Human Fertilisation & Embryology Authority

Authority meeting - agenda

12 September 2018, HFEA, 10 Spring Gardens, London, SW1A 2BU.

Agenda item	Time
1. Welcome, apologies and declaration of interests	1.00pm
2. Minutes of 27 June 2018 Authority meeting **HFEA (12/09/18) 888** For decision	1.05pm
3. Chair's report (verbal)	1.10pm
4. Chief Executive's report (verbal)	1.20pm
5. Committee chairs' reports (verbal)	1.30pm
6. Performance report **HFEA (12/09/18) 889** For information	1.40pm
7. Business plan 2019/20 – outline **HFEA (12/09/18) 890** For decision	2.00pm
Break	**2.30pm**
8. State of the sector (presentation) For information	2.45pm
9. Donor anonymity and direct-to-consumer genetic testing **HFEA (12/09/18) 891** For information	3.25pm
10. Standard licence condition T53 - screening **HFEA (12/09/18) 892** For decision	3.50pm
11. Any other business	3.55pm
12. Close	4.00pm

Minutes of Authority meeting 27 June 2018

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

Details:	
Meeting	Authority
Agenda item	2
Paper number	HFEA (12/09/18) 888
Meeting date	12 September 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 27 June 2018 held at Church House, 27 Great Smith Street, London SW1P 3NZ

Members present	Sally Cheshire Kate Brian Andy Greenfield Anthony Rutherford Bishop Lee Rayfield	Yacoub Khalaf Margaret Gilmore Bobbie Farsides Ruth Wilde Anita Bharucha
Apologies	Anne Lampe	
Observers	Steve Pugh, Department of Health and Social Care	
Staff in attendance	Peter Thompson Nick Jones Richard Sydee Clare Ettinghausen Catherine Drennan Erin Barton	Dan Howard Sumrah Chohan

Members

There were 10 members at the meeting, 7 lay members and 3 professional members.

1. Welcome, apologies and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members and members of the public to the fourth 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 Anne Lampe.

1.3. Declarations of interest were made by:

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

2. Minutes of Authority meeting held on 09 May 2018

2.1. Members agreed the minutes of the meeting held on 09 May 2018 for signature by the Chair.

3. Chair's report

3.1. The Chair attended Fertility Fest on 11 May. This event centred on the 40th anniversary of IVF. The Chair took part in a panel which discussed the triumphs and challenges of IVF.

3.2. Also on 11 May, the Chair spoke at the British Infertility Counselling Association's (BICA) 30th anniversary conference, on improving clinic leadership, the importance of emotional support for patients and counselling.

3.3. On 30 May 2018 the Chair, Authority member Kate Brian, and the Director of Strategy and Corporate Affairs, met Professor Lesley Regan, President of the Royal College of Obstetricians and Gynaecologists (RCOG). This was a follow up to a previous event at the RCOG in March that the Chair and Professor Regan participated in. The HFEA and RCOG committed to working together more closely on a range of issues related to fertility treatment.

3.4. Also on 30 May, the Chair and Chief Executive had the HFEA annual accountability meeting with the Department of Health and Social Care (DHSC). The DHSC agreed that the HFEA has had a very successful year and delivered all its objectives in the 2017/18 business plan. The Chair thanked Authority members and HFEA staff for the role that everyone played in this achievement.

3.5. On 6 June, the Chair and the Senior Management Team (SMT) met Jane Stewart and Raj Mathur from the British Fertility Society (BFS) to discuss how we can develop a more strategic relationship. Key issues discussed included such as NHS commissioning, treatment add-ons, ovarian hyperstimulation syndrome (OHSS) and clinic leadership.

3.6. On 18 June the Chair met Nicola Blackwood, the new Chair of the Human Tissue Authority (HTA). Both Chairs committed to work together on issues of shared interest.

3.7. The Chair also attended the Scientific and Clinical Advances Advisory Committee (SCAAC) on 18 June.

4. Chief Executive's report

4.1. On 24 May the Chief Executive attended an event at the Institute for Government to mark the publication of a report examining the first five years of NHS England.

4.2. On 30 May, as the Chair mentioned, the Chief Executive also attended the HFEA annual accountability meeting. The Chief Executive also thanked staff and Authority members for their hard work.

4.3. On the 6 June, again as the Chair also mentioned, the Chief Executive met Jane Stewart and Raj Mathur of the BFS.

4.4. On 12 June the Chief Executive attended the HFEA's Audit and Governance Committee meeting.

4.5. On the 18 June, the Chief Executive attended the SCAAC meeting.

4.6. Lastly, on 26 June the Chief Executive attended an event at the House of Lords to mark the launch of a new report from the Institute for Government and the Health Foundation, on the future funding of health and social care. The report looks at previous attempts to depoliticise controversial public policy issues and the HFEA was cited as one successful case study of that. The Chief Executive reminded members that they had been sent a link to the report.

Press Coverage

LaingBuisson report

4.7. Recently, a report on the financial state of the private fertility sector was published by a well-known healthcare research company, LaingBuisson, in which reference was made to the HFEA and which made use of HFEA data.

Guardian interview and comment for You and Yours

4.8. The Chief Executive gave an interview to the Guardian two weeks ago, on the theme of treatment add-ons. He explained the work we have been doing to ensure the introduction of add-ons is responsibly done and clearly explained to patients, highlighting the traffic light system introduced last year. The article was published last week.

4.9. We also provided a comment on treatment add-ons and overseas treatment to Radio 4's You and Yours programme.

4.10. The Chief Executive explained that on each occasion the HFEA emphasised the value, not just of the traffic light system, but of our website overall, using this coverage as a chance to raise awareness of topics such as responsible innovation.

Comment for i newspaper

4.11. Last week we provided a comment for the i newspaper on the development of IVF within the context of the 70th anniversary of the NHS.

4.12. The Chief Executive noted that we can look forward to more coverage related to the 70th anniversary over the coming weeks, especially as IVF was specifically referenced by the Secretary of State in Parliament recently, as an example of the NHS's excellence and innovation.

Data requests

4.13. The Chief Executive reported that our Register continued to be a considerable press resource, and this month we provided data on (among other areas):

- Male infertility (to the BBC Victoria Derbyshire show)
- Treatment numbers (to the Sunday Express)
- Egg freezing (to BBC Capital)
- Patient ethnicity (to BBC Impact)
- Patients aged over 50 (to the Mail on Sunday)

5. Committee Chairs' reports

Licence Committee

5.1. The Chair of the Licence Committee advised members that the Committee met on 3 May to consider an executive update regarding one clinic. The Committee noted the update.

Statutory Approvals Committee

5.2. The Chair of the Statutory Approvals Committee (SAC) advised members that the Committee met on 26 April and 24 May. All applications considered in April were approved: five pre-implantation genetic diagnosis (PGD) applications and two special direction applications. In May one mitochondrial donation application; four PGD applications; and one special direction application was considered. All applications were approved.

Executive Licensing Panel

5.3. The Chair of the Executive Licensing Panel (ELP) advised members that the Panel had met four times since the last Authority meeting, on 10 May, 25 May, 8 June and 22 June. 17 items were considered in total: one initial licence application; three renewal applications; five interim inspection reports; seven variation of licence applications; and one executive update. All were approved.

5.4. The Licensing Officer considered four applications, which were all approved: two change of licence holder and two EU import certificate applications.

Audit and Governance Committee

5.1. The Chair of the Audit and Governance Committee (AGC) advised members that the Committee had met on 12 June. Aside from the usual standing items and updates from internal and external audit, the committee received reports on: annual accounts; HR, people planning and processes; a digital programme update; resilience, business continuity management and cyber security; the strategic risk register; whistle blowing and fraud; and contracts and procurement.

5.2. The Chair of AGC thanked the Director of Finance and Resources and the Head of Finance for the work they had contributed towards the creation of the Report of the Audit and Governance Committee activity 2017/18.

Scientific and Clinical Advances Advisory Committee

5.3. The Chair of the Scientific and Clinical Advances Advisory Committee (SCAAC) advised members that the Committee considered four items during their 18 June 2018 meeting.

5.4. The four items covered: selecting sperm for intracytoplasmic sperm injection; treatment add-ons; supporting research; and the potential regulation of so-called embryo-like entities.

Remuneration Committee

5.5. The Chair advised members that the Remuneration Committee had met that morning.

6. Report of the Audit and Governance Committee activity 2017/18

6.1. The Chair of the Audit and Governance Committee (AGC) presented a report summarising the Committee's activity during the year and giving its opinion on the HFEA's risk management and internal control arrangements. The report supports the Accounting Officer's Annual Governance Statement.

6.2. During this period AGC scrutinised regular reports on the progress of the remainder of the IfQ programme (covering data submission and the migration of the Register to a new database), the HFEA response to IT and cyber incidents as well as overall data and cyber security.

6.3. The Chair of AGC explained that the Committee had provided scrutiny and challenge to the remainder of the IfQ work in order to receive assurance that risks were being effectively managed. Approval had been given to go ahead with the final work needed for this.

6.4. The Chair of the AGC thanked staff for the high quality support provided to the Committee.

Decision

6.5. The Chair noted that one financial control (assurance that the HFEA had adequate and effective systems of control, governance and risk management in place) had been rated as 'moderate' during the internal audit carried out by the Government Internal Audit Agency. She enquired if there were any specific improvements that had been suggested and it was confirmed that the recommendations had been implemented.

7. Performance report

7.1. Members were presented with a paper summarising performance up to the end of April 2018, with financial data covering both April and May.

7.2. The Director of Strategy and Corporate Affairs outlined activity in what was a busy period. This included changes being developed for the Statutory Approvals Committee (SAC) to assist with increasingly heavy agendas; work towards the 40th anniversary of IVF, including the development of a social media campaign; the preparation of a report on egg freezing in the summer and one on the state of the sector for the autumn; developing the qualitative work on the pilot national patient survey with YouGov; and the Code of Practice update.

7.3. The Chair noted the Science Museum exhibition about would open on 5 July 2018 and members had received invitations to the launch.

7.4. Members thanked the Director of Strategy and Corporate Affairs for the new 'Authority Update' newsletter which was now circulated to them.

7.5. The Chair of SAC highlighted that there was a lot of background work going on regarding this Committee, in particular with respect to mitochondrial donation applications.

7.6. The Director of Compliance then reported on overall performance and the IfQ programme.

7.7. Overall performance was good. The organisation experienced technical issues with its IT systems from 19 April to early May, which affected a number of processes and therefore key performance indicators (KPIs).

7.8. Three KPIs were classified as red (outstanding errors; average number of working days from day of inspection to the day the draft report is sent to the PR; and Opening the Register requests responded to within 20 working days) and one as amber ('unplanned' leavers).

7.9. The Director of Compliance reported that the HFEA was on track with the IfQ programme and provided an overview of milestones and decision points. A beta version of PRISM was live with feedback being taken from clinics. Positive progress was being made in data migration, but this still remained the biggest risk to delivery.

7.10. The Chair asked if we were confident there would be no further IT issues. The Director of Compliance confirmed that although this could not be guaranteed, all the appropriate and available steps had been taken. The Chief Executive clarified that there had not been any data at risk during the issues experienced in April and May.

7.11. The Authority members who work in fertility clinics were asked if they felt positive about the proposed data submission changes; they confirmed they were.

7.12. The Authority members had a discussion around clinics updating their Choose a Fertility Clinic page on the HFEA website and the lack of up to date information regarding egg and sperm donor availability. It was confirmed that the executive looked into this at inspections, but did not have the resources to interrogate data thoroughly for every clinic in between inspections. It was agreed that the messaging about this, including during inspection, should be looked into.

7.13. The Director of Finance reported that annual accounts had been signed by the Chief Executive today and would now be provided to the National Audit Office. It was reported that we were still awaiting approval from the DHSC for additional capital expenditure on IfQ work.

Decision

7.14. Following discussion, the members noted the latest performance report.

8. Code of practice

8.1. This item was introduced by the Chief Executive who confirmed that the updated Code of Practice had been subject to consultation and that detailed responses had been received from over 100 respondents, with many from professional organisations. The Chief Executive thanked all contributors for their comments.

8.2. The Policy Manager explained that of the 33 guidance notes in the Code of Practice, 23 had been updated. Changes were reported to members in groups and the feedback received during the consultation was highlighted.

Least substantive changes

8.3. These related to areas where no feedback, or positive feedback, had been received:

- Egg sharing
- Screening
- Data protection
- Import and export of gametes and embryos
- Single European Code
- Data submission
- Corrections and minor clarifications

Decision

8.4. Following discussion of the evidence base regarding reducing the quarantine period for screening, and confirmation that the impact on patients will be monitored on an ongoing basis, all of the changes to the Code of Practice, regarding the areas listed above, were approved.

Ovarian hyperstimulation syndrome (OHSS), Consent, Surrogacy and Storage

8.5. The Policy Manager presented information on planned changes to these areas of the Code of Practice, in addition to changes made following the consultation.

Decision

8.6. Members approved the changes regarding OHSS, noting that the changes were sensible and pragmatic.

8.7. There was a discussion around consent, with members highlighting uncertainties over the process of receiving and taking consent electronically and whether a particular process being used in a clinic at present was sufficient. The Head of Legal reassured members that the process highlighted was sufficient under the new guidance.

8.8. Suggestions for new wording to this section of the Code of Practice were made and it was agreed to discuss this further outside of the meeting. Otherwise, the Members approved the changes regarding consent.

8.9. Members approved the changes regarding extension of storage. They noted that, although it is for Parliament to change the law, there is increased concern from clinicians about the 10 year storage period and the impact on some patients.

8.10. Subject to clarifying in the Code of Practice that determining suitability for surrogacy should be a clinic level decision, the Members approved the changes regarding surrogacy.

Substantive changes

8.11. The following areas of guidance were covered in this group:

- Leadership
- Patient support
- Information provision to patients
- Counselling
- Discussion of implications

Decision

8.12. Members approved the changes regarding leadership, noting that examples of good leadership and support for PRs would be further developed by a specific project on leadership taking place later this year.

8.13. Members approved the changes regarding patient support, noting that patient support was strengthened via the amendments.

8.14. Members approved the changes regarding information provision.

8.15. Members approved the changes regarding counselling.

8.16. Members discussed the importance of ensuring that there is a distinction between counselling and a discussion of implications and whether the Code of Practice was clear about who should undertake the discussion of implications. It was agreed that work on a final proposal for the discussion of implications section of the Code would be continued outside of the meeting and considered by relevant Members prior to approval.

9. Voluntary contact register

9.1. The Chief Information Officer presented a paper on ongoing work to develop a new vision and approach for the voluntary contact register, known as the Donor Conceived Register (DCR).

9.2. The Chief Information Officer provided members with background about the DCR and how the service was run. In April 2017 responsibility for the DCR transferred from the DHSC to the HFEA. We sought to retender the service to ensure a high-quality service was provided, offering value for money. One bid was received from the National Gamete Donation Trust, the current provider. The bid failed to meet our quality and price criteria and the contract was not awarded.

9.3. The Chief Information Officer outlined the options considered going forward, to ensure we were able to provide a stable, long term service. This included the preferred option, to develop a new service provided by industry and sector leading suppliers, with oversight from the HFEA.

9.4. The Chief Information Officer outlined progress to date, including engagement with different stakeholders, and confirmed that a consultation on an outline service model would start in July. The plan was for the new service to go live in October or November 2018, with continual monitoring to ensure quality.

9.5. The Authority was asked to note:

- The update on progress made to establish a new Voluntary Contact Register service
- The update on consultation, engagement and dialogue with stakeholders, including DCR
- The proposed timeline for the implementation of the new service
- How performance of the new service will be reviewed and monitored.

9.6. The Chair emphasised that this report reflected the general direction the HFEA would take to support patients. She asked the Executive to come back to Authority with the outcome of the consultation.

Decision

9.7. Members were pleased with the direction the work was taking. In discussion it was noted that it was important to raise the profile of the consultation amongst donor conceived people who have not yet expressed a view. Members also asked why it would not be preferable to provide the service in-house. It was accepted that the range of skills required were best sourced elsewhere. Members were happy for the consultation to proceed and that an update would be provided to Authority in September.

10. Donor information requests

10.1. The Donor Information Manager provided members with information about donor information requests (known as Opening the Register (OTR)) and associated counselling support.

10.2. The Donor Information Manager outlined performance in relation to OTR requests, providing data about the number of applications received. Whilst application numbers were unpredictable, the number of donor-conceived applications has steadily risen since 2010, with 78 applications in 2017 compared with 45 in 2016.

10.3. The Donor Information Manager also provided information about releasing identifying information. The first application for identifying information from an adult donor-conceived person, with an identifiable donor, was received in 2013. 11 such applications have been received in total to date. The first Donor Sibling Link (DSL) match was made in 2015, and there have been nine matches in total.

10.4. The Donor Information Manager provided information about the quality of the OTR service. Responses from OTR applicants had been positive, with the majority of people rating specific areas of the process as good, very good or excellent. Survey responses from users of the support service, which began in 2014 and is run by PAC-UK, had all rated the service as good or excellent.

10.5. The Donor Information Manager briefly spoke about DNA testing websites, and their potential impact on those affected by donor-conception. Such sites raised issues about anonymity which would be considered by the Executive and advice provided to the Authority in due course.

10.6. The Donor Information Manager also spoke about future work, including considering the impact of DNA testing websites and preparations for 2023, when the first cohort of adult donor-conceived people turn 18. DSL will also be reviewed.

10.7. The Authority was asked to note:

- the update on OTR activity and performance
- the supportive way in which OTRs are handled
- the positive feedback received about the support service, and the arrangements for its continuation

- potential impact of DNA testing ancestral websites
- the steps the Donor Information Team is taking to plan for the future of the OTR service

10.8. The Authority was also asked to agree:

- That we continue the counselling service on a rolling contract basis with PAC-UK.

Decision

10.9. Members praised the OTR service and the work done by the Executive. The Chief Executive highlighted the need to prepare for 2023 and consider the potential challenges and resource implications.

10.10. It was agreed that further information would be presented to Authority in September, regarding DNA websites, to determine the scale of this work.

10.11. Members agreed to continue the counselling support service with PAC-UK.

11. Egg freezing and infertility treatment – trends and figures

11.1. The Chair explained that this item was deferred and that it would be presented to Authority in September, when more information could be provided.

12. Any other business

12.1. The Chair thanked Authority Member Bishop Lee Rayfield, for whom this was his last Authority meeting, for his service over the last six years.

13. Chair's signature

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

Signature

Chair

Date

Performance report

Strategic delivery:	☒ Safe, ethical, effective treatment	☒ Consistent outcomes and support	☒ Improving standards through intelligence
Details:			
Meeting	Authority		
Agenda item	6		
Paper number	HFEA (12/09/18) 889		
Meeting date	12 September 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)	The Senior Management Team (SMT) reviews performance in advance of each Authority meeting, and their comments are incorporated into this Authority paper. The Authority receives this summary paper at each meeting, enhanced by additional reporting from Directors. Authority's views are discussed in the subsequent SMT meeting. The Department of Health and Social Care reviews our performance at each DHSC quarterly accountability meeting (based on the SMT paper).		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: Performance report		

1. Introduction

1.1. The attached paper summarises our performance up to the end of July 2018.

2. Reviewing performance

2.1. SMT reviewed the July performance data at its August 28 meeting.

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

3. Recommendation

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

HFEA performance scorecard

Dashboard – July data

Overall performance – RAG status (all indicators)

People – capacity

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

⇩
Leavers: 2 (19.1%)

Engagement – Website traffic

Website sessions this month
Arrow tracks performance since last month

⇧
24,063

Licensing end-to-end

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

★
69 working days

Money – budget

Summary Financial Position - July 2018

	Year to Date			Full Year		
	Actual £'000	Budget £'000	Variance £'000	Forecast £'000	Budget £'000	Variance £'000
Income	2,071	2,057	(14)	6,495	6,491	(4)
Expenditure	2,005	2,060	55	6,330	6,268	(62)
TOTAL Surplus / (Deficit)	66	(3)	69	165	223	(58)

Commentary

The above table is a summary of our financial position as at 31 July 2018. We are currently below our budget position by £58k, largely due to the underspends in our Legal costs.

The issue relating to treatment form submission has now been successfully resolved. The trend in treatment volumes continue to be upward and is reflected in the excess of YTD income over budget.

Overall performance – July 2018

SMT reviewed the overall performance picture on 28 August. There were 3 red indicators.

We are currently in the process of upgrading our outdated HR system to a more effective and modern one which we will launch in September 2018. This unfortunately means that we are unable to report on sickness data at the current time, although the trend is stable. Managers are currently capturing this manually and when the new system goes live we will retrospectively accurately update this data and will be able to report on it for previous months.

From late May until early August we had no reliable google analytics data, owing to our opt in cookie banner, introduced following new GDPR rules, which made it more likely that people would opt out of analytics tracking. Between 50 and 70 percent of people did this. As such, the data set is incomplete and difficult to derive any insight from. A new cookie banner was rolled out in early August which should rectify this, while still enabling the public to opt out if they wish and for us to comply with GDPR. In August we will also be able to start comparing with last years' analytics data as August 2018 was the first complete month with the new site.

Overall, July performance is generally good. The 3 red key performance indicators (KPIs) shown in the 'overall status - performance indicators' bar chart on the dashboard are as follows:

Red indicators

For some months now, we have had consistently high volumes at SAC meetings, resulting in pressure on agendas and the possibility of items being deferred. This month, 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 to process. This will also impact KPIs for the next month or so as these items reach the end of the process. 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 exacerbated by the need to bed in mitochondrial donation processes effectively; this has taken a great amount of effort and patience from the committee, staff, advisors and the centre involved, and we have taken great strides to ensure there are more peer reviewers to undertake this important work. We are particularly grateful to SAC for their continued expertise and care.

- 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 the seven sets of minutes from the June SAC (due for sign off in July) took, on average 22 working days to complete, with 14% being completed within the 20 working day target.
- Percentage of PGD applications processed within three months. Our target is 100%, but in July 29% were completed in this timeframe, with an average processing time of 70 working days.
- 3 month rolling average figure – Percentage of all PGD applications processed within 3 months for the three months to date. Our target is 100% but for the three months to July this dropped to 50%, due primarily to the July processing times.

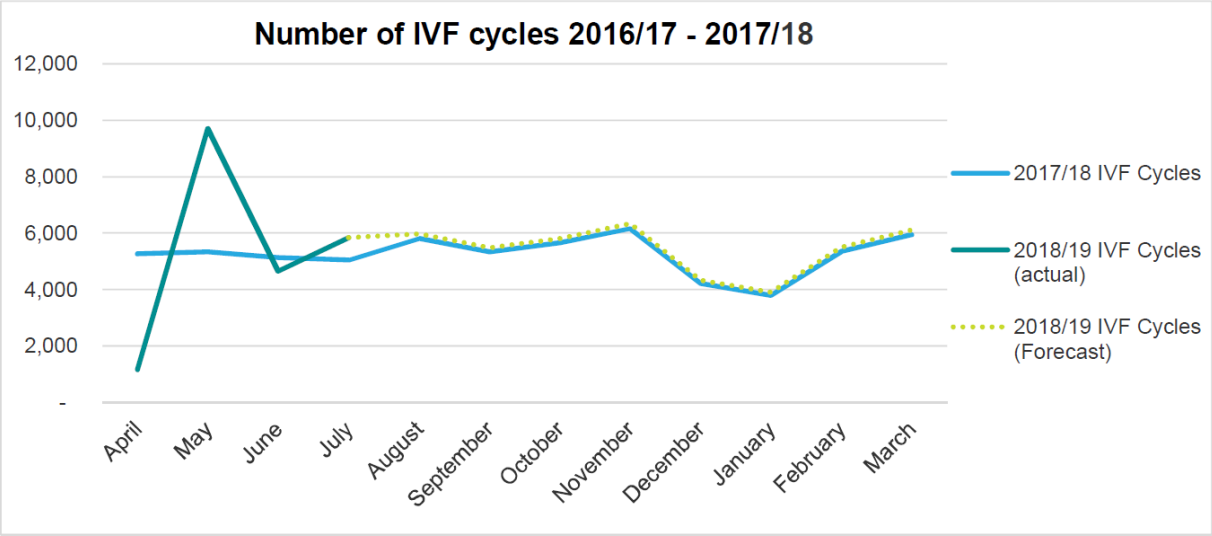
Amber indicators:

- 'Unplanned' leavers: Our target is to remain within 5 - 15% headcount turnover for the year. Performance in July was 19.1%. This figure has been consistently high for 18 months, but this is a slight dip compared to June (20.7%). The overall planned and unplanned leavers for the year is 27.7% (28.7% in June). Our recent organisational change programme was the primary driver of this high turnover for some time. That process is now complete, but turnover has continued; public sector pay and lack of development opportunities are now the primary drivers. Of the 11 unplanned leavers over the last 12 months, nine of these had been at the organisation for longer than two and a half

years (and six of these for over six years) which suggests that many staff find the HFEA a stimulating place to work. It also does not suggest a general trend towards problem turnover. Although turnover is not surprising in a small organisation given the issues identified above, we know that continuing turnover at this rate involves a loss of experience which may in turn have an impact on teams. Our ongoing work on the people strategy will support staff retention.

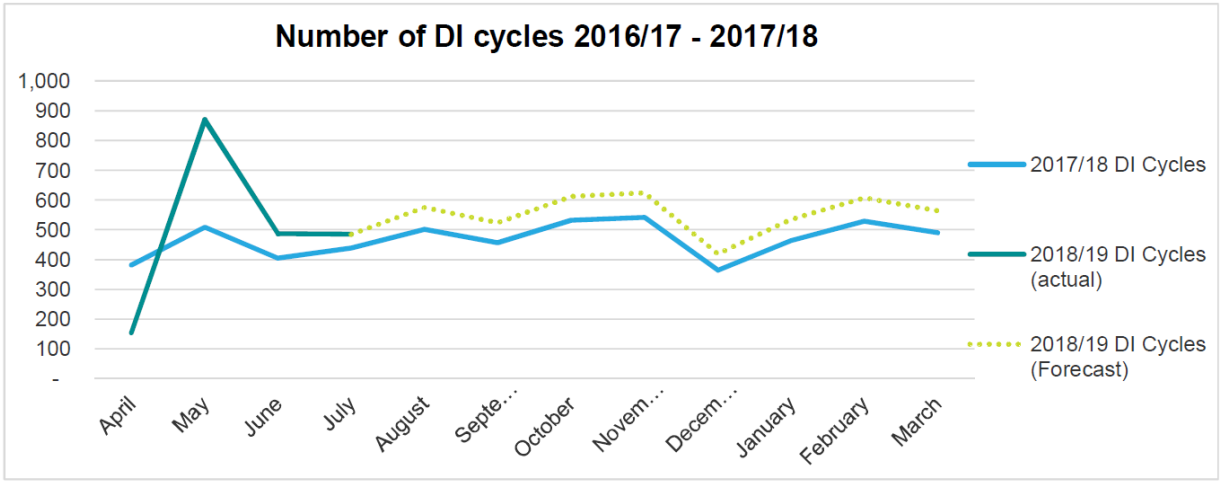
- Outstanding errors - 12 month running total: Our target is to decrease this number. If the number increases by more than 5%, we rate this indicator as red, reductions between 0 and 5% are amber. Current performance is a reduction of about 3%.
- Average number of working days from day of inspection to the day the draft report is sent to the PR: Our target is for 90% of reports to be sent within 20 working days of inspection. In July, performance was 78% in 20 working days, based on nine reports. Of these, seven were within the KPI and two were not. In July one was sent at 24 working days due to workload pressures and the other at 33 working days due to issues finding a research peer reviewer and then further correspondence between the centre and peer reviewer being necessary.

2017/18 Income



IVF Cycles	YTD Volume	YTD £
2017/18 IVF Cycles	10,581	846,480
2018/19 IVF Cycles	10,863	869,040
Variance	282	22,560

The data for the first two months of this year have been skewed due to system issues experienced in April. The year-to-date figure is the correct number of cycles and value. A review will be undertaken at the end of the first quarter.



DI Cycles	YTD Volume	YTD £
2017/18 DI Cycles	891	33,413
2018/19 DI Cycles	1,024	38,400
Variance	133	4,988

Despite the system issues mentioned above, the volume of DI cycles in the first two months of the year are higher than 17/18 by 15%. The reasons for this as yet are unknown.

HFEA Income & Expenditure
for the four months ended

31/07/2018

	Year to Date			Full Year		
	Actual	Budget	Variance	Forecast	Budget	Variance
	£'000	£'000	£'000	£'000	£'000	£'000
Income						
Grant-in-aid	233	233	-	934	934	-
Licence Fees	1,799	1,777	(23)	5,416	5,416	-
Other Income	4	-	(4)	4	-	(4)
Seconded Salary reimbursed	34	47	12	141	141	-
Total Income	2,071	2,057	(14)	6,495	6,491	(4)
Revenue Costs						
Salaries (excluding Authority)	1,372	1,303	(69)	3,931	3,911	(20)
Staff Travel & Subsistence	57	65	9	159	162	3
Other Staff Costs	33	42	8	126	126	-
Authority & Other Committees costs	81	91	10	300	280	(20)
Facilities Costs incl non-cash	235	218	(17)	711	708	(3)
IT costs	61	70	10	233	211	(22)
Legal / Professional Fees	87	173	86	585	585	-
Other Costs	80	98	18	285	285	-
Total Revenue Costs	2,005	2,060	55	6,330	6,268	(62)
TOTAL Surplus / (Deficit)	66	(3)	(69)	165	223	(58)

Management commentary

Income.

Our income year-to-date is £23k (1.3%) above budget. Last month we reported that there were some issues with our billing system which appear to have been resolved. The actual volumes of IVF and DI are 2.9%/15% higher than the same period last year.

Expenditure.

As at the end of quarter two there has been higher than budgeted activity in the areas detailed below:

Salaries £69k above budget - a result of overspends on agency staff (£140k) offset by underspends in salary costs from staff vacancies carried early in Q1.

Facilities £17k above budget - additional desks space through to the end of quarter 2 exceeded budget - late notification of increased costs from landlord.

IT Costs £10k under budget - due to reversal of an accrual in June not required (15k), underspends in our Low value assets and Internet costs (£4k), reduced by an overspend in our Support and Consumable costs (£9k) of which £8k relates to support/subscription costs.

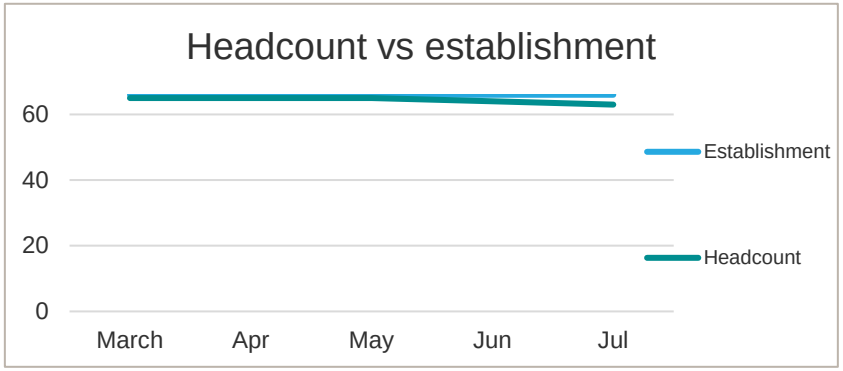
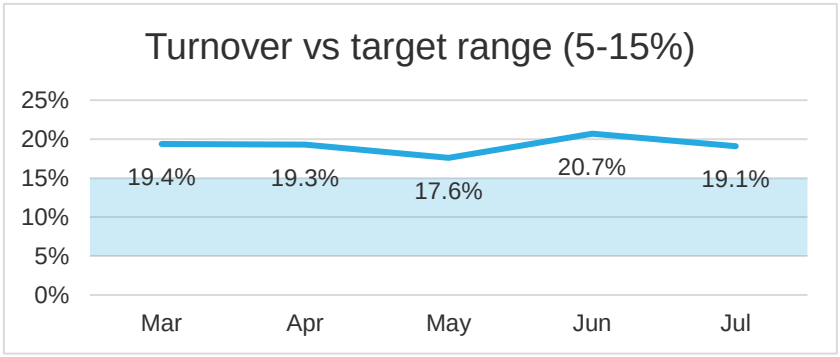
Legal and Professional fees under budget- where Legal is underspent by £34k due to little activity in areas such as Policy, FOI, HR and the Inspectorate. The balance of the underspend relates to the contingency funds being held to meet pending litigation costs.

Other Costs £18k under budget - mainly in the Strategy directorate where the profile of the budget suggested there should have been more activity (Stakeholder Events £10k, Patient Survey £10k, off-set by overspends in HFEA and Digital Publications £9k/£5k).

Forecast Outturn.

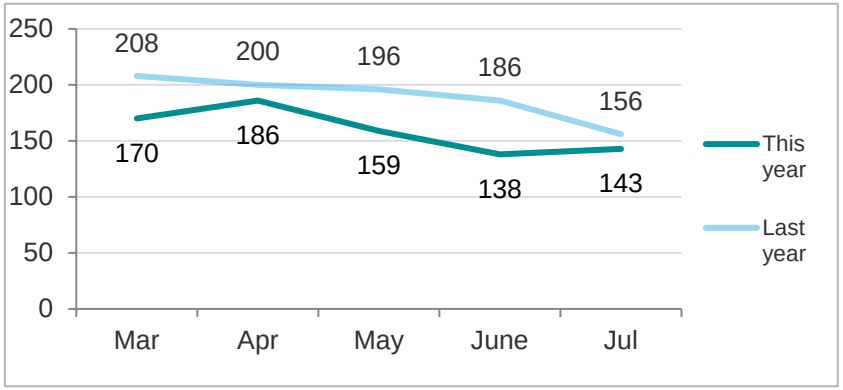
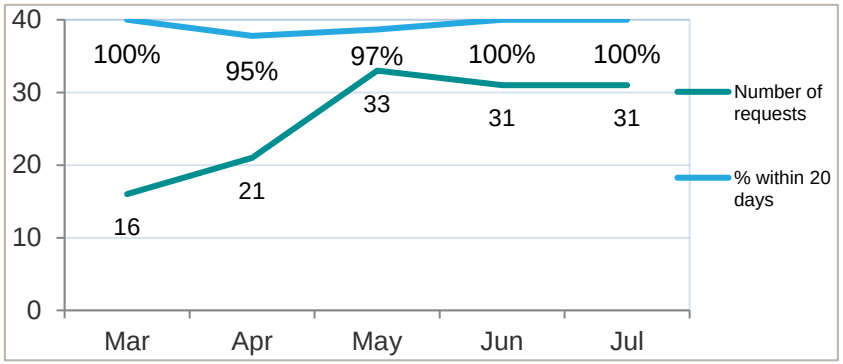
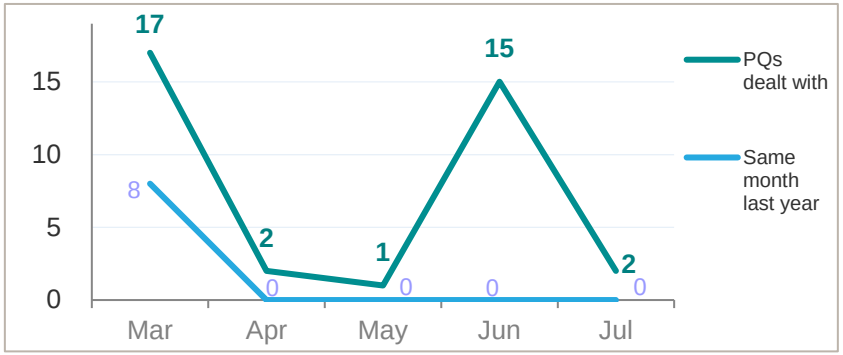
We are forecasting a surplus of £164k which is £58k below the planned budget. However, uncertainty remains in relation to pending litigation and the final outturn relating to income, we have drawn up a number of possible areas to utilise any emerging underspend.

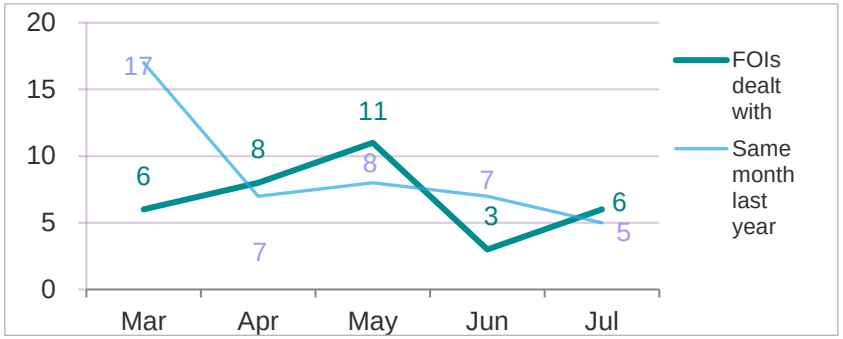
People – key performance and volume indicators

Indicator	Score	RAG	Recent trend[1]	Notes
Current headcount by month Staff in post/headcount	63/66	⇩		Overall volume (capacity) indicator.
Turnover: Establishment ('unplanned') leavers (% establishment turnover for the year). This is done monthly for the rolling year to date.	19.1%	⇩		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.	N/A	N/A	We are unable to provide sickness performance data for the last 3 months since we are in the process of replacing our HR system. Once the new system is in place, data will be retrospectively reported.	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)

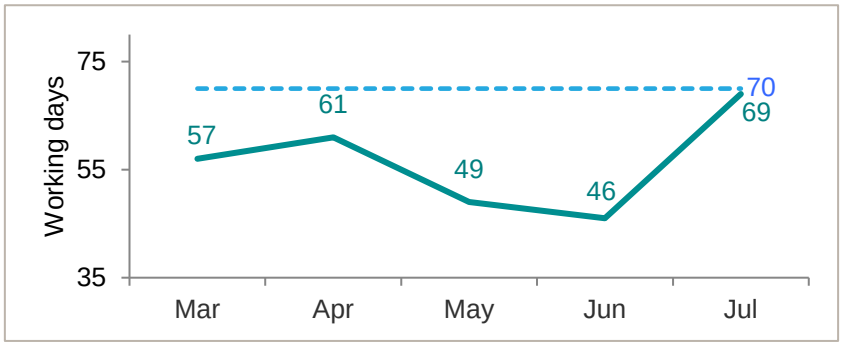
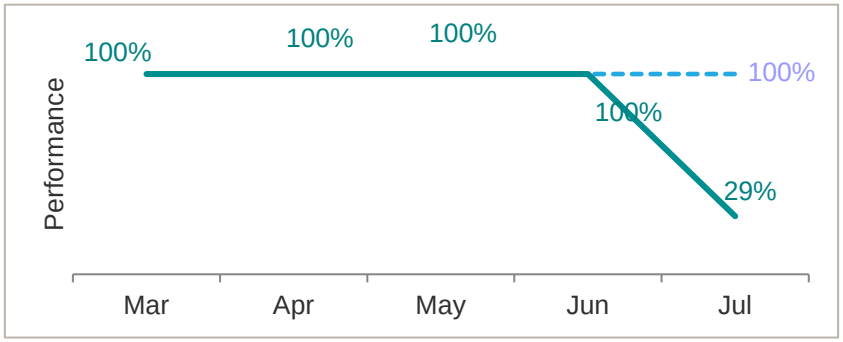
[1] KPIs, where applicable, are show as a blue dashed line in graphs. This line may be invisible when performance and target are identical (eg, 100%). Our establishment turnover KPI is a range, which is shown as a blue band in the graph.

Information – key performance and volume indicators

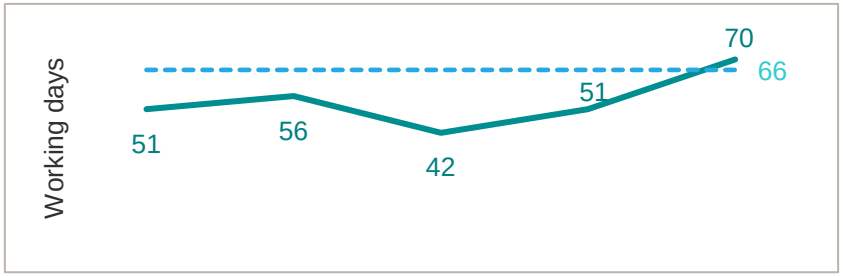
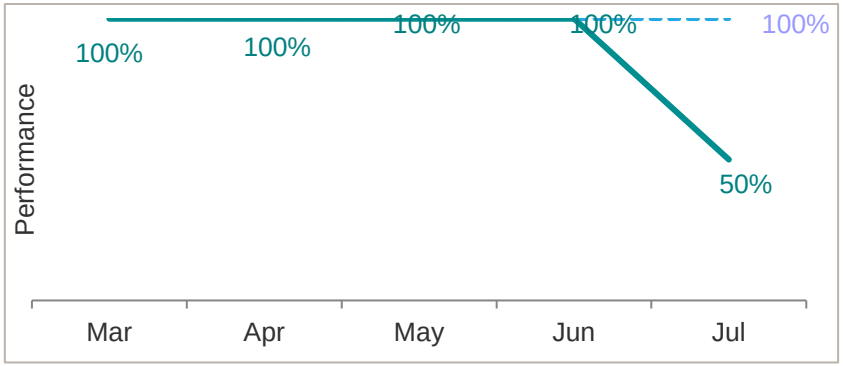
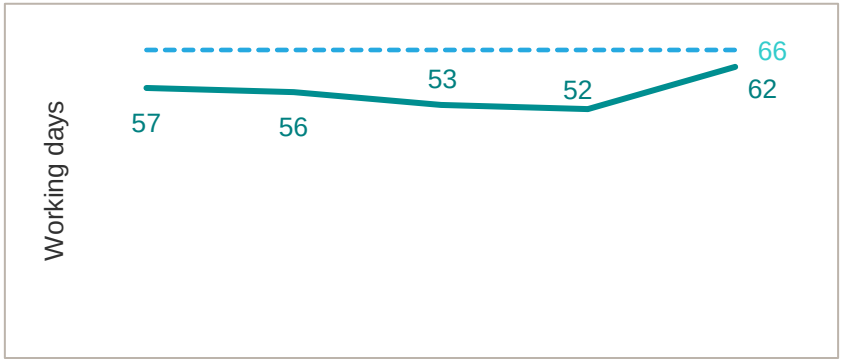
Indicator	Score	RAG	Recent trend	Notes
Number of emailed public enquiries received (compared with same month last year)	143	⇧		Volume indicator.
Percentage of Opening the Register requests responded to within 20 working days	100%	★		KPI: 100% of complete OTR requests to be responded to within 20 working days (excluding counselling time) HFEA technical issues impacted the KPI this month. See full explanation above.
Number of requests for contributions to Parliamentary questions	2	⇩		Volume indicator.

Indicator	Score	RAG	Recent trend	Notes
Number of Freedom of Information (FOI) requests	6	⇧		Volume indicator.

Inspection and licensing process – key performance and volume indicators

Indicator	Score	RAG	Recent trend[2]	Notes
Average number of working days taken for the whole licensing process, from the day of inspection to the decision being finalised (signed off by the chair)	69	★		KPI: Less than or equal to 70 working days.
Monthly percentage of PGD applications processed within three months (66 working days).	29% (4/14)	⇩		KPI: 100% processed (i.e. considered by SAC) within three months (66 working days) of receipt of completed application.

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

Indicator	Score	RAG	Recent trend[2]	Notes
Average number of working days taken (in the month).	70	⇧		
Cumulative 3 month (rolling average) percentage of PGD applications processed within three month KPI (66 working days)	50% (10/20)	⇩		KPI: As above. We are reporting against a three-month rolling average rather than an annualised average, since this will allow us to see trends, without being affected by negative performance from a year ago which has been addressed.
Average number of working days taken (cumulative 3 month picture).	62	★		

Business plan 2019-2020 - outline

Strategic delivery:	☒ Safe, ethical, effective treatment	☐ Consistent outcomes and support	☐ Improving standards through intelligence
Details:			
Meeting	Authority		
Agenda item	7		
Paper number	HFEA (12/09/18) 890		
Meeting date	12 September 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	To approve the outline objectives for 2019/20, as the basis for drafting the next business plan.		
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: outline business plan content 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. Since the start of the strategy, the Corporate Management Group (CMG) has had an outline plan in place to ensure that, across the three years, the strategy is delivered through our business plans. CMG has also regularly reviewed delivery, re-planning work as necessary.

1.3. In August, CMG held its annual planning meeting to begin the process of drafting next year's business plan. We reviewed the strategy at this stage and have included in this outline 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. Looking back over the first 18 months, it is clear that we have made good progress in a number of key strategic areas and we are on track to deliver the strategy as planned.

1.4. By the end of this calendar year, we will begin to discuss our next strategy. We will aim to publish the new strategy in the first few months of 2020.

2. 2019/20 business plan outline

2.1. The outline business plan (attached at Annex A), flows from the CMG discussion in August, and many 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. The focus in the third year of our 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.

2.3. As a reminder, the table below summarises our strategic objectives and the progress we've made toward achieving them:

Safe, ethical, effective treatment	
Objectives	1. Ensure that all clinics provide consistently high quality and safe treatment 2. Publish clear information so that patients understand treatments and treatment add ons and feel prepared 3. Engender high quality research and responsible innovation in clinics
What we've done in the first 18 months:	Published detailed information about treatment add ons, with traffic light ratings for patients. Updates to these are now a routine task for SCAAC. Published more information about clinic performance in the state of the sector report. Increased the emphasis on consistent standards in our inspection programme, continued to focus on learning from incidents and events and embedded this into our ways of working. Started the leadership project to define what good clinic leadership looks like.

	Started developing a dashboard to provide clinics with benchmarking data through PRISM.
To do:	Continuing our leadership project, engaging with clinic staff, and particularly PRs, to share good performance and model excellent leadership in clinics, running an event for PRs later in 2018 and in 2019. Further embedding patient feedback into the inspection and licensing regimes to enable more targeted regulatory interventions. Establishing quality criteria to recognise excellent patient care in clinics and allow patients to easily assess the quality of the care provided. Presenting further benchmarking data to clinics, to allow them to review their own performance.
Consistent outcomes and support	
Objectives:	4. Improve access to treatment 5. Increase consistency in treatment standards, outcomes, value for money and support for donors and patients.
What we've done in the first 18 months:	Provided information for those considering going abroad for treatment on how they might access services in the UK, with a regular talk at fertility shows. Began work on the national patient survey. Worked with NHS England and other stakeholders on drafting commissioning guidance. Provided more information about access to donor treatment. Produced guidance on support for patients, donors and donor-conceived people for the Code of Practice. Reviewed how clinics publish success rates on their own websites. Collaborated with NHS Choices to establish links with our new website and put new patients in touch with better information about services.
To do:	Engaging with the sector to ensure compliance with requirements in the new Code of Practice on patient support. Reviewing the effectiveness of our work to encourage embryo research, seeking new ways to encourage and support research, working with research centres and PRs. Involving our stakeholders in defining and establishing the factors that lead to successful outcomes. Engaging with the sector about the benchmark price for treatment. Managing counselling support services for Register applicants.

Improving standards through intelligence	
Objective:	6. Use our data and feedback from patients to provide a sharper focus in our regulatory work and improve the information we produce
What we've done in the first 18 months:	Established the Intelligence team to ensure we have the analytical capability and capacity to extract more value from the data we hold. Published our information strategy on how we will analyse, publish and use data. Published more and better reports using our data, such as the Fertility Trends report. Began to collect high quality patient feedback, on our website, through focus groups and the pilot national patient survey and started to analyse and use this intelligence.
To do:	Publishing and acting on the findings of the pilot national patient survey. Continuing to analyse Register data on success rates and explore with professionals the key factors behind success at the clinic level. Reviewing our patient engagement channels and piloting a new patient forum to ensure we have access to feedback to inform our activities.

2.4. The full list of activities proposed for inclusion is presented in Annex A in a very summarised form – there will be more descriptive detail in the ensuing full draft business plan, which will come to the Authority in November.

3. Planning timetable for 2019/20

Key dates

3.1. The business plan for 2019/20 will take shape over the next few months. The table below lists the main milestones in the process.

Date	Item
August 2018	Initial CMG discussion (done)
September 2018	Authority approval for outline BP for 2019/20

October 2018	2019/20 BP drafted
November 2018	Authority approval for full draft BP for 2019/20
December 2018	Submission of approved draft to DH; budget discussions
January 2019	DH considers draft; budget discussions continue
February 2019	DH comments on draft; budget near-final
March 2019	Near-final draft submitted to DH; budget confirmed
April 2019	Year-end figures added as relevant. Approval and publication.

4. Recommendation

4.1. The Authority is asked to approve the outline business plan for 2019/20, for further development.

Annex 1 – Outline business plan content for 2019/20

Strategy area	Business plan 2019/20
Safe, ethical, effective, treatment	
Standards	Regulation of clinics
	Good governance of licensing decisions
	Processing applications for PGD and mitochondrial donation
	Work to define quality criteria to recognise excellent patient care in clinics and allow patients to easily assess the quality of the care provided.
	Revision of the Code of Practice (in October 2019).
	Continuation of work on encouraging and supporting leadership in clinics, with the aim of improving standards and consistency over time.
	Policy project to review guidance on electronic consent and a wider review of HFEA consent forms to ensure that these remain fit for purpose.
	Provide data to clinics through PRISM to allow them to benchmark their performance against the sector
Evidence	Annual horizon scanning and Scientific and Clinical Advances Advisory Committee work, including ongoing review of add ons.
	Responding to new developments and media reports.
	Continue to refine the way we publish information about the evidence base for treatments on our website, based on feedback from users.
Research	Further work on embryo research, ongoing monitoring of the impact of earlier work including a review of rate of consent for embryo research. We will investigate ways that HFEA can support and encourage research.
	We will consider ways to collaborate with research centres and continue involving researchers in our intelligence work.
	Information provision for researchers requesting access to Register data.
Consistent outcomes and support for patients and donors	
Access	Advice and information about accessing services.
	Working with clinics, sperm banks and voluntary organisations to consider what more could be done to improve the availability of donor sperm and eggs.
Outcomes	Continue to focus on consistency and success rates on inspection.
	Continue to analyse Register data on success rates and explore with professionals the key factors behind success at the clinic level.

Strategy area	Business plan 2019/20
	Continue to communicate about the importance of reducing multiple births to ensure safe outcomes for patients and relaunch the multiple births stakeholder group.
	Evaluate areas of regulatory concern as revealed through inspection.
	Annual fertility trends report
Value	Share benchmarking information with commissioners, working in collaboration with NHS England and others.
	Engage with stakeholders on commissioning guidance produced by the HFEA.
Support	Managing counselling support services for Register applicants.
	Reviewing the impact of new technologies on donor anonymity.
	Monitoring and evaluating new pre-1991 donor-conceived Register contract.
	Improving the emotional experience of care in clinics, by continuing to encourage best practice in clinics, and focusing on support at inspection. Ensuring that best practice is applied to donors and donor conceived people as well as to patients. Failure to provide suitable support will become a non-compliance at inspection in 2019.
	Undertaking early scoping to understand requirements for the organisation to effectively support donor conceived people born after the 2005 lifting of donor anonymity. These donor conceived people will be able to access data from 2021 (non-identifying) and 2023 (full identifying information).
Improving standards through intelligence	
Data	Publish our data, through Choose a Fertility Clinic and statistical reports.
	Maintain the Register and facilitate access via Opening the Register (OTR) requests.
	Access to information under various regimes.
	Gain intelligence through ongoing participation in EU competent authority events, for as long as the UK remains in the EU.
Regulation	More targeted and responsive interventions through applying the intelligence available.
	Review of the risk tool, to improve clinics' access to feedback about their own performance.
Feedback	Respond to a range of enquiries from the public, clinics and other stakeholders.
	Analyse patient feedback obtained from our website (including Choose a Fertility Clinic ratings), social media and the national patient survey, continue

Strategy area	Business plan 2019/20
	to seek patient experience information through other channels and share it with professional stakeholders. We will continue to embed the use of feedback into inspection processes.
	Review our patient engagement channels and pilot a new patient forum to ensure we have access to feedback to inform our activities.
Efficiency	Ensure that we retain the staff we need in order to operate a good quality service, and continue to implement our People Strategy for 2017-2020.
	Continue to engage on emerging international work to take full advantage of expertise.
	Ensure our infrastructure and central systems are efficient and responsive.
	Review of records management and embedding of information governance function.
	Ensure the HFEA is easy to deal with and offers a professional service.
	Comply with government requirements, including General Data Protection Regulation. Review the impact of any regulatory changes caused by Brexit.
	Collaborative work and shared services.
	Survey stakeholders about our performance as a regulator.
	Preparation for moving to new office premises in 2020, to ensure the best use made of Crown Estate property.
	Undertake a review of fees, informed by our forecasting model.
	Implementing a review of our licensing function to ensure it remains fit for purpose
	Developing our strategy for 2020-2023

Donor anonymity and direct-to-consumer genetic testing

Strategic delivery:	☐ Safe, ethical, effective treatment	☒ Consistent outcomes and support	☐ Improving standards through intelligence
Details:			
Meeting	Authority		
Agenda item	9		
Paper number	HFEA (12/09/18) 891		
Meeting date	12 September 2018		
Author	Laura Riley, Head of Regulatory Policy, Sumrah Chohan, Donor Information Manager.		
Output:			
For information or decision?	For information		
Recommendation	To note.		
Resource implications	-		
Implementation date	-		
Communication(s)	-		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	-		

1. Introduction

1.1. Multiple commercial direct-to-consumer genetic testing websites offer users DNA-based information for family history or ancestral ethnicity purposes, or for generalised health information. Popular DNA testing websites include Ancestry.com, 23andMe, MyHeritage and FamilyTree DNA.com.

1.2. Customers send the company a saliva sample from which their DNA is extracted. They then receive their results directly from a secure website or in a written report.

1.3. These websites, based in the UK and globally, offer different types of DNA tests:

- Autosomal DNA – DNA is matched using any of the 22 pairs of autosomal chromosomes as opposed to sex chromosomes
- Y-DNA – genealogical DNA is tested to trace father's-line ancestry
- MtDNA – mitochondrial DNA is tested to trace mother's-line ancestry

1.4. Many DNA testing websites now also offer optional additional services to help identify genetic relatedness between their users, by 'matching' them with other users in their database.[1],[2]

1.5. DNA testing and matching websites are affordable and easy to use. They have seen a huge increase in users in recent years, allowing the providers of these services to be able to create greater numbers of more accurate 'matches'.

1.6. Since the introduction of direct-to-consumer DNA testing websites the number of people who have DNA tested via such sites globally is estimated to have increased dramatically from less than 2 million people in 2000, to perhaps over 14 million in 2018.[3]

1.7. DNA websites advertise on UK television and other media, including online through various social media outlets such as Facebook, making them widely known, especially within the donor conception community.

2. The HFE Act and sperm, egg and embryo donation

2.1. The HFE Act 1990 assumes gamete and embryo donor anonymity as a default position. Identifiers and non-identifying information about donors are held by HFEA within a secure, centrally managed repository system. The HFEA's register, our consent forms and other HFEA practice all work within the expectation that we will preserve donor anonymity, unless specific conditions are met.

2.2. Donor-conceived people and donors have a statutory right of access to information held on the Register as follows:

- 16-year-old donor-conceived people can find out:

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[1] https://customercare.23andme.com/hc/en-us/articles/212170838-Privacy-and-display-settings-in-DNA-Relatives

[2] https://blog.myheritage.com/2017/08/new-review-match-page-discover-how-you-are-related-to-your-dna-matches/

[3] *Personal genetic testing and the implications for the donor conception community*, by Debbie Kennett, published in BioNews 939, *26 February 2018,* https://www.bionews.org.uk/page_96385

  - if they are donor-conceived
  - non-identifying information about their donor
  - the number, gender and year of birth of any donor-conceived genetic siblings
  - if their donor has removed their anonymity (since 2005)
  - if they might be related to an intended spouse or partner
- 18-year-old donor-conceived people can find out:
  - identifying information about their donor (if the donor is identifiable)
  - identifying information about their donor-conceived genetic siblings, if both sides consent (via Donor Sibling Link (DSL)
- Donors can:
  - find out the number, gender and year of birth of any children conceived from their donation
  - remove their anonymity - which is relevant to those who donated before the law changed on 1 April 2005

2.3. Parents have no statutory rights to access Register information although in 2004 they were granted discretionary access rights to the following information:

- non-identifying information about their donor
- the number, gender and year of birth of any donor-conceived genetic siblings
- if their donor has removed their anonymity (since 2005)

2.4. in view of the statutory right of access of donor-conceived people and donors to information held on our Register with some limitations under the Act; HFEA provides the Opening The Register (OTR) service based on verified data held on the Register. HFEA also funds the voluntary Donor Conceived Register (DCR) service for pre-1991 donors who want to provide their identifiers and for donor-conceived people who want to access these, or to seek out other people who were born from the same donor. HFEA offers and funds some professional counselling support to enquirers around these services.

2.5. People discovering donation information outwith the Act's provisions have none of the rights or protections set out above. We note that there are some different and far-reaching implications for people trying to discover information about their donor and their donors' identity via DNA testing and matching websites, as opposed to using the managed OTR or DCR services that we currently provide.

2.6. HFEA systems must work in line with the HFE Act and we do not intend to substantively change our current OTR or DCR arrangements. However, we recognise that direct-to-consumer genetic testing and matching services present a fundamental change to the context in which we work.

3. The effect on donor anonymity

3.1. Genetic 'matching' services provide 'matches' for the users within their databases between named individuals, highlighting the degree of their genetic relatedness. 'Matches' made between second cousins (or any closer relative) are deemed to be a good start for identity tracing. A match

even with a second cousin indicates great-grandparents in common, making other descendants then relatively easy to trace if approximate time frames and country locations are known.[4]

3.2. The sites allow the named matches made to contact each other directly within their systems. Most users tend to use their real names.

3.3. Further to this, in the knowledge of the names of confirmed genetic relatives provided from the matching service, people may then be able to infer further family (and donor) relationships by searching on other social media sites (such as Facebook) or other websites.

3.4. This means that individual donors or donor-conceived people who are not registered users on the genetic testing sites or their closely-related family members can potentially be identified.

3.5. Over time, the huge growth in the size of the commercial testing and matching databases has given these sites a considerable speed and power (in terms of likelihood of finding genetic matches).

3.6. Other commercial groups on social media also offer advice and share information about using DNA testing websites to find a donor's identity, such as DNA Detectives.[5] There are also some voluntary, closed searching and peer support groups geared towards donor conceived people available on social media including Facebook. We do not know how many of these groups are in existence.

3.7. Some recent academic publications have explored commercial DNA matching services and their potential impact for the various groups of people affected by donor conception.[6] Patient groups such as the Donor Conception Network are also developing information materials and support around these sites for families who are considering, or who have used, donor conception.

3.8. Issues that have been raised include

- the profound implications of discovering unexpected information about close genetic relationships for the existing relationships between parents, children and their siblings, and for any new personal relationships between those 'matched' or otherwise discovered
- emotional and practical questions around unexpected ancestry, ethnicity or cultural information
- questions from a health perspective about unexpected genetic inheritance

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[4] http://www.whodoyouthinkyouaremagazine.com/blog/what-dna-testing-can-tell-you-about-your-family-history

[5] https://thednadetectives.com/about-the-company/

[6] *The end of donor anonymity: how genetic testing is likely to drive anonymous gamete donation out of business,* Joyce C. Harper, Debbie Kennett, Dan Reisel. *Human Reproduction*, Volume 31, Issue 6, 1 June 2016, Pages 1135–1140, https://doi.org/10.1093/humrep/dew065,
Also:
Personal genetic testing and the implications for the donor conception community, by Debbie Kennett Appeared in BioNews 939, 26 February 2018, https://www.bionews.org.uk/page_96385,
Also:
Direct-to-consumer DNA testing: the fallout for individuals and their families unexpectedly learning of their donor conception origins, Human Fertility, Marilyn Crawshaw, 11 Jul 2017, https://doi.org/10.1080/14647273.2017.1339127

- that the impact of 'unexpectedness' is relevant whether people are searching for family history or for generalised health information purposes, or if they have a specific search in mind (such as for their donor)
- that donors or donor-conceived people who have not consented to be registered and matched on a DNA testing website can still potentially have their identity inferred through further searching, provided a confirmed genetic match has been made with a close genetic relative of theirs
- that widely-used genetic matching services and the ease of further searching for identifiable information via social media present a novel and fundamental change in the context of the current anonymous donation presumption in UK law and in HFEA practice.

3.9. DNA matching services all offer practical 'how-to' tips for searching for genetic relatives, encouraging matched users to contact each other. These tend to be illustrated with examples of relatively distant genetic relationships being uncovered, rather than very close genetic relationships.

3.10. Services tend not to offer prominent warning to users that complex issues can arise from unexpected genetic relatedness information, though this is given 'in the small print'. Some offer some upfront information about unexpected findings but may not always fully outline the complexities.[7],[8],[9] DNA matching websites offer only very basic advice on whether or how to make contact with others, based on matches.

3.11. We found no DNA testing and matching services that mention that a need for professional emotional support may arise from relatedness matching, or via further inference from matching. No service offers professional emotional support to users, nor signposts to other available support.

4. Who is affected by relatedness inference made possible via direct-to-consumer DNA testing?

4.1. For the HFEA's purposes, the possibility of relatedness inference via direct to consumer DNA testing affects:

- all sperm, egg and embryo donors,
  - whether they donated as part of licensed donation post HFE Act 1990, or who did so pre-HFE Act, and pre-or post- 2005 donors.
  - from 2005, donors began to be able to be identifiable to their donor-conceived offspring once the donor-conceived person reached the age of 18 and requested this information from the HFEA. The first of these requests to HFEA for identifiable information will be possible from 2023.
- All donor-conceived people, of any age, and whether the individual already knows that they are DC or not.

[7] https://support.ancestry.com/s/article/US-AncestryDNA-for-Adoptees-Search-Strategies
[8] https://support.ancestry.com/s/article/Finding-Living-People
[9] https://eu.customercare.23andme.com/hc/en-us/articles/204380504

- Recipient parents and families (who may or may not have told the donor-conceived individual of their origins, or who are unaware of the individual's DC origins.)
- The genetic relatives of either donor-conceived people or of donors, who may or may not be aware of any donor conception involvement within their family.

4.2. Other groups affected by the possibility of relatedness inference via direct-to-consumer DNA testing include

- people coming into donation
- people coming into fertility treatment involving donated sperm, eggs or embryos
  - We consider that these individuals will need to be made aware of this possibility, as part of the standard information to consider in discussion with a health care professional, before moving ahead with their donation or treatment.
- groups on social media who offer advice and share information on using DNA matching to find out a donor's identity.
  - these groups may be used by people searching in relation to their own genetic origins or on behalf of another person, such as their donor-conceived child.
  - This can include families who used an identifiable donor (post-2005), but where the donor-conceived child is currently aged under 18 and their parents wish to seek to establish a relationship with their donor before the child reaches 18 years old and can request this information from the HFEA for themselves.
  - We do not know how many of these groups on social media are in existence.

5. HFEA responses

5.1. Donor-conceived people or their families are free to identify their donors (or vice versa) by accessing DNA testing and matching websites based in the UK or overseas. The HFEA has no regulatory powers in relation to this. The growth of these sites has been valuable for many people seeking information, but there is a good argument that more prominent, detailed information in relation to donor conception would better prepare users for the potential issues that might arise. In addition, more signposting to available support may be useful.

5.2. The HFEA strategy 2017-2020, puts patients (including donors and donor-conceived people) and the quality of care and support they receive at the centre of our work. Our primary consideration is around what we can do to assist people who are affected under the current Act.

5.3. Currently licensed centres are not required to mention DNA testing services or their implications at donation or treatment to prospective donors or patients. In the course of clinical information provision, implications discussions or counselling, centres will usually describe the system of managed information provision provided by the HFE Act and how that works, which may imply that there are some benefits to managed information-giving under the current system.

5.4. However, the risks or benefits for donor-conceived people, for recipient parents or their family members, or for donors and their family members, of seeking or responding to unmanaged information revealed by DNA matching websites, is unlikely to be discussed in any detail. We could provide such information ourselves and require clinics to offer it to donors and patients via an update to the Code of Practice.

5.5. However, we could go further given limitations on the HFEA's reach, and mindful of the needs of people who are already affected by donor conception. We could ask DNA genetic testing and matching companies to provide more prominent, detailed and information in relation to donor conception. We have no regulatory levers with companies to require this, however.

Summary of possible HFEA responses

1	HFEA to raise awareness and signpost to available information and support	The HFEA to raise patient and donor awareness through providing information regarding the use of DNA testing websites and the implications, via • information on HFEA website • signposting to the available support (primarily peer support groups online). • information on HFEA donor and recipient consent forms. • training for clinics • guidance for clinics to discuss DNA matching and its implications with intended parents and donors.
2	Dialogue with DNA testing websites	The HFEA could look to have a dialogue with the larger UK-based DNA testing websites to encourage them to have prominent information on their websites about possibly uncovering unexpected information, especially for people affected by donor-conception, including signposting to available support.

6. Recommendations

6.1. **The Authority is 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 DCR and 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

Standard licence condition T53 - screening

Strategic delivery:	☒ Safe, ethical, effective treatment	☐ Consistent outcomes and support	☐ Improving standards through intelligence
Details:			
Meeting	Authority		
Agenda item	10		
Paper number	HFEA (12/09/18) 892		
Meeting date	12 September 2018		
Author	Anna Quinn, Scientific Policy Manager Paula Robinson, Head of Planning and Governance		
Output:			
For information or decision?	For decision		
Recommendation	The Authority is asked to: • Note and approve the proposed revision of standard licence condition T53. • Note the intended implementation and communication plan.		
Resource implications	Licensing team to amend their list of standard licence conditions and amend clinic licences on renewal.		
Implementation date	1 October 2018 (with the new edition of the Code of Practice)		
Communication(s)	Clinic Focus article in October 2018		
Organisational risk	☒ Low	☐ Medium	☐ High
Annexes	Annex A: SABTO guidance (for information)		

1. Background

1.1. In order to ensure the safety of patients and of future children born through donor assisted reproduction, prospective egg, sperm, and embryo donors must be screened for certain diseases before they can be accepted as donors. Standard licence conditions T52 and T53 together set out the legal requirements for laboratory tests and storage prior to the use and/or storage of donor eggs or sperm, and embryos created using donor eggs and sperm. In addition, the HFEA Code of Practice states that centres should screen and quarantine donated gametes and embryos in line with guidance from the relevant professional bodies. Licence condition T53 current sets out the following requirements:

> T53: The centre must ensure that the laboratory tests required by licence condition T52 meet the following requirements, namely:
>
> a) the test must be carried out by a qualified laboratory, which has suitable accreditation (for example by CPA (UK) Ltd or another body accrediting to an equivalent standard), using CE marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge,
> b) blood samples must be obtained within a timeframe specified by the Authority, and
> c) 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.

1.2. For some time, the sector has struggled with the quarantine requirements set out in T53c, as they are at odds with the relevant professional body guidance.

1.3. The European Tissues and Cells Directive (EUTCD) requirements relating to donor screening and quarantine are directly reflected in licence condition T53. The EUTCD requires a quarantine period of a minimum 180 days for donated sperm. If NAT testing is used in addition to serology testing, repeat testing (and quarantine) is not required.

1.4. The current joint professional body guidance[1], which dates from 2008, considers quarantine requirements when NAT testing is used, taking advice from the expert advisory group on AIDS. The advice received at the time stated that there were no data to confirm whether a NAT that was negative for HIV in plasma would necessarily be negative for HIV in semen. The guidelines therefore recommend that detection of blood-borne viruses in egg, sperm and embryo donors should be carried out by using serological testing to detect antibody or antigen as appropriate. They do not recommend a shorter quarantine period when NAT testing is used in addition to serological testing.

1.5. An overseas sperm bank informed the HFEA in 2017 that they no longer quarantine nucleic acid amplification technique (NAT) tested donor sperm, and asked whether we would consider this

[1] Association of Biomedical Andrologists, Association of Clinical Embryologists, British Andrology Society, British Fertility Society, Royal College of Obstetricians and Gynaecologists. UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors (2008). Human Fertility. 2008 Jan 1;11(4):201-10.

suitable for donor sperm they export to our clinics. This query alerted us to the potential for varying practice within the sector, with the risk that centres not necessarily completing serological testing alongside NAT testing, or not quarantining samples after any NAT testing has been done. This is important, since NAT testing could miss recently acquired infections.

2. Actions taken

2.1. Since this issue came to light, we have engaged with the relevant bodies, including the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO), Association of Clinical Embryologists (ACE), the British Fertility Society (BFS), and the Association of Biomedical Andrologists (ABA). A meeting was held with these groups on 15 February 2018 where recommendations were agreed relating to NAT testing and quarantine requirements. The professional bodies present at this meeting agreed to support the recommendations until the 2008 guidelines could be updated. The recommendations were taken to SaBTO, who agreed to consider the evidence in this area and publish an addendum to their donor selection criteria report 2017 (see Annex A). As a result of this work, we have now arrived at an improved, up to date and clear articulation of standard licence condition T53.

2.2. In order for this change to be implemented, we are now seeking the Authority's approval for the new wording. We also set out below how we propose to implement the revision to the standard licence condition.

2.3. Development of the improved T53 occurred alongside the work on the Code of Practice update for October 2018. At its meeting in June 2018 the Authority agreed a change to guidance note 11 of the Code of Practice, to reference SaBTO's recommendations. The new Code of Practice guidance also includes reference to SaBTOs additional recommendation of NAT testing for all egg donors.

3. Changes to T53 – screening requirements

3.1. Standard licence condition T53 is one of a group of licence conditions under the heading of 'Donor selection and laboratory tests'. Licence condition T52 covers the requirements for donor selection, laboratory tests and storage, and requires no changes.

3.2. The proposed new wording of standard licence condition T53 is:

> T53: The centre must ensure that the laboratory tests required by licence condition T52 meet the following requirements, namely:
>
> a) The test must be accredited by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. CE marked testing kits must be used where appropriate.
> b) Blood samples must be obtained within a timeframe specified by the Authority, and
> c) Donor sperm must be quarantined for a minimum of 180 days, after which repeat serological testing is required. If the blood sample taken at the time of donation is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, the donor sperm must be quarantined for a minimum of three months, after

which a further donor blood sample should be taken and subjected to repeat serological and NAT testing.

3.3. There are two key changes to note in the new version of the licence condition:

- Updated reference to specify that tests must be accredited by UKAS. This had been updated because the current wording is out of date.
- Paragraph c is now clear and includes the requirement that when NAT testing is used in addition to standard serological screening, donated sperm must be quarantined for three months.

4. Implementation of the revised T53

4.1. Since this is not a new licence condition, but providing clarity around an existing issue, it is not necessary to conduct a large-scale relicensing exercise in this case.

4.2. We therefore propose to update our 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 of T53 will then be included on all new or renewed licences issued to clinics after that date.

4.3. Until all clinics have received an updated licence, a process that will happen naturally in the course of our inspection and licensing work over the next four years, we will continue, as now, to manage any risk of misinterpretation of T53 through our other guidance and our inspection regime.

4.4. We will also highlight the issue to the sector. A Clinic Focus article was sent in August outlining upcoming changes to the Code of Practice, including in relation to screening. We will also to ensure that the changes are communicated and explained via a specific Clinic Focus article dedicated to screening, planned for October.

5. Recommendations

5.1. The Authority is asked to:

- Note and approve the proposed revision of standard licence condition T53.
- Note the intended implementation and communication plan.

Annex A – SABTO Guidance on Screening

The following recommendations have been agreed by SaBTO and will be listed on their website in due course:

Recommendations

All of the following screening options are acceptable practice.

1. **Sperm donation.**

1.1. Serology + quarantine
(this summarises the current approved SABTO recommendation. Note that, despite this evidence based recommendation, centres must currently still adhere to the legal requirement for 6 month quarantine of donor sperm unless testing by NAT in addition to serology.)

Serology test at donation; Quarantine for 5 months; repeat serology and release if negative.

Justification.
The 'window periods' for HBV/HCV/HIV/Syphilis are 66.8/59/11/28 days based on serology alone. Thus the quarantine period for cryopreserved semen and serology testing would be 66.8x2=133.6 days. This has been rounded up to 5 months.

1.2. Serology + NAT + quarantine.

Serology for HBV/HCV/HIV at donation; Quarantine for 3 months and repeat serology and test by NAT; release if negative.

Syphilis: there is no test by NAT for syphilis therefore a negative serology is required after the 3month quarantine period.

Justification.
Testing by NAT in some labs uses 'pooled' samples. Alternatively, individual testing can be done. The 'window periods' for HBV/HCV/HIV are different depending on this practice.
For 'pooled' samples they are 30/4/9 days giving a recommended quarantine period of 30x2=60 days (3 months).
For 'individual' NAT they are 21/3/5 days giving a recommended quarantine period of 21x2=42 days (2 months). By recommending 3 month quarantine we take the precautionary approach to avoid misunderstanding of laboratory procedures.
In relation to Syphilis, both quarantine periods (2 and 3 months) are within the accepted 28day serology window period for syphilis.

1.3. Serology + NAT + Deferral by history.

Note that this option is only considered to be relevant in exceptional circumstances as it is likely that most samples would be cryopreserved for practical considerations. The full donor assessment protocol including genetic testing would be likely to exceed the 3month quarantine period in 1.2. Nonetheless the following option could be appropriate if proceeded by an individual risk assessment and the recipient has given informed consent.

Deferral: An initial screening questionnaire is completed to identify and exclude potentially high risk donors (under preparation by the professional societies).

and

Serology and NAT tests for HBV/HCV/HIV. Serology tests for syphilis. If these tests are negative, the donation can be released.

Justification.

This recommendation provides for an extreme clinical situation where a delay in release of the donation would be clinically detrimental.
Since this protocol is based on the seroconversion rates used to inform blood donation procedures. The risk for infection transmission is most likely further reduced by the low risk process of insemination compared to intravenous transfusion.

2. Egg Donation.

Serology + NAT + Deferral.

There is currently no clinical imperative to require that donated eggs are cryopreserved and most donations are of non-cryopreserved eggs. An obligatory quarantine period is therefore not appropriate.

Given the clinical intervention that is required prior to actual donation, it is practical and appropriate to screen prior to the start of any intervention for the donor (e.g. medication or surgery) rather than at the point of donation.

Deferral: 2 months prior to donation, a screening questionnaire similar to that for sperm donors is completed to identify and exclude a potentially high risk donor.

and

Serology for HBV/HCV/HIV/Syphilis.

Start of medication: At the start of medication for the donor (about 3 weeks prior to the actual donation), serology and NAT tests for HBV/HCV/HIV and serology tests for syphilis. If these tests are negative, donation is released.

If cryopreservation of donated eggs becomes the standard procedure, it would then be appropriate to implement the procedure in 1.2.

Justification.

The screening questionnaire and initial serology tests will exclude high risk donors and those who were not considered to have been high risk but were nonetheless infected. Repeat screening after 2 months, will identify those who may have been infected at the initial screen but were within the window period.

Given that the egg donor will have been under clinical supervision during most of the 2 months from initial testing to donation, the risk of new infection to a low risk donor during this period is very low.