"> • Patients and others turn to us first 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. 	<p>Throughout year –</p> <p>SCAAC add on review in February 2020.</p>
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Aims	Methods and channels	Benefits and outcomes	Timescale
	SCAAC annual review of add on treatments.		
	Guidance for clinics on what information they should publish on their own websites about the add on treatments they offer to patients.	<ul style="list-style-type: none"> Information on clinics' websites is clear and transparent. 	Throughout year
	Undertake user testing of the website to allow us to further refine the way we publish treatment information.	<ul style="list-style-type: none"> Our information and site navigation better meets users' needs and preferences. 	Throughout year
	Responding to new scientific developments and media reports.	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> The horizon scanning panel meets once per year. The Scientific and Clinical Advances Advisory Committee meets to discuss issues identified through horizon scanning three times 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. 	June 2019 Throughout year 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.	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.	<ul style="list-style-type: none"> To assess whether the decisions made at the June 2017 Authority meeting are having a positive impact. 	Q1 2019-20

Aims	Methods and channels	Benefits and outcomes	Timescale
	We will undertake a project to explore ways to support research, including collaborating with research PRs, centres and other research stakeholders.	<ul style="list-style-type: none"> Support clinics and researchers in carrying out high quality research to drive up the quality of treatment and donation. 	March 2020
	Information provision for researchers requesting access to Register data.	<ul style="list-style-type: none"> Information for researchers is provided within 90 calendar days of approval. 	Throughout year
	<p>Review of arrangements for information provision for researchers requesting access to Register data, including:</p> <ul style="list-style-type: none"> how we engage and communicate with researchers using register data. a new data request process for researchers, including guidance and checklists. MOUs with external partners to ensure best use of resources. 	<ul style="list-style-type: none"> Register information is used to best effect, to increase understanding and facilitate good research, and ultimately benefit patients. More researchers can access and use HFEA register data. Increased standardisation and clarity of processes. Greater knowledge about the efficacy and safety of fertility treatment More efficient use of time and resource. 	May 2019

Consistent outcomes and support

Strategic objective 4:

Improve access to treatment.

Providing advice and information about access to treatment and donor conception treatment.	<p>Publishing information and advice about accessing services through various channels and keeping this under review, taking into account user feedback.</p> <p>Providing information for those considering going abroad for treatment on how they might</p>	<ul style="list-style-type: none"> People understand the possibilities and the hurdles and can weigh up the options open to them People can easily find relevant information and signposting on our website, to inform their next steps. 	Throughout year
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Aims	Methods and channels	Benefits and outcomes	Timescale
	access services in the UK, including through seminars at fertility shows.		
	Collaborating with the NHS website (NHS.UK) to put new patients in touch with better information about services when they first realise they may have a fertility issue.	<ul style="list-style-type: none"> • New patients find relevant signposting and advice more easily. • 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.	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.	<ul style="list-style-type: none"> • 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 2020
	Working with clinics, sperm banks and voluntary organisations to consider what more could be done to improve the availability of donor sperm and eggs.	<ul style="list-style-type: none"> • Better understanding of the factors affecting rates of donation and clinic procurement of gametes from overseas. • Sharing good practice with the sector 	March 2020

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.			
<p>Using our outcome data to improve the chances of successful treatment while avoiding adverse outcomes</p>	<p>We will analyse Register and other available data on success rates and work with our professional stakeholders to define and establish the factors that lead to successful outcomes, with a particular focus on service design, publishing our findings.</p> <p>Continuing to publish the annual Fertility trends report.</p> <p>Using data more on inspection and in inspection reports.</p>	<ul style="list-style-type: none"> • Publication of information about success factors (particularly around service design). • Patients are more aware of the factors which may affect their chances of success. • Fertility trends in 2018 report published. • Redesigned inspection reports focusing more on outcomes. • Patients' chance of a live birth is maximised. 	<p>March 2020</p>
<p>Identifying and implementing ways of improving the quality and safety of care.</p>	<p>Continuing our focus on quality and safety of care in inspection activities, in particular through focusing on:</p> <ul style="list-style-type: none"> • the leadership of clinics in providing high quality care • a continued focus on the consent provided by patients and donors • the emotional support provided to patients • ensuring information provided to patients about their choices and care is clear, evidence-based and objective. <p>We will continue to evaluate areas of regulatory concern and identify performance levers.</p>	<ul style="list-style-type: none"> • Improved compliance and a positive impact on the quality of care, support, outcomes and safety of patients. • 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. • If an issue subsequently arises (such as the death of someone with sperm or eggs in storage), the correct consents are more likely to be in place and are legally clear and robust. 	<p>Throughout year</p>

Aims	Methods and channels	Benefits and outcomes	Timescale
	<p>Improved Register data quality, as a result of work done previously under the Information for Quality (IfQ) programme.</p> <p>There will 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.</p>	<ul style="list-style-type: none"> • New data quality strategy implemented to set out clear expectations to clinics about data quality. • Fewer data submission and data accuracy related non-compliances and improved information assurance on inspection and audit. • More 'right first time' data submission from clinics into the Register. • Better service quality for Opening the Register (OTR) applicants. 	Throughout year
	To continue to develop the inspection regime to be more efficient and effective in the regulation of groups of clinics.	<ul style="list-style-type: none"> • 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 us and the clinics involved. 	March 2020
	Work to define quality criteria to recognise excellent patient care in clinics and allow patients to easily assess the quality of the care provided.	<ul style="list-style-type: none"> • Patients have clearer expectations about the quality care that they should receive. 	March 2020

Aims	Methods and channels	Benefits and outcomes	Timescale
Improving value for money, for both patients and NHS commissioners.	<p>Share benchmarking information with commissioners, working in collaboration with NHS England and others.</p> <p>Engage with stakeholders on commissioning guidance produced by the HFEA.</p> <p>Eliciting more feedback from patients as to whether they paid what they expected to for fertility services.</p>	<ul style="list-style-type: none"> • 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 2020
Improving the emotional experience of care before, during and after treatment or donation.	<p>Building on our earlier work to improve the emotional experience of care in clinics by defining and encouraging best practice in clinics and focusing on support at inspection. Training webinars will be delivered to the sector, alongside face to face events.</p> <p>Ensuring that best practice is applied to donors and donor-conceived people as well as to patients.</p>	<ul style="list-style-type: none"> • 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. 	October 2019
Implementation of new donor conceived register service and in addition counselling services for OTR applicants.	<p>New donor conceived register and service launched.</p> <p>New counselling services in place.</p>	<ul style="list-style-type: none"> • 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. • 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. 	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
		<ul style="list-style-type: none"> • Performance management measures put in place for future management of the services. • OTR applicants feel more supported and prepared to deal with the information they receive from us. • Evaluation of the new services provided to the Authority. 	
	Undertaking early scoping to understand requirements for the organisation to effectively support donor conceived people born after the 2005 lifting of donor anonymity.	<ul style="list-style-type: none"> • We are readier to prepare for these donor conceived people to access data from end of 2021 (non-identifying) and 2023 (full identifying information), plans for which will be implemented in the 2020 - 2023 strategy. 	March 2020
	Reviewing the impact of new technologies (such as direct to consumer DNA testing) on donor anonymity.	We have a clearer idea of the options available to the Authority and how these may affect the service provided to donors and donor conceived people in the future.	March 2020

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.

Making more targeted and responsive regulatory interventions, in the interests of quality and consistency, based on our data.	Applying the intelligence available to us from inspections, the sector, patient feedback and analysis of our data to make more targeted and responsive interventions.	<ul style="list-style-type: none"> • 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 2020
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Aims	Methods and channels	Benefits and outcomes	Timescale
	Reviewing our risk tool to improve clinics' access to feedback about their own performance.	<ul style="list-style-type: none"> • Risk tool brought up to date with latest benchmarks and available clinic data (entered through our data submission system, PRISM). • More clinic data published for clinics' own use using Clinic Portal. • Provide data to clinics through PRISM to allow them to benchmark their performance against the sector 	March 2020
Maintaining the Register of Treatments and Outcomes and working with clinics to ensure they are accurately reporting their data.	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.	<ul style="list-style-type: none"> • High quality data available to develop patient information and respond to information requests. • Risk-based regulation and evidence-based policy-making. 	Throughout year
Publishing and supplying the information we hold for the benefit of stakeholders.	Regularly updating Choose a Fertility Clinic (CaFC) information to assist patient choice.	<ul style="list-style-type: none"> • Provide more up-to-date and accurate information to patients. 	Throughout year
	Continued publication of inspection reports on CaFC.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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 of clinic comparison information and to plan future improvements. 	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
	Continuing to facilitate timely access to information from the Register for those who are entitled to it.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • Legal and Parliamentary requirements continue to be met within time limits. 	Throughout year
	To continue to publish statistical and other reports, including the Fertility trends and State of the sector reports.	<ul style="list-style-type: none"> • Our Fertility trends report: <ul style="list-style-type: none"> – 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 – carries ‘official statistics’ status. 	March 2020
		<ul style="list-style-type: none"> • Our State of the sector report 2018-19: <ul style="list-style-type: none"> – 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 	November 2019

Aims	Methods and channels	Benefits and outcomes	Timescale
		<ul style="list-style-type: none"> – increases transparency and maximises opportunities for learning from incidents to improve quality of care for patients. 	
Responding effectively to specific enquiries from individuals.	Continuing to respond to the many individual patient and public enquiries we receive each year.	<ul style="list-style-type: none"> • 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 development of additional information which could be placed (for example) on our website. 	Throughout year
Maintaining our role as the UK's competent authority for ART in the EU ¹ [DN: We will consider how we amend this in light of Brexit]	Gain intelligence through participation in competent authority events and implementation of associated EU decisions.	<ul style="list-style-type: none"> • 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. 	Twice annually Throughout year

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

Aims	Methods and channels	Benefits and outcomes	Timescale
Gaining insight into the patient experience in clinics and encouraging good practice based on feedback.	Analysing and using the intelligence gathered through various patient feedback channels to inform our activities and our messaging to clinics, sharing the information with professional stakeholders.	<ul style="list-style-type: none"> 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 us and our professional stakeholders. 	Throughout year
	Reviewing our patient engagement channels and piloting a new patient forum to ensure we have access to feedback to inform our activities.	<ul style="list-style-type: none"> Patient feedback loop in place to ensure a regular flow of fresh feedback which can be incorporated into our stakeholder interactions and regulatory approach. 	
Ensuring we are a good value organisation and that we make best use of our limited resources.	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, in line with a revised IT strategy.	<ul style="list-style-type: none"> 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. We continue to move away from bespoke systems, standardising our approaches to ensure they are resilient. 	Throughout year
	Ensuring that we retain the staff we need in order to operate a good quality service, and implement our People plan for 2017-2020.	<ul style="list-style-type: none"> We are able to maintain the staff capacity and capability to deliver our strategy and our core statutory duties. 	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
		<ul style="list-style-type: none"> Continuing to develop our staff to ensure they have the skills they need through Civil Service Learning and other means. 	
	Embed revised internal records management, information assurance and information governance arrangements.	<ul style="list-style-type: none"> Completion of implementation of new document management system to ensure that records are securely held and that good practice is followed. Good records management practice is embedded and maintained, including records retention and behaviours. Information governance arrangements comply with latest requirements and roles and responsibilities and are clearly set out for staff. Make best use of the Senior Inspector (Information) post, focussing on information assurance. 	March 2020
	Continue to engage on emerging international work.	<ul style="list-style-type: none"> Take full advantage of expertise and seek opportunities to maximise the potential for exporting our expertise, raising standards overseas and raising revenue for the UK. 	March 2020
	Undertake a fee review informed by our income forecasting model.	<ul style="list-style-type: none"> Best value for money for patients. 	March 2020
	Plan for move to new office premises in 2020.	<ul style="list-style-type: none"> Make the best use of Crown Estate property, in keeping with the wider interests of government property strategy. 	March 2020
	Develop our organisational strategy for 2020 – 2023.	<ul style="list-style-type: none"> Focus our limited resources where we can have the most strategic impact and develop clear aims for the next three years. 	March 2020

Aims	Methods and channels	Benefits and outcomes	Timescale
Ensuring we are easy to deal with and offer a professional service.	Full realisation of the benefits of our improved Register function and processes (including the data submission system and Clinic Portal), including ongoing engagement with and feedback from clinics.	<ul style="list-style-type: none"> • PRISM fully bedded in with clinics and Electronic Patient Record System (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. 	March 2020
	Continuation of engagement arrangements with clinics on fees charged.	<ul style="list-style-type: none"> • 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 general data protection regulation	<p>Ongoing compliance with government requirements, including:</p> <p>Reporting in our annual report on the growth duty and compliance with the regulators' code.</p> <p>Complying with the business impact target by identifying and reporting any 'in-scope activity'.</p> <p>Complying with the general data protection regulation.</p>	<ul style="list-style-type: none"> • We respond to government requirements and new initiatives in a manner consistent with our legal status, and proportionately within our small resource envelope, carefully recognising our duties. • Annual report published including required information. • Compliance with the business impact target for any activities that may be in scope. 	<p>Throughout year</p> <p>June 2019</p> <p>Throughout year</p>
Ensuring we're an effective collaborator and partner in the interests of the efficiency of the wider Department of Health and Social Care group of arm's length bodies (ALBs) and other health organisations.	Continued participation in the collaborative regulatory advice service for regenerative medicine, to provide advice to those working in the life sciences industry.	<ul style="list-style-type: none"> • Continued constructive joint working between us and 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, allowing them to access the right advice more quickly. 	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
	<p>Sharing services and infrastructure with other organisations as practicable.</p> <p>Maximising the benefit of finance resources being shared with the HTA.</p> <p>Using Civil Service Learning as a key learning and development provider.</p> <p>Continuing to receive facilities services from the landlord of our office premises via an SLA.</p>	<ul style="list-style-type: none"> We continue to operate in as efficient a way as possible, extracting maximum value from shared arrangements and seeking other opportunities. 	Throughout year
	<p>Collaborative and partnership working with other ALBs and health regulators UK wide, such as the Care Quality Commission (CQC), NHS England, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom Accreditation Service (UKAS), Health Research Authority (HRA), General Medical Council (GMC) and the devolved nations, maintaining the close positive working relationships that have been developed over the past several years.</p>	<ul style="list-style-type: none"> 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
Maintaining our previously established collaborative information management relationships.	Maintaining our good working relationships with other relevant information management bodies, such as the Government Digital Service (GDS), NHS Digital and being an active member of the National Information Board (NIB).	<ul style="list-style-type: none"> 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 2019]

Financial picture

[Section to be added in Jan/Feb 2019]

Other required information

[Section to be updated in March 2019 to ensure this reflects the most up to date picture]

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).

Our governance structure includes corporate governance tools, a people plan (that we relaunched in 2018) 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 and Social Care 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 us 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 £10billion 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 £5billion 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 and Social Care 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, we have significantly reduced our staffing, in keeping with overall pressures on the public sector and Government expectations. Our staff complement is now 68 (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).

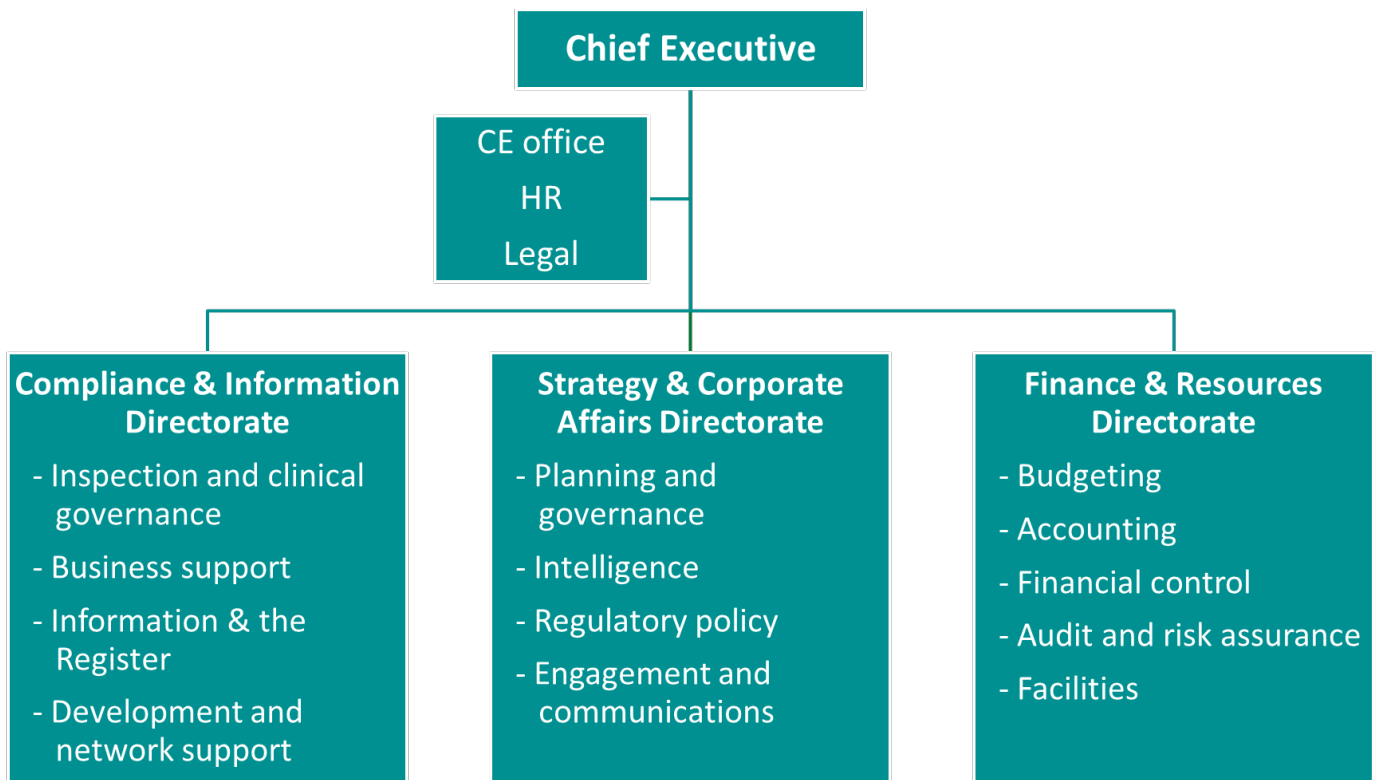
Having made considerable savings, our size will now need to remain stable for the foreseeable future. We need to ensure we retain the capability and capacity to deliver our overall strategy for 2017-2020.

We have a people plan, referenced earlier in this business plan, which sets out how we will ensure we attract and retain the capacity and skills we need in order to deliver our vision of high quality care for everyone affected by fertility treatment. 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 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 and Social Care 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 our 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 and Social Care (in 2014) sets out the critical elements of the relationship between us and the department and other ALBs where relevant. As an ALB, we will continue to manage our assurance and risk management independently and report this to the Authority. We recognise that, on rare occasions, our risks or assurance may have a significant impact or interdependency with the Department of Health and Social Care or other ALBs and understand the correct dialogue and escalation mechanisms for communicating the issues and relevant mitigations.

Equality Act 2010

We remain 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 we fulfil our 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

We maintain 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.

Our 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 to ensure that 'section 33A patient-identifying data' is appropriately protected.

We remain fully compliant with Cabinet Office rules regarding data security and with our 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 we have 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

We have no estate. In April 2016 we moved into NICE's office space in Spring Gardens, taking up 269 square metres.

We work 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.

Looking ahead, our office strategy is to co-locate with other public bodies. To that end, we are planning to move in 2020.

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

We comply with all relevant Department of Health and Social Care 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 Crown Commercial Service (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 and Social Care target for public sector procurement of 23% of procurement spend going to Small and Medium- sized Enterprises 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 and Social Care with quarterly reporting on procurement.

There is no significant non-pay spend that is not via CCS, NICE or Department of Health and Social Care 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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Donor conceived register

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

Details:

Meeting	Authority
Agenda item	9
Paper number	HFEA (14/11/18) 897
Meeting date	14 November 2018
Author	Joanne Anton

Output:

For information or decision?	For decision
Recommendation	<p>The Authority is asked to consider the service delivery options for the Donor Conceived Register and the OTR support service and agree a way forward.</p> <p>Of the four broad options, 'end-to-end' service model option 3 scores the highest (see Annex A).</p> <p>This option has a range of external providers who have expressed an interest. If the Authority is minded to support this option, members may wish to consider the preferred providers' approaches around counselling support and experience with laboratory relationship arrangements</p>
Resource implications	Dependent on the service delivery option chosen
Implementation date	March 2019
Communication(s)	DCR Registrants Panel and more widely
Organisational risk	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High

1. Introduction

- 1.1.** The HFEA is committed to supporting donors and donor conceived people and putting the quality of care they receive at the centre of our work. This paper seeks views on two related aspects of our work on donation: the organisational form of the pre-HFEA voluntary contact register service, the Donor Conceived Register (DCR); and the counselling element of the HFEA statutory scheme that governs applications by donor-conceived individuals, donors and parents for Register information which we call Opening the Register (OTR).
- 1.2.** We took over responsibility for the DCR from the Department of Health in April 2017. At that time the service was provided by the National Gamete Donation Trust (NGDT). In November that year we issued an invitation to tender for the DCR service with a closing date of January 2018. In the event only one organisation bid to run the service but we judged that the quality on offer was insufficient to our stated criteria. The NGDT have, however, agreed to continue to run the DCR until we establish a new service model, though we are working to a transition date of the end of this financial year.
- 1.3.** We issued a consultation on a new DCR service in autumn 2018 but had to pause the consultation when PAC-UK, who had agreed in principle to provide the counselling element of the new DCR service, decided that for strategic reasons they could no longer be involved. Moreover, PAC-UK also decided that they no longer wished to provide the counselling element of our OTR service, though they have given us time to find a new provider. However we have continued to discuss service requirements with stakeholders, including via AFPO and the DCR Panel members.
- 1.4.** Time is therefore tight. We are in situation where we need to find service solutions to distinct but related services. In assessing options, we are keen to see whether new service providers can meet both needs.
- 1.5.** The most significant challenge will be finding the right support service for such a specialised area and for people who have a complex set of needs. Although we are unlikely to find an organisation that is a perfect 'fit' we have identified four options:
 - Option 1: Using the power of direct to consumer DNA testing and matching websites, with counselling provision delivered by the HFEA
 - Option 2: In-house with both the DCR and counselling provision delivered by the HFEA
 - Option 3: Single service externally provided, with the: DCR and counselling provision delivered by (a) GeneHealthUK or (b) the National Fertility Society (NFS). We were recently approached by the Hewitt Fertility Centre's counselling team and Rafan House. These options are set out at 3(c) and 3(d).
 - Option 4: mixed model with the DCR run by an external provider (either (a) GeneHealthUK (b) National Fertility Society (c) the Hewitt Fertility Centre's counselling team or (d) Rafan House) with counselling provision delivered by the HFEA.
- 1.6.** The pros and cons of the options are set out in detail in section three of the paper.

2. Background

Donor conceived register

- 2.1.** The DCR, was set up specifically for people conceived before the HFEA register was set up in August 1991. Unlike, those who were conceived after August 1991, these individuals have no statutory access rights to information about their donor or person born from their donation.
- 2.2.** The Register links these individuals through DNA matching and offers advice and support, via the registration, linking and mediation process. The service also brings people into contact with others in the same situation. The DCR includes a small number of people conceived after August 1991 who may have siblings on the register. Around 400 people are currently registered on the DCR, an online forum exists via social media and members are invited to meet around twice a year. They match around five people a year.
- 2.3.** In thinking about the DCR service it is helpful to see it as comprising three distinct elements: administration and support; DNA testing and matching; and counselling, support and mediation.

Administration and support	DNA testing and matching	Counselling support and mediation
providing guidance and information to existing and new DCR members through a telephone advice line	DNA sampling to industry standards with appropriate accreditation, analysing against an appropriate quantity of polymorphic autosomal DNA markers associated with this	providing counselling sessions, where necessary, and support through the registration or linking process
managing the co-ordination of DNA tests with the agreed supplier	holding securely the DNA data	providing mediation to registrants
providing support and guidance to individuals before, during and after DNA testing	forwarding the results to the administration service with details of results so contact can be made with the registrant	counselling via telephone and face to face if necessary
maintaining the register (in line with industry standards) and confirming register matches with individuals		
processing the results of matching sensitively		
funding the regular meetings of the DCR and other support required, such as raising awareness, publicity and supporting the website and Facebook group		

Opening the Register support service

- 2.4.** The Human Fertilisation and Embryology Act requires the Authority to keep a Register of information about donors and treatments involving the use of donor gametes and embryos in the UK after August 1991. Donor-conceived individuals and donors have a statutory right of access to information held on the Register.
- 2.5.** We currently provide support for DC people and donors where:
- A donor who donated before April 2005 who is considering re-registration to become identifiable on the HFEA Register
 - DC offspring applying for non-identifying information
 - DC offspring applying for identifying information
 - Donors who are aware that DC offspring have applied for identifying information
 - A parent is considering telling their child they are donor-conceived
 - Intermediary services where contact is sought
- 2.6.** We also offer support to donor conceived adults who are considering joining the Donor Sibling Link where they are able to exchange their contact details with people who share the same donor and also if they get a match and want to talk about how they feel about it.
- 2.7.** The OTR service is provided in-house, by HFEA staff, although we offer a support service for people accessing information from the Register, currently delivered by an external post adoption counselling agency, PAC-UK.
- 2.8.** Intermediary services include up to five sessions with support and intermediary worker (per case) - i.e. two per individual and one extra for any meeting. Re-registration and seeking non-identifying information: up to two sessions per individual of implications counselling.
- 2.9.** The current take-up of counselling by OTR applicants is low. In the last three years PAC-UK has delivered 20 hours of counselling, mostly to donors and donor conceived people. We do expect this to increase as more donor conceived people are eligible to receive identifying information about their donor from 2023.
- 2.10.** We will continue to manage this service but as noted above, since the counselling provider to the OTR service has pulled out we need to find a new counselling service.

3. Service options

- 3.1.** Before considering the merits of the four options it is useful to consider a number of broader factors.

The views of users

- 3.2.** The success of any of these options will in large part depend on whether they meet the needs of the users. There is no representative group for those who use the OTR service, but we recently met the newly appointed Chair of the DCR Registrant's Panel to gather feedback on the main service options outlined in this paper. The Panel expressed mixed views, largely formulated based on their own experience of being a donor or donor conceived person. None of the options were completely unacceptable, but neither was there a 'perfect' option from their perspective.

More detailed views are set out against each option later. We received late submissions of interest from the Hewitt Fertility Centre's counselling team and Rafan House which means that it was not possible to gather feedback on these options.

3.3. Overall, the Panel want a service that will deliver:

- An accurate and reliable DNA testing service
- High quality counselling
- A single point of contact
- A helpline that a person can call if they find out they're donor conceived and need support
- The opportunity to meet with other donor conceived people and have access to peer support

3.4. We are grateful to all for their advice and support in developing this proposed new service.

Providing a service for both the DCR and OTR users

3.5. Now that we are in a situation where we need to find a service for both DCR users and OTR users, it makes sense that the same front-end provider covers both services from both an efficiency and a user experience perspective. That said, there are important similarities and differences between the two services and these need to be borne in mind.

3.6. The services are similar because both sets of users may:

- Be seeking information about their donor or person conceived following their donation.
- Potentially be provided with identifying information about their donor.
- Wish to meet their donor and require support mediating that first contact.
- Require support/counselling to help them through this process.
- Both pre-1991 users and those OTR applicant between 1991-2005 have limited access of information.

3.7. They are different because:

- Only OTR users have the statutory right to access information on the HFEA Register about their donor or person conceived following their donation. This means that DCR users are less likely to be able to find out information about their donor or their donation.
- Only DCR users need to provide a DNA sample in order to try and find a match on the DCR Register.
- DCR users may be more likely to feel anger and frustration because of the lack of access to information.
- DCR users are likely to be older than OTR users.

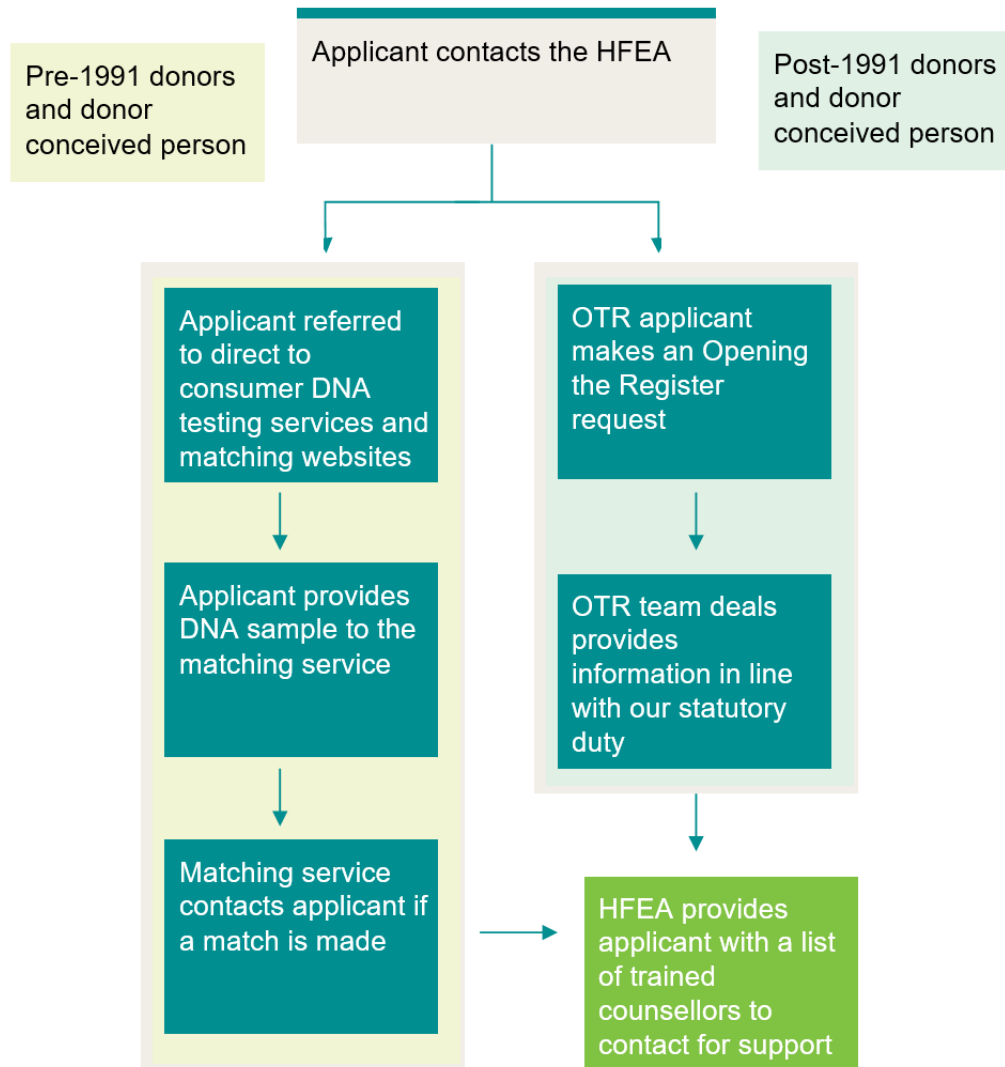
3.8. Considering these differences, the Authority needs to find a support service that can meet the needs of each service. Some users may only require emotional support from those who have knowledge of this area, and who have experience of mediation, whilst others will require experienced counsellors who can provide traditional therapeutic counselling. Some may also benefit from the experience genetic counsellors may have of talking about family dynamics and concealment/sharing of information.

The differing types of counselling available

- 3.9.** The different support requirements of users lend themselves to different counselling provision. The option 3 in this paper is based in different schools of counselling, which are summarised below.
- 3.10.** Genetics counsellors work directly with patients and families offering genetic/genomic information and support allowing them to make health decisions. It is defined as 'a communication process which deals with human problems associated with the occurrence, or the risk of occurrence, of a genetic disorder in a family' (American Society of Human Genetics, 1975). Genetic counselling is not primarily "counselling" in the therapeutic sense. Genetic counselling is non-directive and aims to explain the facts as clearly as possible, giving the person or family accurate information on their options in a way which they can understand, and helping them to make up their own minds.
- 3.11.** Fertility counsellors often provide therapeutic counselling. This form of counselling is more likely to concentrate on building an in-depth relationship with their clients. They are trained to help others cope with emotional and social issues. They offer support to couples and individuals who are undergoing or thinking of undergoing fertility treatment, whether prior, during or after treatment. Counsellors will be either accredited by a recognised counselling body, and/or on a register which is accredited by the Professional Standards Authority.
- 3.12.** Psychotherapeutic counselling differs from traditional counselling in the emphasis it places on the in-depth therapeutic relationship jointly created by the therapist and the client. This relationship is a central factor (UKCP). However, therapeutic counselling and psychotherapy are often considered to be interchangeable therapies that overlap in a number of ways.
- 3.13.** All of the different types of counselling have an element of emotional support and relevant qualifications around that as part of their respective accreditation. Whatever option is chosen we will work with expert stakeholders to help source people with the relevant expertise in providing support, counselling and mediation. Key to the effectiveness of any future support service will be the additional training provided, although there are advantages in considering experienced fertility counsellors who require less training in reproductive medicine, the legal framework and donor conception issues. Given the specialist nature of these issues the HFEA will work with professionals/an agency to provide the necessary training. This approach worked well in the past, including when the HFEA organised the delivery of a two-day training course for post adoption counsellors ahead of the OTR support service.
- 3.14.** The remainder of this section sets out the advantages and limitations of each of the four options. We also reflect feedback from the DCR Registrants Panel where we have it against each option. A table summarising the service qualities of each option is at Annex A of this paper.

Option 1: Using the power of direct to consumer DNA testing and matching websites with counselling provision delivered by the HFEA

- 3.15.** Existing and new DCR registrants could be referred to commercial direct to consumer DNA testing services and matching websites instead of registering to a dedicated Donor Conceived Register. When a match is made they are provided with a list of trained counsellors commissioned by the HFEA. The same pool of counsellors will provide support to OTR applicants. The rest of the OTR service will remain the same. This is a radical option which greatly increases the chance of a match, but with new complexities about control of personal data.



3.16. The advantages are that:

- The use of large commercial DNA testing services and matching websites would increase the likelihood of donors and donor conceived people finding a match. The DCR has around 400 people registered and only matches around five people a year. Genetic testing websites have a global reach far wider than could realistically be achieved by the HFEA.
- The HFEA could commission and train a pool of counsellors to fund sessional counselling when a match is made – either via the genetic testing website or via our OTR service. It is unlikely that we would need to fund additional staff but this could change once we reach 2023 and the number of OTR requests increase.
- This is likely to be the lowest resource option for the HFE, because it would not involve HFEA directly funding the cost of running the DCR database, paying for the DNA test, or an external agency to provide counselling support. However, the Authority could explore paying one-off fees (advertised at c.£.80-100) for people to register on these sites.

3.17. The limitations are that:

- Registering to these websites risk inadvertently disclosing the identity of a donor or of a person's donor conceived origins without their expressed consent. This is opposed to those who register with the DCR with the explicit intention of trying to find their donor or the person conceived from their donation.
- The HFEA would have no oversight over the DNA matching service and the support offered by the commercial genetic testing websites. The Authority raised concerns about such issues when it discussed these websites at its September meeting.
- Potentially difficulty to co-ordinate counsellors without a central contact point for users which would be managed by an external organisation.

DCR Panel feedback on option 1

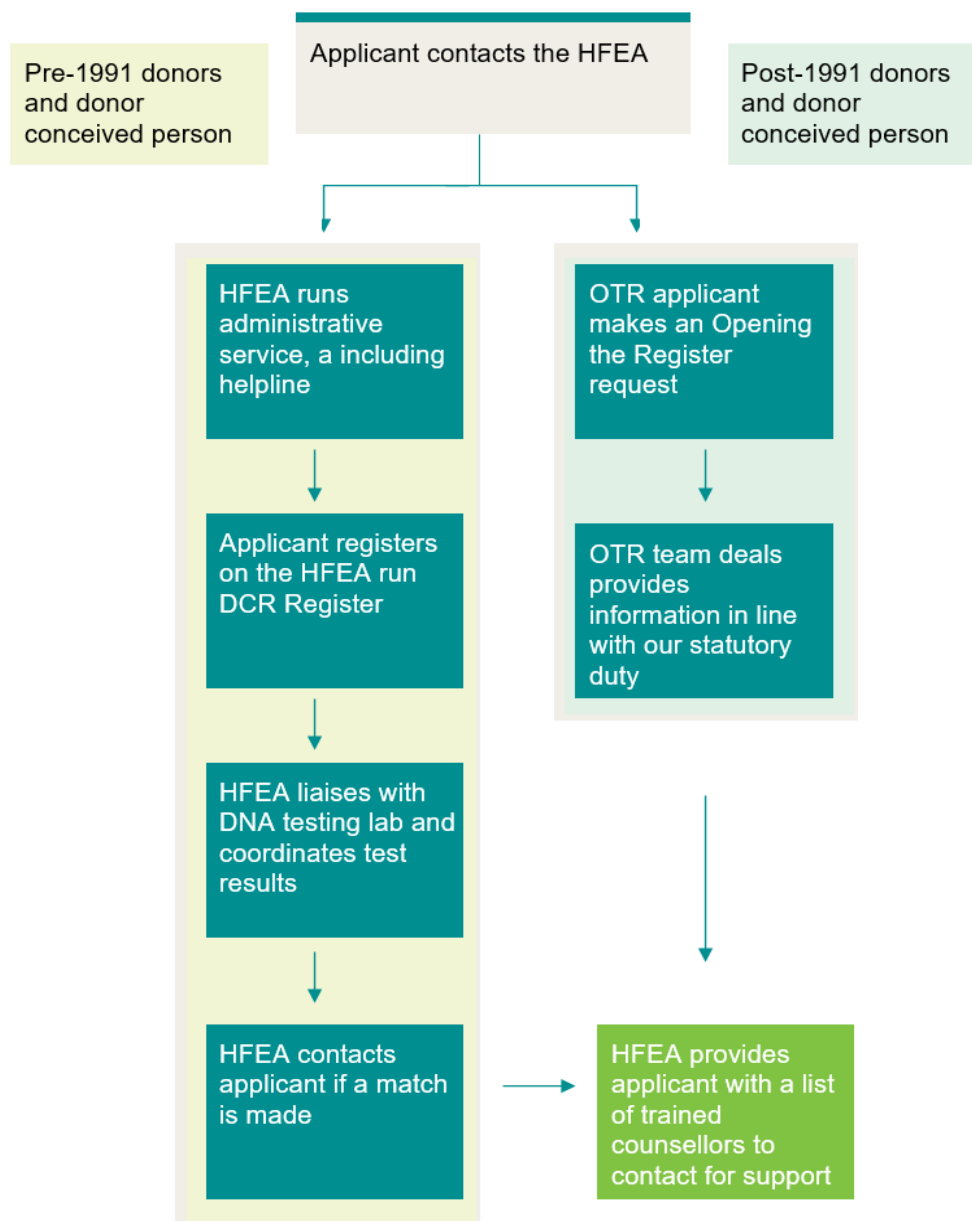
This option received the least favourable feedback. Registrants were concerned that some will not want to share their genetic information with a commercial DNA testing website. Some will not want to risk being identified by anyone else, and others will worry that their information could be passed on to other companies. Also, some donors will not want to register and be matched in this way if there is the possibility that the donor conceived person is unaware that they are donor conceived.

However, some are already registered to these sites and are more favourable because of the wider coverage and are impressed with the high standard of DNA testing that some of these sites offer, in comparison to the DNA service the DCR has received in the past.

Option 2: In-house with both the DCR and counselling provision delivered by the HFEA

3.18. The DCR could be integrated into our work and we contract out the DNA analysis. The DCR database and HFEA Register would be kept separate from each other. We would run the administrative element of the DCR service and manage and train a pool of counsellors. The same pool of counsellors will provide support to OTR applicants. The rest of the OTR service remains the same.

Diagram 2



3.19. The advantages are that:

- Service users only need to contact one organisation as all the information about donors and donor-conceived people will be managed by the HFEA in one place (although information relating to the DCR and OTR will be kept separate and managed differently).
- The HFEA would not need to rely on external agencies (except for DNA testing). Like option 1, we would commission and train a pool of counsellors and could fund sessional counselling when a match is made via our OTR service.

3.20. The limitations are that:

- It may confuse users to have such different systems (one statutory and data-based, the other outside of the HFEA remit and DNA-based), side by side. However, there are international examples where this model exists.
- While absolute costs have yet to be established this is likely to be a relatively costly option offering fewer opportunities to make economies of scale. Previous estimates presented to the Authority suggest that an in-house service would cost at least £28,000 to staff annually, plus £7,000 overheads, plus costs for bespoke DNA analysis arrangements with a laboratory, plus contracted funding counselling/intermediary support for users.
- It would also require an additional member of staff and would divert other HFEA staff from their core functions.
- Potentially difficulty to co-ordinate counsellors without a central contact point for users which would be managed by an external organisation.
- We are, arguably, not suited to running this type of service for the DCR. We are not set up to offer a helpline and we do not have pre-existing relationships with DNA laboratories or have the necessary expertise in providing genetic test results.

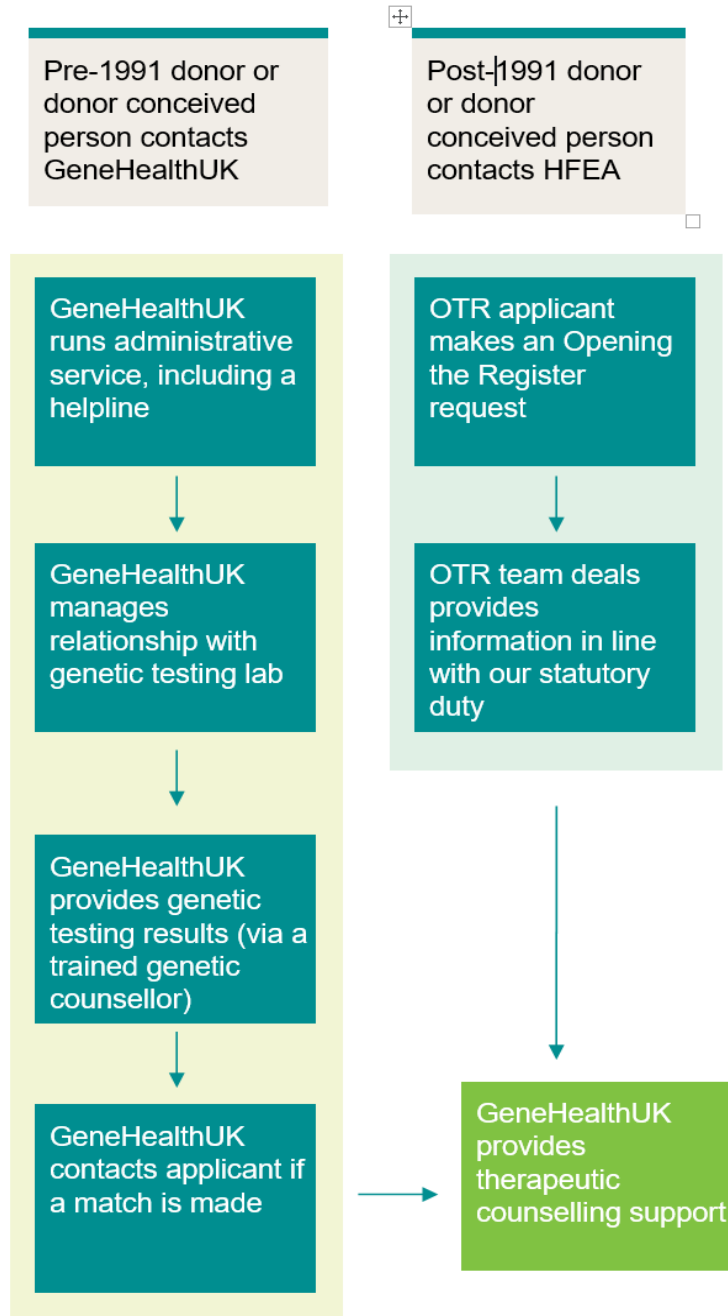
DCR Panel feedback on option 2

This option received mostly favourable feedback with some thinking that the HFEA could run this service well and in symmetry with the OTR service. Some however thought that the quality of the service be impacted as the HFEA doesn't currently have the necessary skills, staff or infrastructure.

Option 3: Single service externally provided with the DCR and counselling provision delivered by an external provider- expressed as Options 3a-3d

- 3.21.** Under service model option 3, the DCR is run by an external provider who could provide an end-to-end service. This end to end service includes an administrative service (eg booking appointments, staffing an information-giving helpline, coordinating the DNA testing part of the DCR service with an appropriate laboratory and managing return of testing and matching results). This service model is set out in diagram 3 below. Although the example provided is for option 3a, the organisational model applies equally to the other options.
- 3.22.** This external provider end-to-end service model also provides emotional support specifically tailored to donor conception issues, with the capacity for making arrangements to provide premises for one-to-one counselling with a trained counsellor, including face-to-face counselling if requested.
- 3.23.** All of the providers in options 3a-3d have expressed an interest in providing an end-to-end DCR service. They primarily differ in their counselling approach and experience and existing interaction with genetic testing as part of their current work. We ask members to note, however that all of these providers are happy to work with the HFEA to provide accredited counsellors who are suitably trained (in relation to donor conception issues) should they be commissioned by HFEA to provide this service.
- 3.24.** Please note that expressions of interest for end-to-end service provision were based on the following rough funding guides: £7-10,000 for setup costs with some flexibility based on a realistic proposal, plus £45-50,000 running costs per year that includes the whole service, and OTR support, and requiring ability to provide the specified service within these costs during a three year initial contract. All of the providers discussed under option 3 have indicated that they can deliver the service within our budget.
- 3.25.** Please note that option 3c and 3d were later to express their interest to HFEA, and therefore as providers they were unfortunately not able to be included in our discussion of service model options with the DCR Panel.
- 3.26.** All of the agencies in options 3a- 3d have also expressed an interest in taking over the provision of counselling support to OTR applicants as needed. Please note that the rest of the OTR service would remain the same as is currently provided under this service model.
- 3.27. Option 3 (a) GeneHealthUK** is a UK-wide private genetic counselling and testing company who could provide an end-to-end service, and are open to the possibility of recruiting additional counsellors with different expertise than their current service remit requires. They are registered with the Association of Genetic Nurses (AGNC), the Genetic registrations board (GCRB), are ISO accredited and have CQC inspections. The company provides fertility and disease-facing genetic testing and counselling via their own laboratory arrangements. They will also soon be offering genetic counselling for PGD with an IVF company. They have 14 sessional counsellors, who mostly work alongside their NHS practice.

Diagram 3



3.28. The advantages are that:

- This agency already has an established structure in place to offer an end to end service, including established links with genetic testing laboratories. They already provide an end to end service of counselling and testing services, albeit not around donor conception issues.
- They have administrative and booking services, laboratory relationships and a flexible team of sessional counsellors who are used to working the phone or face to face. The counsellors are willing to have HFEA led training around post donor conception issues (in the same way that we trained PAC-UK before they began offering the OTR support services).

- The counsellors have direct experience of handling genetic test results and the sensitivities of disclosing that information.
- The counsellors understand the counselling issues around family dynamics and concealment/sharing of information because this comes up in families around genetic conditions. They are happy with the small numbers in relation to the DCR and OTR services and if numbers expand in future. They are interested in this area of work and are enthusiastic about working with us.

3.29. The limitation is that:

- Counsellors who work for GeneHealthUK are not exclusively therapeutic counsellors and they have no direct experience of adoption or post donation support. They do however have experience of fertility and embryo testing. They are open to the possibility of hiring additional counsellors with therapeutic experience and knowledge of the area. Training on the specific issues relating to these services would be required (as with the other options).

DCR Panel feedback on option 3(a) GeneHealthUK

This option also received some positive feedback. Some liked it because it sounds similar to the service already in place. They are encouraged that an external agency wants to run the service, and that they would have counsellors with experience of DNA testing to provide genetic test results. They also like that this model could provide an end to end service. They felt that additional counsellors with therapeutic experience would need to be recruited to provide the more emotional support that is sometimes required. They thought that some counsellors who already provide support to DCR Registrants might be interested in working with this model or other external agencies.

3.30. Option 3(b): The National Fertility Society (NFS) is an umbrella group for advanced specialist fertility counsellors. Their members are registered with the British Association for Counsellors and Psychotherapists (BACP) or the National Counselling Society (NCS). They are a relatively new organisation which has been operating for around 17 months. They have around 40 counsellors who have completed their NFS Advanced Specialist Fertility Counselling Diploma and 140 members in total, with new cohorts awaiting training. Their courses have been recognised by the NCS and met the standards of their registration with the Professional Standards Authority.

3.31. The advantages are that:

- NFS counsellors have fertility counselling experience, with experience of donor conception. They recently designed a counselling course for their fertility counsellor members on 'counselling donor conceived children and adults', though we have no assessment of the quality of that training.
- They can provide telephone counselling, and face to face counselling is possible. They sometimes use FaceTime with children or parents. The majority of their counsellors are already working with children, but in general counselling and are trained to support any age group. They also have counsellors with experience in adoption. They are happy with the small numbers in relation to the DCR and OTR services and if numbers expand in future.

3.32. The limitations are that:

- They are relatively new organisation, and as yet unproven.

- They do not have the necessary structures in place, but they do think they could have it ready in time for March 2019. In considering this option the Authority will wish to weigh clearly the relatively untested nature of the NFS with the provision of such sensitive services.
- The NFS do not have pre-existing links with DNA labs or experience of providing genetic test results. However, they could put this in place if this was a requirement. Training on the specific issues relating to these services would also be required (as with the other options).

DCR Panel feedback on 3(b) The National Fertility Society (NFS)

This option is also fairly similar to what happens already with the DCR and received some positive feedback. However, around 25% of the feedback said that for some people accepting counselling from a fertility counselling organisation could be difficult. Whilst some people are accepting of donor conception or are ambivalent, some are strongly against it. This option could therefore be a barrier to access for some people.

3.33. Option 3 (c): Hewitt Fertility Centre's counselling team comprises of four experienced fertility counsellors who provide therapeutic counselling and support to people undergoing fertility treatment and the group is based in Liverpool. They are either already accredited with the British Infertility Counselling Association (BICA) or working towards accreditation.

3.34. The advantages are that:

- They have a multi-disciplinary team of experienced counsellors with relevant experience of gamete donation, donor registration and re-registration, guiding recipients through the donation pathway, record keeping, assisting the donor conceived and parents of donor conceived children with accessing information regarding their donors, providing counselling to gametes donation participants and the use and interpretation of the information from DNA testing in the process of matching donor to recipients.
- They are an established and fully functional counselling service who provide implications counselling service to donors and their partners and recipients, in line with BICA guidelines and the BACP ethical framework. The service covers referrals, allocation and booking processes for Cheshire and Merseyside. They offer continuity of support before, during or after treatment regardless of outcome. They have a partnership relationship with the Donor Conception Network. They have partnerships with their satellite sites in Wigan, Chester and Leighton.
- There is a genetics department on site in the Liverpool Women's Hospital with geneticists and genetic counsellors. They are part of the training programme for genetic counsellors, therefore the genetics service already has several genetic counsellors who are aware of the service and treatments they provide, which allows them to have a strong working partnership with them.

3.35. The limitations are that:

- They don't currently provide support to donor conceived people, however they could address this by establishing new guidelines in partnership with BICA. These protocols could focus on managing the expectations of the donor conceived (for instance and guidance to approaching siblings) with their mental health and safety in mind. They could 'Skype' or 'Facetime' in order for support to be provided nationally. Alternatively, contracts with other experienced counsellors could be set up.
- Although there was not sufficient time to seek feedback from the DCR Registrants Panel on this option, akin to option 3(b), we have heard that some people may find it difficult to accept counselling from a fertility counselling organisation.

3.36. Option 3 (d) Rafan House is a clinically-governed psychotherapeutic clinic, based in London. Their fourteen specialists have worked with families, children and adults with complex narratives, conflicts of interest between needs, unexpected disclosures and safeguarding issues. They belong to professional bodies, including the ACP (for child adolescent work) BPC, HCPC, BCAP, AFT (for adults and family). Many also have additional qualifications or other professional specialist areas (eg Anna Freud training, BICA membership, adoption experience, addictions, abuse, merged families and infertility).

3.37. The advantages are that:

- Rafan House counsellors have experience of delivering high quality counselling to families and individuals requiring psychotherapeutic support on a range of issues that could be relevant to the needs of the DCR and OTR users. They have experience of providing counselling to people with infertility and around adoption and IVF. They are the only service provider who currently has experience of adoption.
- They are not a fertility organisation or directly associated with a fertility clinic which may be preferable to some DCR users who may find accepting counselling from a fertility counselling organisation difficult.
- They have experience of bringing in specialists as associates when needed. They have close relationships with specific other professionals in their field where a wider inter disciplinary-team is needed. They would be willing to recruit people with additional expertise, if they comply with their governance arrangements and protocols.
- They already run 'Parent Hour,' a non-clinical but highly qualified advice line for parents who are unsure how to communicate difficult information or talk to their child about life events or need help forming their own narrative first. The consultants are well trained on the boundaries and limitations of these conversations and when to move the conversation on to a clinician.

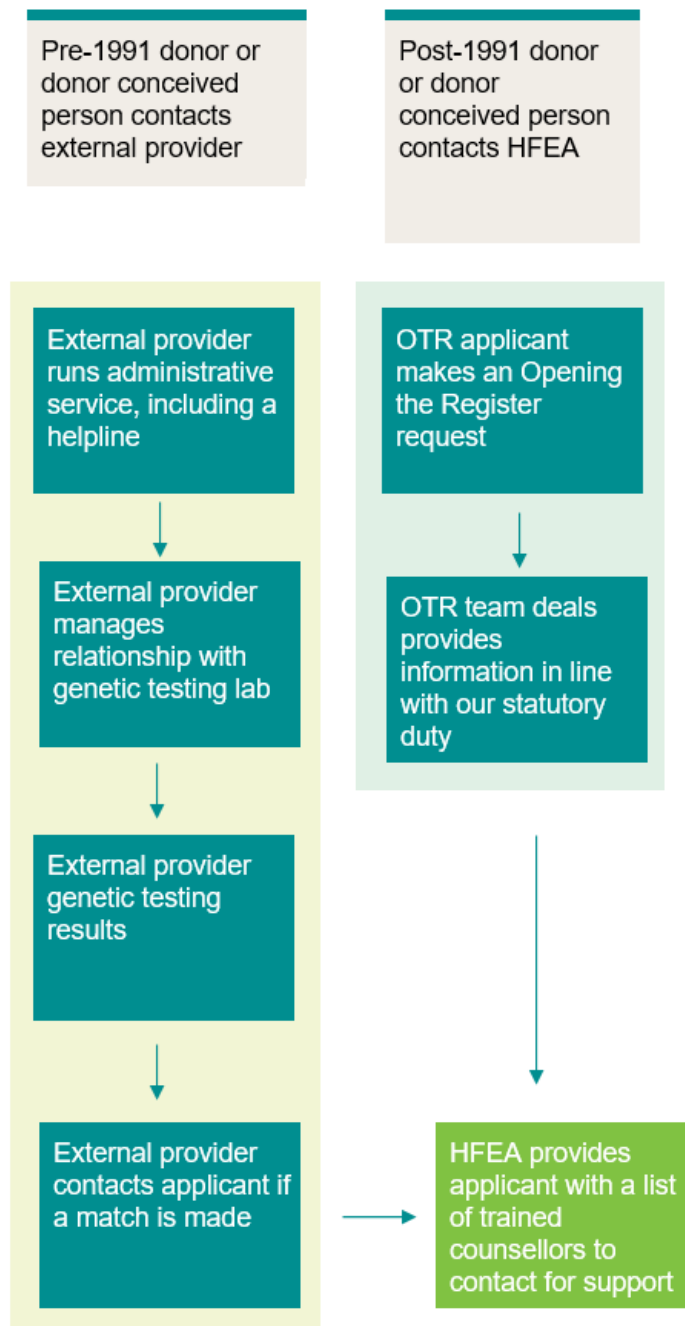
3.38. The limitations are that:

- They do not have a genetic counselling experience or currently have links to a genetic testing laboratory but are willing to work with the HFEA to establish a relationship with a suitable laboratory.

Option 4: mixed model with the DCR run by an external provider (either of 3(a) – 3 (d) with counselling provision delivered by the HFEA counselling provision

3.39. In this model, the external provider provides the administrative and DNA function for the DCR and the HFEA manages and trains a separate pool of counsellors. The HFEA provides the applicant with a list of trained counsellors that they can contact themselves directly for support.

Diagram 4



3.40. The advantages are that:

- An external supplier provides the DCR service whilst the HFEA can oversee the process for providing counselling support to DCR and OTR users. This would overcome the challenge of using an agency who doesn't have direct experience of this specialist type of counselling.
- It wouldn't require an additional HFEA staff, but this could change in the future.

3.41. The limitations are that:

- It would involve additional resources from HFEA staff managing the pool of counsellors (ie, managing invoices from multiple counsellors), but this would be limited. It could however increase in the future.
- Potentially difficulty to co-ordinate counsellors without a central contact point for users which would be managed by an external organisation.
- DCR users would need to contact two organisations for this service, one for the administrative and DNA testing elements, and the HFEA for the counselling service.

DCR Panel feedback on 4

This option received the least feedback. However, some Panel members did not like the way that a registrant would need to contact two organisations, rather than have a single point of contact.

4. Recommendation

- 4.1.** The service model options have been scored in the table set out at Annex A. Options within service model 3 scored highest within our criteria- specifically the expressions of interest from options 3(a), 3(c) and 3(d). These options already have the infrastructure in place to provide an end-to-end service for the DCR. Discussion with stakeholders such as the DCR Panel have made it clear that a 'seamless' user experience is important to potential users.
- 4.2.** A difference between the option 3 providers is perhaps the extent to which they already have the closest relevant counselling skills and expertise in place, and have ongoing relationships with genetic laboratories. However, we note that while no potential service provider that has expressed an interest to us has exactly equivalent experience of the current DCR service providers, all of these potential service providers are open to training and employing the relevant counselling staff, and open to making appropriate laboratory arrangements. Any externally-commissioned provider arrangement would be run under a service level agreement (SLA) between HFEA and the provider to set up and monitor the operation of the service.
- 4.3.** The Authority is asked to consider these options and agree a way forward.

5. Next steps

- 5.1.** The Executive will continue to work with stakeholders to develop the chosen service specifications and an SLA for delivering the DCR and OTR counselling support service ready for implementation in March 2019.
- 5.2.** Given the low contract value, the specialist nature of service and the limited number of providers, we propose negotiating individual contracts with specialist providers rather than following a formal tender process. We will ask those who expressed interest in providing a service within the Authority's preferred service model to provide us with detailed costings for comparative review and ultimately approval by the Accounting Officer. We will undertake due diligence before entering into any contractual agreement.
- 5.3.** We expect some dual running to support a smooth transition between service providers and the details will be discussed with the current providers NGDT and the new provider(s) in due course. Once the new service is in place, we will work with the new provider(s), involving DCR, to ensure that appropriate performance monitoring and review is in place.

Annex A: Service options summary table

Service qualities	Option 1: Using the power of direct to consumer DNA testing and matching websites with counselling provision delivered by the HFEA	Option 2: DCR and counselling provision delivered by the HFEA 5.4.	Option 3a: End-to-end service delivered by GeneHealthUK	Option 3b: End-to-end service delivered by the National Fertility Society (NFS)	Option 3c: End-to-end service delivered by the Hewitt Fertility Centre counselling team	Option 3d: End-to-end service delivered by Rafan House	Option 4: mixed model with the DCR run by an external provider (either of options 3(a)-3 (d) with counselling provision delivered by the HFEA
Do they have the infrastructure in place to provide an end to end service for the DCR?	X	X	✓	X	✓	✓	X
Can they provide a staffed information helpline and book in counselling appointments	✓ if resourced by HFEA	✓ if resourced by HFEA	✓	✓	✓	✓	✓
Can they provide genetic testing and matching where needed to a reliable clinical grade standard?	X	✓	✓	✓	✓	✓	✓
Do they already have a relationship with a relevant genetic testing laboratory?	X	X	✓	X	✓	X	✓ if delivered by GeneHealthUK or Hewitt
What service has the greatest likelihood of finding genetic matches for DCR users?	✓	X	X	X	X	X	X
What service can run a separate DCR register where both donors and donor conceived person consent to being matched?	X	✓	✓	✓	✓	✓	✓
Can they provide therapeutic counselling for DCR and OTR users?	✓ if commissioned and trained by the HFEA	✓ if commissioned and trained by the HFEA	✓ (only if additional therapeutic counsellors are recruited and trained by the HFEA)	✓ if trained by the HFEA	✓ if trained by the HFEA	✓ if trained by the HFEA	✓ if commissioned and trained by the HFEA
Do they have counsellors with experience of conveying genetic information/discussing test results for DCR users?	X	X	✓	✓ only if additional genetic counsellors are recruited	✓	✓ only if additional genetic counsellors are recruited	✓ if delivered by GeneHealthUK or Hewitt or if additional genetic counsellors are recruited by the NFS or Rafan
Do they have counsellors with experience of fertility or donation?	✓ if commissioned and trained by the HFEA	✓ if commissioned and trained by the HFEA	✓ fertility counselling and PGD via genetic counselling practice Plus if additional counsellors with experience of donation are recruited	✓	✓	✓	✓ if commissioned and trained by the HFEA
Do they have counsellors with experience of discussions with a family relationship dynamic?	✓	✓	✓	✓	✓	✓	✓
Do they have counsellors with experience of adoption issues	X	X	X	X	X	✓	✓ if delivered by Rafan House
Total score	5	6	9	7	9	9	8 (GeneHealthUK) 7 (NFS) 8 (Hewitt) 8 (Rafan)

Strategic risk register

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

Details:

Meeting	Authority
Agenda item	10
Paper number	HFEA (14/11/2018) 898
Meeting date	14 November 2018
Author	Helen Crutcher, Risk and Business Planning Manager

Output:

For information or decision?	For information
Recommendation	The Authority is asked to note and comment on the latest edition of the strategic risk register.
Resource implications	In budget
Implementation date	Ongoing
Communication(s)	The risk register is reviewed monthly by the Senior Management Team (SMT), and presented at every Audit and Governance Committee (AGC) meeting. AGC last reviewed the risk register at its meeting on 9 October and will review it again at its meeting on 4 December.
Organisational risk	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High
Annexes	Annex 1: Strategic risk register Annex 2: HFEA risk management policy

1. Risk management developments

- 1.1. We have revised the risk policy and processes to reflect recent changes in risk management roles. These changes were signed off by CMG in September and the risk policy went to the Audit and Governance Committee (AGC) in October. AGC approved this subject to some minor revisions related to descriptions of risk tolerance and appetite.
- 1.2. We define risk appetite as the general level of risk that we are willing to accept, as opposed to risk tolerance, which is the particular level we are willing to accept in relation to specific aims. Our risk appetite is expressed within our risk management policy, which is formally agreed by AGC. However, the Authority have not reviewed our statement of risk appetite for some time, and so we have included the risk policy as annex 2 to this paper. The section on risk appetite is 2.3 and the Authority may wish to discuss this element of the policy.
- 1.3. For context, the last time that the Authority decided to temporarily change its overall appetite to risk, the organisation was under threat of abolishment and consequently could not avoid accepting a high degree of risk.
- 1.4. Any revisions made to this will be reflected in the policy as relevant and taken into account in future reviews of risk. The final agreed policy will be circulated to AGC for their reference and re-launched with staff.

2. Latest reviews

- 2.1. SMT reviewed all risks, controls and scores in the strategic risk register at its meeting on 29 October. One of the six risks was above tolerance.
- 2.2. The risk register was discussed at AGC on 9 October. No changes were made to the risk scores at that time, although the committee requested additions related to estates and Brexit. Any comments from the Authority will be fed into the Committee's next review on 4 December.
- 2.3. SMT and AGC's comments are summarised on page 23 of the risk register, at Annex 1.

3. Recommendation

- 3.1. The Authority is asked to
 - note and comment on the latest edition of the strategic risk register
 - discuss and agree the current appetite of the Authority to risk, as outlined at section 2.3 of the risk policy.



Strategic risk register 2018/19

Risk summary: high to low residual risks

Risk area	Strategy link*	Residual risk	Status	Trend**
C1: Capability	Generic risk – whole strategy	12 – High	At tolerance	↔ ↔ ↔ ↑
CS1: Cyber security	Generic risk – whole strategy	9 – Medium	Above tolerance	↔ ↔ ↔ ↔
LC1: Legal challenge	Generic risk – whole strategy	8 – Medium	Below 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	↔ ↔ ↔ ↔
FV1: Financial viability	Generic risk – whole strategy	6 – Medium	Below 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, SMT or the Authority (eg, ↑ ↔ ↓ ↔).

Recent review points are: SMT 8 August ⇒ SMT 3 September ⇒ AGC 9 October ⇒ SMT 29 October

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
3	4	12 - High	2	3	6 - 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
<p>Below tolerance.</p> <p>Indications to date are that income is in line with the predictive income model and there has been a small increase in treatment cycles from last year; this risk is therefore stable.</p> <p>We have now forecast an underspend on our legal budget, following the resolution of a pending appeal. CMG are in the process of considering options for the effective reallocation of this money, to achieve the maximum strategic benefit.</p>

Causes / sources	Mitigations	Timescale / owner
There is uncertainty about the annual recovery of treatment fee income – this may not cover our annual spending.	<p>Heads see quarterly finance figures and would consider what work to deprioritise or reduce should income fall below projected expenditure.</p> <p>We have established a model for forecasting treatment fee income and this reduces the risk of significant variance, by utilising historic data and future population projections. We will refresh this model quarterly internally and review at least annually with AGC.</p>	Quarterly, ongoing, with AGC model review at least annually - next review due in 2019 - Richard Sydee

<p>Our monthly income can vary significantly as:</p> <ul style="list-style-type: none"> • it is linked directly to level of treatment activity in licensed establishments • we rely on our data submission system to notify us of billable cycles. 	<p>Our reserves policy takes account of monthly fluctuations in treatment activity and we have sufficient cash reserves to function normally for a period of two months if there was a steep drop-off in activity.</p> <p>If clinics were not able to submit data and could not be invoiced for more than three months we would invoice them on historic treatment volumes and reconcile this against actual volumes once the submission issue was resolved and data could be submitted.</p>	<p>Ongoing – reserves policy to be reviewed by AGC in December 2018 Richard Sydee</p> <p>In place – Richard Sydee</p>
<p>Annual budget setting process lacks information from directorates on variable/additional activity that will impact on planned spend.</p>	<p>Annual budgets are agreed in detail between Finance and Directorates with all planning assumptions noted. Quarterly meetings with Directorates flag any shortfall or further funding requirements.</p> <p>All project business cases are approved through CMG, so any financial consequences of approving work are discussed.</p>	<p>Quarterly meetings (on-going) – Morounke Akingbola</p> <p>Ongoing – Richard Sydee</p>
<p>Inadequate decision-making leads to incorrect financial forecasting and insufficient budget.</p>	<p>Within the finance team there are a series of formalised checks and reviews, including root and branch analyses of financial models and calculations.</p> <p>The organisation plans effectively to ensure enough time and senior resource for assessing core budget assumptions and subsequent decision making.</p>	<p>In place and ongoing - Richard Sydee</p> <p>Quarterly meetings (on-going) – Morounke Akingbola</p>
<p>Project scope creep leads to increases in costs beyond the levels that have been approved.</p>	<p>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.</p> <p>Any exceptions to tolerances are discussed at Programme Board and escalated to CMG at monthly meetings, or sooner, via SMT, if the impact is significant or time-critical.</p> <p>Finance training was provided to all project managers to improve project budgeting following some very minor (less than £5,000) overspends. There has been a renewed focus on project budgeting at Programme Board from Q2.</p>	<p>Ongoing – Richard Sydee or Morounke Akingbola</p> <p>Monthly (on-going) – Morounke Akingbola</p> <p>Ongoing – Wilhelmina Crown</p>
<p>Failure to comply with Treasury and DHSC spending controls and finance policies and guidance leads to serious reputational risk and a loss of</p>	<p>The oversight and understanding of the finance team ensures that we do not inadvertently break any rules. The team’s professional development is ongoing and this includes engaging and networking with the wider government finance community.</p>	<p>Continuous - Richard Sydee</p>

financial autonomy or goodwill for securing future funding.	All HFEA finance policies and guidance are compliant with wider government rules. Policies are reviewed annually, or before this if required. Internal oversight of expenditure and approvals provides further assurance (see above mitigations).	Annually and as required – Morounke Akingbola
Risk interdependencies (ALBs / DHSC)	Control arrangements	Owner
DHSC: Legal costs materially exceed annual budget because of unforeseen litigation.	Use of reserves, up to contingency level available. The final contingency for all our financial risks would be to seek additional cash and/or funding from the Department.	Monthly – Morounke Akingbola
DHSC: GIA funding could be reduced due to changes in Government/policy.	A good relationship with DHSC Sponsors, who are well informed about our work and our funding model.	Accountability quarterly meetings (ongoing) – Richard Sydee
	Annual budget agreed with DHSC Finance team alongside draft business plan submission. GIA funding has been provisionally agreed through to 2020.	December/January annually – Richard Sydee

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
4	4	16 – High	4	3	12- Medium
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
<p>At tolerance.</p> <p>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.</p> <p>Turnover remains high. Evidence suggests that the two main drivers of high turnover are the continuing constraints on public sector pay and the relatively few development opportunities in small organisations like the HFEA. Consequently, we are carrying a handful of vacancies, and in some areas, there is a trend towards over-reliance on key individuals. Work continues to improve the offer to staff, with the aim of increasing the likelihood of staff staying in post and developing at the HFEA, rather than leaving, although we are limited by a small organisation with little room to offer opportunities for promotion and wider government pay constraints. Elements of this include the PerkBox benefits scheme for staff, buying and selling of annual leave policy and ongoing cultural change work.</p> <p>We have run the 2018 staff survey and are in the process of analysing the results. These will be discussed by CMG in November and at the all staff awayday in December and will be used to identify further improvements.</p> <p>AGC will receive a paper on HR data in December, to consider the situation in the round, including ongoing strategies for the handling of these risks. Looking further ahead, we need to find ways to tackle the issues of pay and development opportunities, to prevent this risk increasing further. An idea we are keen to explore is whether we can build informal links or networks with other public sector or health bodies, to develop clearer career paths between organisations.</p>

Causes / sources	Mitigations	Timescale / owner
High turnover, sick leave etc., leading to temporary knowledge loss and capability gaps.	<p>Organisational knowledge captured via documentation, handovers and induction notes, and manager engagement.</p> <p>We have developed corporate guidance for all staff for handovers. A checklist for handovers is circulated to managers when staff hand in their notice. This checklist will reduce the risk of variable handover provision.</p>	<p>In place – Yvonne Akinmodun</p> <p>Checklist in use – Yvonne Akinmodun</p>
	<p>Vacancies are addressed speedily, and any needed changes to ways of working or backfill arrangements receive immediate attention.</p> <p>CMG and managers prioritise work appropriately when workload peaks arise.</p>	<p>In place – Yvonne Akinmodun</p> <p>In place – Peter Thompson</p>
Poor morale could lead to decreased effectiveness and performance failures.	<p>Communication between managers and staff at regular team and one-to-one meetings allows any morale issues to be identified early and provides an opportunity to determine actions to be taken.</p> <p>New intranet (launched in October 2018) should also improve internal communications.</p>	<p>In place, ongoing – Peter Thompson</p> <p>In place – Jo Triggs</p>
	<p>Staff survey results for 2017/18 informed the development of the people strategy. The all staff awayday in January 2018 gave staff a chance to feed back in further detail. The strategy was launched in April 2018.</p> <p>New benefit options have been implemented, including PerkBox and a buying and selling of annual leave policy (launched July 2018).</p>	<p>Annual survey and staff conferences – Yvonne Akinmodun/</p> <p>In place - Peter Thompson</p>
Increased workload either because work takes longer than expected or reactive diversions arise.	<p>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 at monthly meetings.</p>	<p>In place – Paula Robinson</p>
	<p>Oversight of projects by both the monthly Programme Board and CMG meetings, to ensure that projects end through due process (or closed, if necessary).</p> <p>We are re-launching our interdependencies matrix in autumn 2018, which supports the early identification of interdependencies in projects and other work, to allow for effective planning of resources.</p>	<p>In place – Paula Robinson</p> <p>Review underway autumn 2018 – Paula Robinson</p>

	<p>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.</p>	<p>Partially in place – further work to be done in 2018/19 - Paula Robinson</p>
	<p>Team-level service delivery planning for the next business year, with active involvement of team members. CMG will continue to review planning and delivery.</p> <p>Requirement for this to be in place for each business year.</p>	<p>In place – Paula Robinson</p>
	<p>Planning and prioritising data submission project delivery, and therefore strategy delivery, within our limited resources.</p>	<p>In place until project ends in Autumn 2018 – Dan Howard</p>
<p>Future increase in capacity and capability needed to process and assess licensing activity including mitochondrial donation applications.</p> <p>Since Summer 2017, we have experienced resource pressures relating to the Statutory Approvals Committee, caused in part by mitochondrial donation applications and also the increasing complexity and volume of PGD conditions.</p>	<p>Licensing processes for mitochondrial donation are in place (decision trees etc).</p> <p>An external review of the HFEA licensing processes was carried out to assess current capabilities and processes and make changes for the future. We are in the process of implementing the relevant proposals. As part of this, recruitment is underway in October 2018, for two new posts within the governance team, to support the licensing function and ensure our committees are supported effectively.</p> <p>To mitigate the present capacity and capability issues, the executive has signed up more experienced mitochondria peer reviewers, have received feedback on the process and have made administrative changes to improve it. This includes improvements to the application form, to prevent additional administration and/or unnecessary adjournments.</p>	<p>Licensing review implementation underway from September 2018 – Paula Robinson / Clare Ettinghausen</p>
<p>Implementing the People Strategy to maximise organisational capability 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.</p>	<p>A leadership awayday in November 2017 and an all staff awayday in January 2018 focused on building an HFEA culture following organisational changes. Small focus groups have since been utilised to make the most of staff time and involve wider staff in developing proposals. The next staff away day is planned for December 2018.</p>	<p>Ongoing – Yvonne Akinmodun</p>
<p>Following organisational change implementation and a period of churn, a number of staff are simultaneously new in</p>	<p>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 are provided where required.</p>	<p>In progress – Peter Thompson</p>

<p>post. This carries a higher than normal risk of internal incidents and timeline slippages while people learn and teams adapt.</p>	<p>Knowledge management via records management and documentation and the HR team has revised onboarding methods to make them clearer and more effective.</p>	<p>In place – Yvonne Akinmodun</p>
<p>The future office move, occurring in 2020, may not meet the needs of staff (for instance location), meaning staff decide to leave sooner than this, leading to a significant spike in turnover, resulting in capability gaps.</p>	<p>We will consult with staff, to ensure that their needs are taken into account, where possible, when planning for the move.</p> <p>We plan to explore possible knowledge and capability benefits arising from the office move, such as the potential to open up closer working and career progression with other health regulators.</p>	<p>Early engagement with staff and other organisations underway and ongoing – Peter Thompson</p>
<p>The new organisational model may not achieve the desired benefits for organisational capability</p> <p>Delay in completing our digital projects means that elements of the new model have not been fully implemented. It will therefore take more time for us to validate whether the changes have been effective.</p>	<p>The model will be kept under review following implementation to ensure it yields the intended benefits.</p> <p>The staff survey provided an opportunity for staff to reflect on whether change has been well managed. The results will help to inform any further actions related to the model.</p>	<p>A review of the new model was presented to AGC in June 2018. Staff survey in October 2018 – Peter Thompson</p>
<p>Failure to appoint new Authority members before existing members' terms of office expire, leads to loss of knowledge and impacts on formal decision making.</p>	<p>Confirmation for three new Authority appointments was received in July and a fourth new member was confirmed in September for appointment in January 2019.</p> <p>Training has been made available at the earliest opportunity to boost the capability of new appointees once in post.</p>	<p>In place and further Authority recruitment underway from October 2018 – Peter Thompson</p>
<p>Risk interdependencies (ALBs / DHSC)</p>	<p>Control arrangements</p>	<p>Owner</p>
<p>Government/DHSC:</p> <p>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.</p>	<p>We were proactive in reducing headcount and other costs to minimal levels over a number of years.</p> <p>We have also been reviewed extensively in the past eg, the Triennial Review in 2016.</p>	<p>In place – Peter Thompson</p>
<p>Government/DHSC</p> <p>The UK leaving the EU may have unexpected operational consequences for the HFEA which divert resource and threaten our ability to deliver our strategic aims.</p>	<p>The department has provided early guidance about the impact of a no-deal Brexit on the import of gametes and embryos. Further guidance is due to follow in November 2018. We continue to work closely to ensure that we are prepared and can provide detailed guidance to the sector at the earliest opportunity, to limit any impact on patients. We have provided ongoing updates to the sector.</p>	<p>Communications ongoing – Peter Thompson</p>

	<p>Once more is known, and at the earliest feasible opportunity, we will commence a project to ensure that we fully consider implications and are able to build enough knowledge and capability to handle the effects of Brexit, as a third country in relation to import and export of gametes.</p>	<p>Implementation project be initiated when more is known- meanwhile watching brief and close communications ongoing- Laura Riley</p>
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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	3	9 - 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	↔ ↔ ↔ ↔

Commentary
<p>Above tolerance.</p> <p>We have undertaken further cyber security (penetration) testing of the new digital systems such as PRISM and the Register, to ensure that these remain secure. The results have not revealed any significant issues.</p> <p>There has been no evidence to suggest the national cyber risk has been further heightened. We continue to assess and review the risk and take action as necessary to ensure our security controls are robust and are working effectively. A cyber security audit was recently undertaken, the results of which are expected shortly.</p>

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).	<p>AGC receives reports at each meeting on cyber-security and associated internal audit reports.</p> <p>The Vice Chair of the Authority is regularly appraised on actual and perceived cyber risks.</p> <p>Internal audit report on data loss (October 2017) gave a ‘moderate’ rating, and recommendations are being actioned and reported at each CMG Risk and AGC meeting. Fieldwork for a further cyber security internal audit report was undertaken in August. This will be reporting in Autumn 2018.</p> <p>A final report on cyber security will be signed off by AGC before any decision is made to go live with PRISM.</p>	<p>Ongoing regular reporting - Nick Jones/Dan Howard</p> <p>Ongoing – Dan Howard</p> <p>To occur Autumn 2018</p>

<p>Changes to the digital estate open up potential attack surfaces or new vulnerabilities. Our relationship with clinics is more digital, and patient identifying information or clinic data could therefore be exposed to attack.</p>	<p>The website and Clinic Portal are secure and we have been assured of this.</p> <p>The focus now is on obtaining similar assurance through penetration testing report to the SIRO in relation to the remaining data submission deliverables (PRISM).</p> <p>The second of three rounds of penetration testing has been completed and there have been no significant issues found so far.</p>	<p>Penetration testing underway throughout development and ongoing - Nick Jones/Dan Howard</p>
<p>There is a risk that IT demand could outstrip supply and so IT support doesn't meet the business requirements of the organisation and so we cannot identify or resolve problems in a timely fashion.</p>	<p>We continually refine the IT support functional model in line with industry standards (ie, ITIL). We undertook an assessment of our ticketing systems and have now purchased a new system. This will be launching in November. Alongside implementation we will introduce ways to capture user feedback.</p> <p>We have an agreement in place for additional support delivered by a third party. However, this is drawing to a close in autumn 2018. We have developed two subsequent proposals, for server maintenance for the next 6 months and for interim development cover. We plan to investigate a longer-term more permanent agreement soon. We will also continue to assess other options such as partnering with other organisations.</p>	<p>Approved per the ongoing business plan – Dan Howard</p> <p>Short term arrangement was finalised in May ongoing options are in the process of being reviewed – Dan Howard</p>
<p>Confidentiality breach of Register or other sensitive data by HFEA staff.</p>	<p>Staff are made aware on induction of the legal requirements relating to Register data.</p> <p>All staff have annual compulsory security training to guard against breaches of confidentiality.</p> <p>Relevant and current policies to support staff in ensuring high standards of information security.</p> <p>There are secure working arrangements for all staff both in the office and when working at home (end to end data encryption via the internet, hardware encryption)</p> <p>Further to these mitigations, any malicious actions would be a criminal act.</p>	<p>In place – Peter Thompson</p> <p>Our review of current IT policies is ongoing – Dan Howard</p>
<p>There is a risk that technical or system weaknesses lead to loss of, or inability to access, sensitive data, including the Register.</p>	<p>Back-ups of the data held in the warehouse in place to minimise the risk of data loss. Regular monitoring takes place to ensure our data backup regime and controls are effective.</p> <p>We are ensuring that a thorough investigation takes place prior, during, and after moving the Register to the Cloud. This involves the use of third party experts to design and implement the configuration of new architecture, with security and reliability factors considered.</p>	<p>In place – Dan Howard</p> <p>Results of penetration testing have been positive. The new Register will be in use from Autumn 2018 – Dan Howard</p>

<p>Business continuity issue (whether caused by cyber-attack, internal malicious damage to infrastructure or an event affecting access to Spring Gardens).</p>	<p>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. The next Business Continuity test is in the process of being planned.</p> <p>Existing controls are through secure off-site back-ups via third party supplier.</p> <p>A cloud backup environment has been set up to provide a further secure point of recovery for data which would be held by the organisation. The cloud backup environment for the new register has been successfully tested. Once the final penetration tests are complete we will utilise this functionality as we go live with our new register and submission system.</p>	<p>BCP in place, regularly tested and reviewed annually – Nick Jones</p> <p>Undertaken monthly – Dan Howard</p> <p>The new Register cloud backup environment will come into use in Autumn 2018 - Dan Howard</p>
<p>The corporate records management system (TRIM) is unsupported and unstable and we are carrying an increased risk of it failing.</p> <p>The organisation may be at risk of poor records management until the new system is functioning and records successfully transferred.</p>	<p>A comprehensive review of our records management practices and document management system (TRIM) has started including the formation of a working group. A formal project has been initiated, for delivery of a new system in 2019.</p> <p>We are continuing to manage the existing risk with the TRIM system by minimising changes and monitoring performance regularly. All staff have been reminded to continue to use TRIM to ensure records are complete.</p>	<p>Project to be delivered within 2018/19 business year – Peter Thompson</p>
<p>Cloud-related risks.</p>	<p>Detailed controls set out in 2017 internal audit report on this area.</p> <p>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.</p>	<p>In place – Dan Howard</p>
<p>Risk interdependencies (ALBs / DHSC)</p>	<p>Control arrangements</p>	<p>Owner</p>
<p>None.</p> <p>Cyber-security is an 'in-common' risk across the Department and its ALBs.</p>		

LC1: There is a risk that the HFEA is legally challenged given the ethically contested and legally complex issues it regulates.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
4	5	20 – Very high	2	4	8 - Medium
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
<p>Below tolerance.</p> <p>We accept that in a contested area of public policy, the HFEA and its decision-making will be legally challenged. Legal challenge poses two key threats:</p> <ul style="list-style-type: none"> that resources are substantially diverted that the HFEA’s reputation is negatively impacted by our participation in litigation. <p>These may each affect our ability to regulate effectively and deliver our strategy. Both the likelihood and impact of legal challenge may be reduced, but it cannot be avoided entirely. For these reasons, our tolerance for legal risk is high.</p> <p>The Chief Executive reached an agreement with the appellant to settle the CaFC appeal. Actions agreed in the process of settlement, including some minor changes to the presentation of data on the website, have been implemented.</p>

Causes / sources	Mitigations	Timescale / owner
Assisted reproduction is complex and controversial and the Act and regulations are not beyond interpretation. This may result in challenges to the way the HFEA has interpreted and applied the law.	Evidence-based and transparent policy-making and horizon scanning processes. Horizon scanning meetings occur with the Scientific and Clinical Advances Advisory Committee on an annual basis.	In place – Laura Riley with appropriate input from Catherine Drennan
	Through constructive engagement with third parties, the in-house legal function serves to anticipate issues of this sort and prevent challenges or minimise the impact of them. Where necessary, we can draw on the expertise of an established panel of legal advisors, whose experience across other sectors can be applied to	Ongoing – Catherine Drennan In place – Peter Thompson

	put the HFEA in the best possible position to defend any challenge.	
	Case by case decisions on the strategic handling of contentious issues in order to reduce the risk of challenge or, in the event of challenge, to put the HFEA in the strongest legal position.	In place – Catherine Drennan and Peter Thompson
	We undertake good record keeping, to allow us to identify and access old versions of guidance, and other key documentation, which may be relevant to cases or enquiries and enable us to see how we have historically interpreted the law.	In place – Catherine Drennan
<p>Committee decisions or our decision-making processes may be contested. ie, Licensing appeals and/or JRs.</p> <p>Note: Inspection rating on CaFC may mean that more clinics make representations against licensing decisions.</p>	<p>Panel of legal advisors in place to advise committees on questions of law and to help achieve consistency of decision making processes.</p> <p>The Head of Legal has put measures in place to ensure consistency of advice between the legal advisors from different firms. These include:</p> <ul style="list-style-type: none"> • Provision of previous committee papers and minutes to the advisor for the following meeting • Annual workshop (next due March 2019) • A SharePoint site for sharing questions, information and experiences is in development 	<p>In place – Peter Thompson</p> <p>Since Spring 2018 and ongoing – Catherine Drennan</p>
	<p>Maintaining, keeping up to date and publishing licensing SOPs, committee decision trees etc. to ensure we take decisions well.</p> <p>Consistent decision making at licence committees supported by effective tools for committees.</p> <p>Standard licensing pack distributed to members/advisers (refreshed in April 2018).</p> <p>Project underway from November 2018 to implement changes in the light of the findings of an external licensing review, to make the licensing process more efficient and robust.</p>	<p>In place, further development underway as part of the licensing review implementation project – Paula Robinson</p>
	<p>Well-evidenced recommendations in inspection reports mean that licensing decisions are adequately supported and defensible.</p>	<p>In place – Sharon Fensome-Rimmer</p>
<p>High-profile legal challenges have reputational consequences for the HFEA which risk undermining the robustness of the regulatory regime and affecting strategic delivery.</p>	<p>Close working between legal and communications teams to ensure that the constraints of the law and any HFEA decisions are effectively explained to the press and the public.</p> <p>The default HFEA position is to conduct litigation in a way which is not confrontational, personal or aggressive.</p>	<p>In place – Catherine Drennan, Joanne Triggs</p> <p>In place – Peter Thompson,</p>

		Catherine Drennan
Involvement of the Head of Legal in an increased number of complex Compliance management reviews and related advice impacts other legal work.	<p>The Compliance team stay in close communication with the Head of Legal to ensure that it is clear if legal involvement is required, to allow for effective planning of work.</p> <p>The Compliance management team will monitor the number and complexity of management reviews to ensure that the Head of Legal is only involved as appropriate.</p>	In place – Sharon Fensome Rimmer, Nick Jones
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.	<p>Risks considered whenever a new approach or policy is being developed.</p> <p>Business impact target assessments carried out whenever a regulatory change is likely to have a significant cost consequence for clinics.</p> <p>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.</p> <p>Major changes are consulted on widely.</p>	In place – Clare Ettinghausen
The Courts approach matters on a case by case basis and therefore outcomes can't always be predicted. So, the extent of costs and other resource demands resulting from a case can't necessarily be anticipated.	Scenario planning is undertaken with input from legal advisors at the start of any legal challenge. This allows the HFEA to anticipate a range of different potential outcomes and plan resources accordingly.	In place – Peter Thompson
Legal proceedings can be lengthy and resource draining and divert the in-house legal function (and potentially other colleagues) away from business as usual.	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 workload should this become necessary.	In place – Peter Thompson
HFEA process failings could create or contribute to legal challenges, or weaken cases that are otherwise sound,	<p>Licensing SOPs were improved and updated in Q1 2018/19, committee decision trees in place.</p> <p>Advice sought through the Licensing review on specific legal points, so that improvements can be identified and implemented. A project to implement these is underway.</p>	<p>In place – Paula Robinson</p> <p>From October 2018 – Paula Robinson</p>
	Up to date compliance and enforcement policy and related procedures to ensure that the Compliance team acts consistently according to agreed processes.	In place but in the process of being reviewed Q3 2018/19 – Catherine Drennan

<p>Legal parenthood consent cases are ongoing and some are the result of more recent failures (the mistakes occurred within the last year). This may give rise to questions about the adequacy of our response when legal parenthood first emerged as a problem in the sector (in 2015).</p>	<p>The Head of Legal continues to keep all new cases under review, highlighting any new or unresolved compliance issues so that the Compliance team can resolve these with the clinic(s).</p>	<p>In progress and ongoing – Catherine Drennan, Sharon Fensome-Rimmer, Nick Jones</p>
<p>Storage consent failings at clinics are leading to a significant diversion of legal resource and additional costs for external legal advice.</p>	<p>We have taken advice from a leading barrister on the possible options for a standard approach for similar cases.</p> <p>The Head of Legal made significant amendments to guidance in the Code of Practice dealing with consent to storage and extension of storage. This guidance should mean that clinics are clearer about their statutory responsibilities.</p>	<p>Done in Q1 2018/19 – Catherine Drennan</p> <p>Revised version of the Code comes into force November 2018 – Laura Riley</p>
<p>GDPR requirements require a large number of changes to practice. If we fail to comply with the requirements, this could open the HFEA up to legal challenge and possible fines from the Information commissioner’s office.</p>	<p>The GDPR project introduced a number of new and updated policies and processes, to ensure that the HFEA complies with the requirements. These will now be bedded into BAU to ensure that they are effective.</p> <p>The project was handled proactively, with a joint HFEA and HTA project team and sponsored directly by the Director of Finance and Resources to ensure senior oversight. Although the project was closed in October, ongoing actions are being closely monitored to ensure effective compliance. AGC have regular updates on progress.</p>	<p>Ongoing- Richard Sydee</p>
<p>Risk interdependencies (ALBs / DHSC)</p>	<p>Control arrangements</p>	<p>Owner</p>
<p>DHSC: HFEA could face unexpected high legal costs or damages which it could not fund.</p>	<p>If this risk was to become an issue then discussion with the Department of Health and Social Care 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 DHSC would be involved in resolving it.</p>	<p>In place – Peter Thompson</p>
<p>DHSC: Legislative interdependency.</p>	<p>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</p>	<p>In place – Peter Thompson</p>

<p>We are experiencing a delay in the final ministerial sign-off of the 2018 Code. We expected sign-off in October ready for launch in November and this is currently looking unlikely. Further delays have various impacts, for instance for clinics, who may become unsure about which guidance to follow, and this may result in increased queries for the inspection and legal teams. Our reputation may also suffer.</p>	<p>necessary, this would include agreeing any associated implementation budget.</p> <p>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.</p> <p>Sign-off for key documents such as the Code of Practice in place – though we are dealing with unexpected delays at present, We are in ongoing communication with DHSC about the delays and we have provided clear messaging to clinics and inspectors, with updates about the likely publication date.</p>	
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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 - High	2	3	6 – Medium
Tolerance threshold:					6 - Medium

Risk area	Risk owner	Links to which strategic objectives?	Trend
Regulatory effectiveness 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	↔ ↔ ↔ ↔

Commentary
At tolerance. Data submission work continues at a good pace. Clinics are on course to be using the new system (PRISM) by Autumn.

Causes / sources	Mitigations	Timescale / owner
IfQ has taken longer than planned, and there will be some ongoing development work needed leading to delays in accessing the benefits.	Data Submission development work is now largely complete, with clinic implementation and access to it following by Autumn 2018. Oversight and prioritisation of any remaining development work will be through the IT development programme board.	Completion of data submission project Autumn 2018 – Nick Jones
Risks associated with data migration to new structure, compromises record accuracy and data integrity.	Migration of the Register is highly complex. IfQ programme groundwork focused on current state of Register. There is substantial high-level oversight including an agreed migration strategy which is being followed. The migration will not go ahead until agreed data quality thresholds are met. AGC will have final sign off on the migration.	Autumn 2018 with regular reporting on progress prior to this – 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	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	In place regular reviews to occur once the Register

focus on or deem critical for accuracy.	anticipate future needs and build these into the design. Further scoping work would occur periodically to review whether any additions were needed. The structure of the new Register makes adding additional fields more straightforward than at present.	goes live – Nick Jones
Risk that existing infrastructure systems – (eg, Register, EDI, network, backups) which will be used to access the improved data and intelligence are unreliable.	Maintenance of desktop, network, backups, etc. core part of IT business as usual delivery. In March 2018 CMG agreed to a new approach, including some outsourcing of technical second and third line support, this will provide greater resilience against unforeseen issues or incidents. As noted above under CS1, we are considering proposals for ongoing external support.	In place with work underway to improve arrangements in Autumn 2018 – Dan Howard
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. Two vacancies in the inspection team have been filled. There will be a period of bedding in once the new starters join.	In place – Nick Jones
Failure to integrate the new data and intelligence systems into Compliance activities due to cultural silos.	Work is underway in 2018 to further define and bed in HFEA culture in the light of organisational changes. The people strategy was agreed in spring 2018.	Ongoing - Yvonne Akinmodun
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 data submission project. Plan in place to deal with any inability to supply data. The Compliance management team are considering how to manage any centres with EPRS systems who are not ready to provide Register data in the required timeframe. This may include regulatory sanctions. Early engagement with EPRS providers means the risk of non-compliance is slim.	Ongoing - Nick Jones
Data migration efforts are being privileged over data quality leading to an increase in outstanding errors	The Register team uses a triage system to deal with clinic queries systematically, addressing the most critical errors first.	In place – Nick Jones
	We undertake an audit programme to check information provision and accuracy.	In place – Nick Jones
Excessive demand on systems and over-reliance on a few key expert individuals – request overload – leading to errors	PQs and FOIs have dedicated expert staff to deal with them although they are very reliant on a small-number of individuals. We have systems for checking consistency of answers.	In place – Clare Ettinghausen / Caylin Joski-Jethi

	There is a dedicated team for responding to OTRs and all processes are documented to ensure information is provided consistently	In place – Dan Howard
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.	The intelligence strategy focuses in part on making the best use of the information gleaned from patients, and converting our mix of soft and hard data into real outcomes and improvements. This includes a new patient survey we piloted in 2018 to give us qualitative and quantitative data on patient’s experience of fertility treatment in the UK. We are currently in the process of reviewing the findings of this survey.	Plan to be developed following the pilot patient survey 2018 – Clare Ettinghausen /Caylin Joski-Jethi/Jo Triggs
Risk interdependencies (ALBs / DHSC)	Control arrangements	Owner
None	-	-

ME1: There is a risk that patients and our other stakeholders do not receive the right information and guidance from us.

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	Clare Ettinghausen 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.	↔ ↔ ↔ ↔

Commentary
<p>At tolerance.</p> <p>The last few months have seen us undertake several high-profile pieces of work to present more and better information to stakeholders, examples include the new egg freezing report, which was published in September, the Code of Practice consultation and various messaging around the 40th anniversary of IVF and Fertility Week.</p> <p>The national patient survey pilot project was developed with input and clear direction from the Intelligence Advisory Board which includes both Authority member representatives and external experts. This survey data will better inform HFEA information provision and other interventions. The results of this are currently being reviewed.</p> <p>We are in the process of revisiting our wider communications strategy to ensure that it remains fit for purpose. This will be presented to the Authority in January 2019.</p>

Causes / sources	Mitigations	Timescale / owner
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.	When there are messages that need to be conveyed to clinics through the inspection team, staff work with the team so that a co-ordinated approach is achieved and messages that go out to the sector through other channels (eg clinic focus) are reinforced. When there are new or important issues or risks that may impact patient safety, alerts are produced collaboratively by the Inspection, Policy and Communications teams.	In place - Sharon Fensome-Rimmer, Laura Riley, and Jo Triggs

<p>Patients and other stakeholders do not receive the correct guidance or information.</p>	<p>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.</p> <p>The new publication schedule uses HFEA data more fully and make this more accessible.</p> <p>Policy team ensures guidance is created with appropriate stakeholder engagement and is developed and implemented carefully to ensure it is correct.</p> <p>Ongoing user testing and feedback on information on the website allows us to properly understand user needs.</p> <p>We have internal processes in place which meet the Information Standard.</p> <p>We are actively reviewing options for delivery of the Donor Conceived Register (DCR) to ensure the new service meets the needs of donor conceived people and is an improvement on the existing service. The Authority will consider options in November 2018. We will regularly measure the quality of service and effectiveness after go-live.</p>	<p>In place and reviewed periodically (next review due Winter 2018/19) – Jo Triggs</p> <p>Ongoing - Caylin</p> <p>In place – Laura Riley, Jo Triggs</p> <p>In place –Jo Triggs</p> <p>In place, although this standard is being phased out – Jo Triggs</p> <p>Interim arrangement in place and ongoing plans being considered November 2018 - Nick Jones</p>
<p>We are not able to reach the right people with the right message at the right time.</p>	<p>We have an ongoing partnership with NHS.UK to get information to patients early in their fertility journey and signpost them to HFEA guidance and information.</p> <p>Planning for campaigns and projects includes consideration of communications channels.</p> <p>When developing policies, we ensure that we have strong communication plans in place to reach the appropriate stakeholders.</p> <p>Extended use of social media to get to the right audiences.</p> <p>The communications team analyse the effectiveness of our communications channels at Digital Communications Board meetings, in order to ensure that they continue to meet our user needs.</p>	<p>In place – Jo Triggs</p> <p>In place and ongoing – Jo Triggs</p> <p>In place - Laura Riley, Jo Triggs</p> <p>In place– Jo Triggs</p> <p>Ongoing – Jo Triggs</p>
<p>Risk that incorrect information is provided in PQs, OTRs or FOIs and this may lead to misinformation and</p>	<p>PQs and FOIs have dedicated expert staff to manage them.</p>	<p>In place - Clare Ettinghausen</p> <p>Clare Ettinghausen</p>

misunderstanding by patients, journalists and others.	We have systems for checking consistency of answers and a member of SMT must sign off every PQ response before submission.	/SMT - In place
	There is a dedicated OTR team and all responses are checked before they are sent out to applicants to ensure that the information is accurate.	In place - Dan Howard
Some information will be derived from data, so depends on risk above being controlled.	See controls listed in RE1, above.	
There is a risk that we provide inaccurate information and data on our website or elsewhere.	All staff ensure that public information reflects the latest knowledge held by the organisation.	In place - Caylin Joski-Jethi, Laura Riley, and Jo Triggs
	The Communications team work quickly to amend any factual inaccuracies identified on the website.	In place – Jo Triggs
	The Communications publication schedule includes a review of the website, to update relevant statistics when more current information is available.	In place – Jo Triggs
Risk interdependencies (ALBs / DHSC)	Control arrangements	Owner
NHS.UK: The NHS website and our site contain links to one another which could break	We maintain a relationship with the NHS.UK team to ensure that links are effectively maintained.	In place – Jo Triggs
DHSC: interdependent communication requirements may not be considered	DHSC and HFEA have a framework agreement for public communications to support effective co-operation, co-ordination and collaboration and we adhere to this.	In place – Jo Triggs

Reviews and revisions

SMT review – October 2018 (29/10/18)

SMT reviewed all risks, commentary, controls and scores and made the following detailed points:

- SMT reflected on the inclusion of Brexit and the future office move on the register and agreed to wording in relation to these risks. It was clear that the nature of these risks and the mitigations needed would become clearer over time.
- FV1 – SMT discussed the financial position in relation to the legal budget. Underspending against budget could impact on wider organisational funding, so SMT took the view that any underspend should be effectively re-allocated towards achieving our strategic aims. The Director of Finance was currently collating proposals, which would be considered in the coming weeks.
- C1 – SMT discussed capability challenges. An ongoing dialogue with CMG and AGC about capability risks was helpful for considering these in the round and would inform ongoing planning of mitigations. The recruitment to two new posts in the licensing team would ultimately provide more capability and resilience and address resource pressures. SMT decided that given the wider context, much of which is outside of its direct control, to raise the residual likelihood of this risk at this time.
- LC1 – SMT discussed legal risk and the recent settlement of an appeal against Choose a Fertility Clinic. SMT agreed that this left the organisation in an improved position in relation to legal risk and reduced

the inherent likelihood somewhat to a score of 4 (likely) rather than 5 (almost certain). The residual likelihood had reduced, which brought the overall risk score down to a medium score of 8, which was below tolerance. Interdependent risk in relation to the ministerial sign off of the Code of Practice was being managed proactively, although we were reliant upon the department and, ultimately, the minister.

AGC review – October 2018 (08/10/18).

AGC reviewed the risk register and scores and did not raise any of these. The committee requested two additions to the register:

- AGC had discussed estates earlier in the meeting and felt that the risks around the office move that would happen in 2020 should be captured in the strategic risk register, owing to the possibility of this impacting turnover and therefore capability.
- AGC requested that Brexit, though not considered a significant strategic risk to the Authority, should also be reflected in the register, given the uncertainty around this and possibility that there may be implications as yet unknown or not fully understood.

SMT review – September 2018 (03/09/18)

SMT reviewed all risks, commentary, controls and scores and made the following detailed points:

- LC1 – A full deep dive had been done with the CE and Head of Legal to reframe the risk in the light of comments from AGC. More would be known about the upcoming legal case by the end of September.
- C1 – A deep dive review of this risk would happen prior to AGC (13/09/18).

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

		Likelihood				
		1. Rare (≤10%)	2. Unlikely (11%-33%)	3. Possible (34%-67%)	4. Likely (68%-89%)	5. Almost Certain (≥90%)
Impact	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
Risk Score = Impact x Likelihood						

Risk appetite and tolerance

Risk appetite and tolerance are two different but related terms. We define risk appetite as the willingness of the HFEA to take risk. As a regulator, our risk appetite will be naturally conservative and for most of our history this has been low. Risk appetite is a general statement of the organisation's overall attitude to risk and is unlike to change, unless the organisation's role or environment changes dramatically.

Risk tolerance on the other hand is the willingness of the HFEA to accept and deal with risk in relation to specific goals or outcomes. Risk tolerance will vary according to the perceived importance of particular risks and the timing (it may be more open to risk at different points in time). The HFEA may be prepared to tolerate comparatively large risks in some areas and little in others. Tolerance thresholds are set for each risk and they are considered with all other aspects of the risk each time the risk register is reviewed

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 interdependencies in collaboration with relevant other bodies, and so that we can report easily and transparently on such interdependencies to DHSC or auditors as required.

Contingency actions

When putting mitigations in place to ensure that the risk stays within the established tolerance threshold, the organisation must achieve balance between the costs and resources involved in limiting the risk, compared to the cost of the risk translating into an issue. In some circumstances it may be possible to have contingency plans in case mitigations fail, or, if a risk goes over tolerance it may be necessary to consider additional controls.

When a risk exceeds its tolerance threshold, or when the risk translates into a live issue, we will discuss and agree further mitigations to be taken in the form of an action plan. This should be done at the relevant managerial level and may be escalated if appropriate.



Managing risk at the HFEA

HFEA risk policy

1. General approach to risk

1.1. Overview

- 1.1.1. The HFEA's risk management system sits within its wider corporate governance system, which is described in the Annual Governance Statement set out in each year's Annual Report.
- 1.1.2. The overall system of corporate governance is designed to ensure that responsibility and accountability is clear and, that internal controls support the mitigation of strategic and operational risks. It is also designed to ensure that Authority members and the Chief Executive can be assured that appropriate oversight over operational responsibilities is in place. The HFEA complies with the requirements of the *Corporate governance in central government departments: code of good practice*, in so far as they relate to ALBs.
- 1.1.3. The HFEA's general approach to the management of risk is based on the principles of good practice set out in HM Treasury's 'Orange Book' on risk management. Accordingly, the HFEA defines risk management as:
- 'The way in which we identify and deal with uncertainties which threaten success.'
- 1.1.4. The HFEA recognises that good risk management is integral to excellent performance, allowing the organisation to:
- Have increased confidence in achieving desired outcomes
 - Effectively constrain threats to acceptable levels
 - Take informed decisions about opportunities and changes.
- 1.1.5. The HFEA therefore actively considers risks and controls in all business and project planning, and in our ongoing management of our staff and our operational delivery.

1.2. Risk and capability

- 1.2.1. The Authority's attitude to, and management of, the risks it faces in carrying out its functions is robust but proportionate. Risks vary in their likelihood and impact, and the Authority's overall appetite to risk is 'low' (see also later section on risk appetite and tolerance).
- 1.2.2. The framework the HFEA has established to identify and manage risk is proportional to its small size and allows for reasonable controls to be in place, without adversely impacting on the successful delivery of objectives.

2. Risk management structure in the HFEA

2.1. Levels of risk management

- 2.1.1. The HFEA's system of internal risk management gives assurance that the risks the organisation faces when exercising its statutory functions are managed appropriately and mitigated against proportionately. Risks are formally managed at several different levels in the HFEA:
- Strategic risk register – capturing risks to delivery of the HFEA strategy and business plan
 - Operational risk logs – capturing team level risks to functional delivery

- Project/programme risk logs – capturing risks to successful project delivery
- Business continuity risks – managed through the business continuity plan with regular appraisal of business-critical functions
- Internal incidents system – an adjunct to the risk system, which enables understanding of and corporate learning from internal adverse events.

- 2.1.2. Alongside its arrangements for managing risk within the organisation, the HFEA also takes a risk-based approach to the way it regulates the fertility sector. In inspecting and regulating clinics, the Authority uses a risk-based assessment tool, ensuring that the HFEA's regulatory resources are targeted proportionately and reasonably. This tool (and all other processes used by the HFEA in carrying out its functions) is subject to a rigorous quality assurance regime. Regulatory risks will not be discussed further in this policy, which focuses on the management of the HFEA's own risks, rather than clinic-based risks. Clearly there is an interaction between the two, and this is recognised where relevant in the strategic risk register and in operational risks, particularly those of the Compliance and Information Directorate.
- 2.1.3. The Authority takes its responsibilities for information security most seriously. In this regard, the HFEA has a low tolerance for information risks and follows stringent information security good practice. Keeping secure the information the Authority holds, including sensitive personal patient data, is of the highest priority. The HFEA continually works hard to avoid the occurrence of any data losses. Distinct information risks are captured where relevant in the strategic risk register, in operational risk logs maintained by teams, and in project risk logs.

2.2. HFEA in a wider risk context

- 2.2.1. The HFEA engages with the Department of Health and Social Care ALB Risk Network which meets periodically, convened by the Department. This is a forum for discussing common risk issues and systemic risks and the approach of the Department towards risk management.
- 2.2.2. The HFEA has committed to consider system-wide and common, interdependent, risks. The strategic risk register includes sections for identifying risk interdependencies between the HFEA, the Department of Health and Social Care and the wider health and social care system.

2.3. Risk appetite and tolerance

- 2.3.1. Risk appetite and tolerance are two different but related terms. We define risk appetite as the willingness of the HFEA to take risk. As a regulator, our overall risk appetite will be naturally conservative, we are averse to risks which threaten our ability to perform our regulatory functions, and for most of our history our overall risk appetite has been low.
- 2.3.2. Risk tolerance on the other hand is the willingness of the HFEA to accept and deal with risk in relation to specific goals or outcomes. Although our general appetite for risk may be low, where we have identified scope to realise particular strategic aims through innovation, we are not averse to tolerating risk.
- 2.3.3. Risk tolerance will vary according to the perceived importance of particular risks and the timing (it may be more open to risk at different points in time). The HFEA may be prepared to tolerate comparatively large risks in some areas and little in others. For example, because we operate in a regulatory environment, we are often involved in legal cases and our decisions are open to legal challenge. This means that we must be willing to accept a higher level of legal risk, as we have limited control over the number of legal cases that we must deal with. Equally, when our strategy involves extending ourselves into work that is beyond the boundaries of our normal regulatory

remit, we may tolerate greater risk, as we believe the benefits to patients outweigh the threats. On the other hand, we deal with confidential medical data in our Register and we have a statutory duty to maintain this securely. We therefore need to reduce our risk of cyber security threats to a low level and our tolerance for such risk is set as low.

- 2.3.4. Tolerance thresholds are set for each risk and they are considered with all other aspects of the risk each time the risk register is reviewed. For instance, during a period of organisational restructure, the tolerance for this risk might be raised as the activities that need to be undertaken, such as implementing redundancies, are inherently risky. We may choose to accept a higher risk level because it is necessary to take and tolerate certain risks in order to implement and take advantage of a new structure. On the other hand, risk appetite is a general statement of the organisation's overall attitude to risk and is unlikely to change, unless the organisation's role or environment changes dramatically.
- 2.3.5. When putting mitigations in place to ensure that the risk stays within the established tolerance threshold, the organisation has to achieve balance between the costs and resources involved in limiting the risk compared to the cost of the risk translating into an issue. In some circumstances it may be possible to have contingency plans in case mitigations fail, or, if a risk goes over tolerance it may be necessary to consider additional controls.
- 2.3.6. When a risk exceeds its tolerance threshold, or when a risk becomes a live issue, we will discuss and agree further mitigations to be taken in the form of an action plan. This should be done at the relevant managerial level and may be escalated if appropriate. For further detail see the section of this policy on risk escalation.

3. Procedures and roles

3.1. Staffing and structure

- 3.1.1. The Risk and Business Planning Manager leads on risk management organisationally, supported by the Head of Planning and Governance, and is responsible for ensuring:
 - The existence and maintenance of a strategic risk register capturing strategic risks
 - Regular review by senior staff and members, with regular reporting to the Senior Management Team (SMT), Corporate Management Group (CMG), the Authority, Audit and Governance Committee (AGC) and the DHSC Sponsor team
 - That teams apply risk management principles in their own areas, maintaining an operational risk log and including risk management as a key consideration in every project
 - That project risks are actively monitored by project teams and by Programme Board, and that lessons learned from projects are recorded, and learning implemented
 - The maintenance and monitoring of the system and SOP for internal incident reporting, so as to ensure organisational learning from adverse events
 - That business continuity planning remains aligned with overall corporate risk management.
- 3.1.2. The Corporate Management Group (CMG), which comprises Heads of Department and Directors, is responsible for regular reviews of teams' top three operational risks. These risks are reported from teams' operational risk registers, maintained by Heads.

- 3.1.3. The Senior Management Team reviews the strategic risk register on a monthly basis to ensure that it accurately reflects all new and emerging risks. This is then circulated to CMG.
- 3.1.4. Programme Board is responsible for monitoring project risks, referring issues upwards to CMG when necessary. Project managers and sponsors are clear about their obligation to provide reports to Programme Board, on a monthly basis, which include information about the current risk level and sources of risk within the project. Non-reporting results in automatic escalation.

Authority and AGC

- 3.1.5. Both AGC and the Authority have critical roles in the HFEA's risk management process, ensuring appropriate reporting and governance are in place to provide effective assurance. This includes reviewing periodic audits of our risk management arrangements and ensuring that appropriate actions are taken to improve processes.
- 3.1.6. The Authority is accountable for the oversight of the management of risk, part of which it delegates to AGC.
- 3.1.7. The Authority and AGC both receive the strategic risk register for comment on a regular basis. The report goes to every quarterly AGC meeting and comes to Authority at least twice a year.
- 3.1.8. When reviewing the strategic risk register, AGC ensure that the organisation is properly identifying and controlling strategic risks and effectively escalating risk developments to the Authority.
- 3.1.9. The Authority receives the strategic risk register for oversight and information, at which point members are invited to discuss the executive's approach to addressing risks, particularly those which are high or above tolerance.

Internal audit

- 3.1.10. AGC commissions an ongoing internal audit programme which includes audits of risk management, relating to both specific topics of risk, such as cyber security and the general risk management system.
- 3.1.11. Actions following on from internal audits are tracked by AGC and progress is reported by the executive at each meeting. Internal audit provides ongoing assurance that the risk system is working, controls are appropriate and effective, and any issues identified have been effectively addressed.
- 3.1.12. Internal Audit provides AGC with an annual assurance report, which includes a formal opinion, based on their assessment of whether the controls in place support the achievement of our objectives.
- 3.1.13. Periodically, Internal Audit supports the executive to undertake risk assurance mapping exercises focused on a particular risk area, which allow the executive to further understand the make-up of the control environment. This process can help establish whether controls are appropriately split between 'preventative' and 'detective' controls and gain assurance on the operation of controls identified.

3.2. Strategic risk register

- 3.2.1. The HFEA strategic risk register is reviewed on a monthly basis by SMT, with reporting to AGC and Authority.

- 3.2.2. In addition, a grass roots review, starting from a blank sheet of paper, is undertaken periodically, and at least once every three years.
- 3.2.3. The most recent such review was undertaken in 2017, following the publication of the HFEA's three-year Strategy (in April 2017). The purpose of this grass-roots review is to capture afresh the risks to delivering our current strategic aims and business plan. As part of this exercise, we consider the HFEA's current operating context, environment and resources.
- 3.2.4. Ongoing areas of strategic risk include the management of people and resources, legal and cyber security. Other risks relate to specific areas of the current strategy, and the particular challenges involved in delivering them.

3.3. Operational risk logs

- 3.3.1. The operational risk logs that feed into the Authority's strategic risks are reviewed regularly, within teams, and the top risks are reported on a quarterly basis to CMG, which in turn assesses and reports on the key risks to AGC.
- 3.3.2. In addition to noting individual operational risks, and discussing their sources and controls, CMG also takes a managerial overview of current operational risks, identifying prevalent themes and considering whether these are adequately reflected in the strategic risk register, and whether any issues or trends require further discussion and decision-making.
- 3.3.3. This allows for a proactive and proportionate approach to risk management throughout the work of the Authority and its executive. The system facilitates continual identification and monitoring of operational risks, and the regular reviews by CMG act as a prompt for any needed decision as to whether to escalate an operational risk or to recognise a new or emerging issue.

4. Project and programme risks

- 4.1.** Projects are scrutinised by the HFEA's Programme Board. Risk assessment and management are a substantial aspect of this oversight arrangement and both the Project Manager and the Project Sponsor (usually a Director) must report to the Programme Board at monthly intervals. In turn, the Programme Board reports to CMG every month, with a highlight report outlining progress, risks and issues for each live project.
- 4.2.** The Senior Management team is also briefed on current project risks and issues following each monthly Programme Board meeting, enabling prompt management of any new or increasing project risks.
- 4.3.** The Risk and Business Planning Manager is responsible for the HFEA's Programme Management Office (the PMO), which runs the Programme Board. The PMO consists of the Risk and Business Planning Manager and one Programme Support Officer (PSO). The PMO/PSO gives frequent guidance and support to Project Managers on all aspects of project management, including the identification, reporting and management of project risks, and the identification of lessons learned at the end of projects, for future risk prevention purposes. The PMO provides a toolkit, including a risk log and other templates, and both corporate and personalised training for staff in project management methodology as needed.
- 4.4.** One of the main sources of project risk within the HFEA is the amount and complexity of the interrelations between the HFEA's various systems and our legal and regulatory

framework. The PMO therefore offers an interdependencies matrix tool to assist with good risk management at the early planning stage of a project. This is regularly reviewed and kept up to date to reflect any changes in our systems, information assets or structure.

5. Internal incidents

- 5.1.** The HFEA's executive maintains an internal incident procedure, which ensures that any process failures are quickly and thoroughly investigated. This allows CMG to learn lessons and correct procedural vulnerabilities. All reported incidents are recorded, regardless of whether there was a need to investigate in order to understand what went wrong. This is to encourage a learning culture and transparent recording of perceived adverse events.
- 5.2.** The process is relaunched periodically (the last such occasion being in June 2016) to remind new and old staff alike of the importance of identifying and learning from incidents, and to provide clarity to staff about reporting and investigating incidents.

6. Risk escalation

- 6.1.** Where a risk changes or a new one arises where the impact is beyond the capability or capacity of the relevant team to control or mitigate it, or when it becomes a higher-level risk (for instance when a project risk threatens HFEA strategic delivery) it should be escalated. The escalation process depends upon the type of risk, the severity and urgency of it, and where in the organisation it has been recognised as an escalation issue.
- 6.2.** Project risks recognised by the Sponsor can be escalated to the HFEA Programme Board. Programme Board can then report to CMG and highlight any action that is needed that is beyond the project team or programme board's power to implement.
- 6.3.** Operational risks are escalated through monthly CMG meetings. There is a standing item on the agenda and Heads are responsible for raising new operational risks that have arisen and any that are becoming more severe. CMG are then able to note this or offer assistance in planning mitigations.
- 6.4.** If either a project risk or an operational risk needs to be escalated quickly, or between meetings of the Programme Board or CMG, this can also be achieved through weekly SMT meetings, for expediency.
- 6.5.** Severe or increasing strategic risk with high residual risk level and impact on delivery should be added to the strategic risk register. If the risk proximity, likelihood or impact are such that the risk requires immediate counter measures to be put in place, the Risk and Business Planning Manager, Head of Planning and Governance, and the individual raising the risk should consider whether a paper to CMG or a more immediate discussion with the Senior Management Team may be necessary.
- 6.6.** Once the risk has been escalated, CMG or SMT will guide the risk owner to plan an appropriate approach to dealing with the risk. If necessary, additional reporting to AGC or the Authority can also be put in place.

7. Risk management methodology

7.1. The HFEA considers the following as the key stages of risk management:

- Identification
- Clear description
- Likelihood/probability of risk occurring
- Consequences and impact of the risk if it does occur
- What controls or actions can be put in place?
- What is the 'residual risk'?
- Is this tolerable or is a further action plan needed?
- Who is responsible?

7.2. When articulating risks, the HFEA follows the following principles:

- Risks should relate to objectives, and should also include generic risks which affect all objectives
- State risks, NOT impacts
- Avoid defining risks with statements which are simply the converse of an objective

7.3. In considering what controls can be put in place, the HFEA considers the following options, based on a common model:

- Tolerate the risk (ie, do nothing, but be aware)
- Treat the risk (ie, do something to actively reduce the risk)
- Transfer the risk (eg, to an insurer or contractor)
- Terminate (ie, stop doing the activity that causes the risk).

7.4. In setting out controls, the HFEA:

- Assigns internal controls to named individuals with authority to undertake or delegate the relevant actions
- Identifies specific actions
- Keeps on monitoring and reviewing residual risks and internal controls

7.5. In any grass roots review of risks, the HFEA considers the following factors:

External:

- PESTLE model:
 - Political
 - Economic
 - Social
 - Technological
 - Legal
 - Environmental

Operational:

- Delivery:
 - Service/product failure; project (delivery failure)
- Capacity and capability:
 - Resources (money, people, information and evidence, physical assets); planning; relationships (partners, clients, accountability); quality management; operational delivery (overall capacity and capability); reputation (confidence and trust in the organisation)
- Risk management performance and capability:
 - Governance (oversight and scrutiny, propriety, compliance, ethics, due diligence); scanning (failure to identify threats); resilience (capacity to withstand adverse impacts, business continuity); security (of assets and information)

Change

- Environmental changes and challenges
- New targets and performance indicators
- Change programmes
- New projects
- New policies
- Changes in resource availability

8. Assessing and estimating risk:

8.1. The HFEA defines 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.’

8.2. HFEA defines residual risk (also known as ‘exposure’) as:

‘The exposure arising from a specific risk after action has been taken to manage it, and making the assumption that the action is effective.’

8.3. Any given risk score is a combination of:

- The likelihood of something happening
- The impact which arises if it actually does happen

8.4. Risk scoring system

We use a 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

The risk matrix can be seen below:

Risk scoring matrix						
Impact	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
	Risk Score = Impact x Likelihood	1. Rare (≤10%)	2. Unlikely (11%-33%)	3. Possible (34%-67%)	4. Likely (68%-89%)	5. Almost Certain (≥90%)
	Likelihood					

Consensus statement on treatment add-ons

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

Details:

Meeting	Authority
Agenda item	11
Paper number	HFEA (14/11/18) 899
Meeting date	14 November 2018
Author	Laura Riley, Head of Regulatory Policy.

Output:

For information or decision?	For information
Recommendation	To note: the aims of the consensus statement; the continued monitoring of the use of add-ons in clinics; and the plans for disseminating and publishing the consensus statement.
Resource implications	-
Implementation date	End of November 2018
Communication(s)	
Organisational risk	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High
Annexes	

1. Introduction

- 1.1.** The responsible use of innovative treatments in fertility treatment has been an issue of concern to HFEA and many in the sector for some time, and has led to new patient-focused activities supported by HFEA's Scientific and Clinical Advances Advisory Committee (SCAAC), including the new annually-reviewed 'traffic lights' system, which rates the evidence for the effectiveness of the most commonly-offered treatment add-ons. The new 2018 edition of the Code of Practice sets out clear expectations which will be inspected against, that clinics will offer information to patients about the evidence for efficacy and safety of any treatment add-ons that they are offered.
- 1.2.** In September 2017, the HFEA held a meeting with key stakeholders to discuss how the sector can work together to tackle the issue of treatment add-ons. At this meeting we agreed to set up a working group tasked with developing a consensus statement on the responsible use of treatment add-ons in fertility services.
- 1.3.** The statement is intended to be applicable to current practice but also relevant to the introduction of new treatment add-ons into clinical practice in future. The consensus statement is intended to mark the start of a change of culture within the sector towards more responsible practice relating to the offer and use of treatment add-ons.
- 1.4.** In March 2018, the working group, mostly consisting of signatory organisations- relevant professional societies, regulators and patient group representatives, met for the first time to discuss high level issues. The meeting agreed that HFEA should put together a first draft of the statement and circulate to the group for comments. In July, [the Guardian](#) carried an article setting out the Authority's and professional societies' concerns about how some unevidenced add-ons are being offered to patients.
- 1.5.** We circulated the first draft of the statement in August, setting out key principles and listing signatory organisations' responsibilities. Comments were gathered from the working groups over the following weeks. Based on the feedback received, a second draft was developed with a shorter introduction and which focused on clarifying seven key principles.
- 1.6.** This draft was discussed in detail at a second working group meeting on October without making substantive changes and with final comments agreed over email. At the meeting, representatives of ESHRE and other UK-based professional societies said that they hoped to work together to develop practical tools for members to support the introduction of the consensus statement principles. These would include best practice guidance and training events and clarifying expectations around declarations of interest.
- 1.7.** The professional bodies mentioned areas outwith the remit of the Act where similar principles might be helpfully applied, for example around unevidenced tests and immunosuppressive treatments offered by some fertility clinics or recurrent miscarriage clinics around 'natural killer' cells found in the woman's bloodstream or uterine environment. The RCOG President said that the College will develop guidance materials for members around this area, complementing the consensus statement and in line with its principles, as well as information materials for patients.
- 1.8.** The October meeting also discussed plans for dissemination and publication of the final consensus statement. HFEA will coordinate the Communications functions for signatories, and all agreed that the final consensus statement will contain the logos of all signatory organisations and official signatures. The final statement will be held on signatory organisations websites, including

the HFEA website. The consensus statement will be simultaneously press-released by the signatories and will form the basis of journal articles to be simultaneously published in journals relevant to the fertility sector (eg Human Reproduction and Human Fertility) in early 2019. The statement will also inform discussion at the HFEA annual conference in 2019, and other conferences for the sector next year.

- 1.9.** The HFEA's new Leadership events in November 2018 convene Persons Responsible from licensed clinics, providing a useful opportunity to convey messages to clinic leaders.
- 1.10.** HFEA inspections will in future include a checklist seeking information from clinics about what add-ons they offer and how (accompanied by what information) these are presented to patients. We will continue to refer to GMC guidance on advertising in clinical practice to challenge any unsubstantiated claims for add-ons in relation to fertility treatment success, and if necessary referring to the Advertising Standards Authority.
- 1.11.** HFEA will also develop workshops in 2019 for clinics around the key consensus statement principles, an approach to cross-sector dialogue which has previously worked successfully with changing clinic culture to reduce the incidence of multiple births.

2. Text of the consensus statement on treatment add-ons

- 2.1.** The text of the consensus statement is close to being finalised with the aim to reach agreement before the end of November, to be followed by journal article publication and press activity (see paragraph 1.8 above).
- 2.2.** In view of this, the text is provided to Authority members in confidence.

3. Recommendations

- 3.1. The Authority is asked to note:**
 - that the consensus statement aims to support partnership working by signatories towards the responsible use of treatment add-ons in fertility services.
 - that the HFEA will continue to monitor the use of add-ons in use in clinics via inspection and other methods and that the consensus statement is likely to inform future work by HFEA towards supporting the aims of the statement.
 - the plans for dissemination and publication of the consensus statement.