

# Authority meeting - agenda

**13 September 2017 Venue: HFEA Offices, 10 Spring Gardens, London SW1A 2BU**

Agenda item	Time
1. Welcome, apologies and declaration of interests	12:45pm
2. Minutes of 28 June 2017 <b>HFEA (13/09/17) 847</b> For decision	12:50pm
3. Chair's report (verbal)	12:55pm
4. Chief Executive's report (verbal)	13:05pm
5. Committee chairs' updates (verbal)	13:15pm
6. Performance report <b>HFEA (13/09/17) 848</b> For information	13:30pm
7. Data submission project <b>HFEA (13/09/17) 849</b> For information	13:45pm
8. Draft business plan 2018/19 <b>HFEA (13/09/17) 850</b> For information	14:05pm
9. Fertility sector report 2016/17 [Draft] <b>HFEA (13/09/17) 851</b> For information	14:25pm
10. <b>Break</b>	<b>15:00pm</b>
11. Investigation into fertility clinics <b>HFEA (13/09/17) 852</b> For information	15:10pm
12. Leadership in clinics <b>HFEA (13/09/17) 853</b> For information	15:30pm
13. Any other business	15:55pm
14. Close	16:00pm

# Minutes of Authority meeting 28 June 2017

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

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## Details:

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Meeting                      Authority

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Agenda item                2

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Paper number              HFEA (13/09/17) 847

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Meeting date                28 June 2017

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Author                        Siobhain Kelly – Senior Governance Manager

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## Output:

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For information or decision?      For decision

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Recommendation              Members are asked to confirm the minutes as a true and accurate record of the meeting

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Resource implications

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Implementation date

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Communication(s)

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Organisational risk               Low                       Medium                       High

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Annexes

## Minutes of the Authority meeting on 28 June 2017 held at 10 Spring Gardens, London SW1A 2BU

Members present	Sally Cheshire (Chair) Kate Brian Dr Anne Lampe Dr Andy Greenfield	Yacoub Khalaf Margaret Gilmore Anita Bharucha Bobbie Farsides
Apologies	Ruth Wilde Anthony Rutherford Bishop Lee Rayfield	
Observers	Steve Pugh (Department of Health)	
Staff in attendance	Peter Thompson Nick Jones Juliet Tizzard Paula Robinson Richard Sydee	Rosetta Wotton Jessica Watkin Anjeli Kara Siobhain Kelly

### Members

There were 8 members at the meeting, 6 lay members and 2 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 2017. As with previous meetings, it was audio-recorded and the recording was made available on our website to enable interested members of the public who could not attend the meeting to listen to our deliberations.
- 1.2. Apologies were received from Ruth Wilde, Bishop Lee Rayfield and Anthony Rutherford.
- 1.3. Declarations of interest were made by:
  - Kate Brian (Regional organiser for London and the South East for Infertility Network UK)
  - Yacoub Khalaf (Person Responsible at a licensed centre)

## 2. Minutes of Authority meeting held on 10 May 2017

- 2.1. Members agreed the minutes of the meeting held on 10 May, for signature by the Chair.

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### 3. Chair's report

- 3.1.** The Chair summarised a range of activities she had undertaken since the Authority meeting on 10 May 2017.
- On 24 May, the Chair and Chief Executive attended the annual accountability meeting with the Department of Health (DH), where it was recognised that the business plan had been delivered alongside ground-breaking work on gene editing, mitochondrial donation and significant progress on the Information for Quality (IfQ) programme and the new website.
  - The Chair reported that all member appraisals are complete and have been submitted to the DH. The Chair thanked members for being available so the deadline was met.
  - The Chair chaired a lively and positive Multiple Births Stakeholder group on 7 June.
  - On 28 June, she chaired the Remuneration Committee at which the committee discussed the annual pay award and performance of the Senior Management Team (SMT).
  - Continuing the programme of clinic visits, the Chair will be visiting Birmingham Women's Clinic with the Director of Strategy and Corporate Affairs and the Head of Regulatory Policy.
  - Finally, the Chair informed the Authority that following the general election, there is a new Minister of State for Health, Philip Dunne MP. No meeting has been arranged yet, but the Chair is looking forward to meeting him in the future.

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### 4. Chief Executive's report

- 4.1.** The Chief Executive reported that he also attended the annual accountability meeting on 24 May and the Multiple Births Stakeholder group meeting on 7 June.
- 4.2.** On 7 June, the Chief Executive attended the Audit and Governance Committee (AGC) meeting.
- 4.3.** On 16 June, Juan Alberto, the Director of Bioethics and Law Observatory of the Universidad del Desarrollo, Chile, visited the Chief Executive to discuss options for the introduction of a legal framework for assisted reproduction in Chile. The Chief Executive has agreed to provide further advice and meet again in the future if required.
- 4.4.** The Chief Executive pre-recorded a keynote speech which will be delivered on 29 June at an international seminar in Mexico on mitochondrial donation. Members were reminded that the first baby born using this technique involved a team of US doctors who went to Mexico to evade US regulations. The event is a collaboration involving the national Bioethics Commission of Mexico, the Institute of Legal Research of the National Autonomous University of Mexico and the British Embassy in Mexico and the Mexican Embassy in Britain.
- 4.5.** The Chief Executive stated that the organisational change programme had made further progress notably that the Planning and Governance team is now in place. A Chief Information Officer has been appointed and is starting in September and an offer has been made and accepted for the new Head of Intelligence, the start date for which is likely to be October.
- 4.6.** The Chief Executive informed members that the changes will enable us to make better use of our information and to inform how we regulate and engage with the sector and wider public about the issues that matter.

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## 5. Committee Chairs' updates

- 5.1.** The Chair of the Statutory Approvals Committee (SAC) reported that the committee met on 25 May and considered and approved seven preimplantation genetic diagnosis (PGD) applications.
- 5.2.** The Chair of SAC noted the increasing complexity of the PGD conditions and added that agendas are lengthening, there are more grey areas and special directions are becoming more common.
- 5.3.** The Chair of the Executive Licensing Panel (ELP) reported that the panel met three times; on 19 May, 2 June and 16 June. The panel approved four renewal licences and deferred one; it considered three interim inspection reports, approved three licence variations and granted two new licences. Members heard that there was also a variation approved by the Licensing Officer.
- 5.4.** The Chair of the Audit and Governance Committee (AGC) informed members that the committee met on 13 June and thanked members and staff for their contribution. Aside from the usual standing items AGC considered:
- Implementation of audit recommendations and contracts and procurement, from the Head of Finance.
  - Cyber security, Business continuity, Information assurance and Security and IfQ, from the Director of Compliance and Information.
  - HR update on reorganisation and post staff survey, from the Chief Executive.
  - Whistle blowing and annual report and accounts, from the Director of Finance and Resources.
  - ALB risk interdependencies and strategic risks 2017/18, from the Head of Planning and Governance.
- 5.5.** The Chair of the Scientific Clinical Advances and Advisory Committee (SCAAC) informed the Authority that the committee met on 19 June and the following items were discussed:
- An analysis of intra-cytoplasmic sperm injection including risks and the fact there is no benefit to using the technique if there is no male factor infertility.
  - A literature review (2015 onwards) of health outcomes in children born following ART and the suggestion of including birthweight in patient information.
  - A literature review of developments in research on embryo culture media and the decision to write to the Medicine and Healthcare products Regulatory Agency (MHRA) to seek clarity on their role and responsibilities in relation to regulating embryo culture media.
  - Developments in embryo research including granting a licence to carry out genome editing on human embryos and growing human embryos in culture up to 13 days.
  - The committee also considered issues which might be important for the Authority to consider in the future.
- 5.6.** The Chair asked that the executive consider how to share issues discussed at SCAAC more widely for the benefit of members who do not attend the meetings.
- 5.7.** The Chair informed members that the Remuneration Committee met on 28 June, as it does annually, to agree the pay award under current public sector pay constraints. Following Treasury approval, staff will be informed and thanked for their hard work in the last year.

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## 6. Performance report

### Strategy and Corporate Affairs

- 6.1.** The Director of Strategy and Corporate Affairs introduced the new version of the performance report which now focuses on key indicators about people, performance, information, licensing and financial data. She said that when the new website goes live, we will add communications performance data to the report. Progress against the strategy will be reflected in separate reports to the Authority.
- 6.2.** The Authority heard that the new website has passed the Government Digital Service (GDS) assessment, which ensures compliance with accessibility and other standards, and is now almost ready to go live.
- 6.3.** The Director of Strategy and Corporate Affairs gave a demonstration of the website, showing how it is designed to give patients quick routes into information – either through the treatment type, the person's situation (same sex couple etc.) or through common tasks. Written information is complemented by key facts, quotes and charts, as well as animation. In future, there will be short films about different treatments.
- 6.4.** Members were shown the new Choose a Fertility Clinic service which combines the Authority's vision with what patients have told us they find most useful. An animation will tell patients that an excellent service means transparent pricing, good emotional support, a good birth rate and a low multiple birth rate. Importantly, the animation educates about birth rates and how it can be unhelpful to dwell on small percentage points when choosing a clinic. Clear birth rates are accompanied by the inspection rating (how well the clinic meets our standards) and a patient rating (what it feels like to be treated there) which is collected directly via the website.
- 6.5.** Members congratulated everyone involved in developing the new website. Staff had worked very hard to get the website ready, it is simple to use and clean to look at and is a high quality service for patients, donors and donor-conceived people.
- 6.6.** Members stressed that it is important that the HFEA website is the 'go to' place for fertility information as it is independent, advertisement free and patient focused. Co-ordinated communications will promote the new website via clinics, partner organisations and social media.

### Compliance and Information

- 6.7.** The Director of Compliance and Information gave an update on the performance indicators in his Directorate. Of the 26 indicators that have a target assigned, almost all are green. Only three are red. Errors in data submissions went above the target threshold in the reporting period. Getting reports to clinics within 20 days has usually been achieved, but 2 reports went over the target for reasons of complexity. The overall licensing performance (from inspection to offer of licence) indicator is at 63 days, well within the target of 70 days.
- 6.8.** Members heard that the annualised rolling target for preimplantation genetic diagnosis application processing is still affected by delays in processing applications earlier in the year; current performance is good. Members agreed that PGD complexity has increased and made some suggestions for managing workload to be discussed with the Executive.
- 6.9.** The Director of Compliance and Information reminded members about the allegations made by a newspaper about practices in a number of clinics. The five clinics have been visited by inspectors

and the reports will be considered in July and August. The committee or panel that considers these reports will decide on any further action as they do with normal business. The Chair added that she understood more clinics had been investigated but their practices were not of further regulatory interest.

### Finance and Resources

- 6.10.** The Director of Finance and Resources informed members that there is a small surplus and an underspend on staff budget. There has been a small fall in income and a 5% drop in activity which is bigger than the projected 3%. Members noted there would have to be a 10% drop in activity for the organisation to be concerned about income.
- 6.11.** Members speculated as to whether NHS commissioning is having an impact on activity, pushing patients to go abroad or not seeking treatment at all. Members agreed that evidence on this would be helpful for forecasting.
- 6.12.** Members heard that staff turnover is currently higher than normal for the HFEA, though only just above tolerance. Pay constraint and lack of promotion opportunities have an impact on this, though some level of turnover can be a good thing, bringing in fresh skills and thinking.

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## 7. Information for Quality: update

- 7.1.** The Director of Compliance and Information reminded members that the IfQ programme budget had expended at the end of April and the programme is drawing to a close with the launch of the website, meaning this is the last IfQ update to the Authority. Outstanding digital products will still come to the Authority and AGC. AGC will also have oversight of benefits realisation.
- 7.2.** The Register migration project and the development of the new data submission system are ongoing. The residual work will be delivered within the 2017/18 business plan, with an additional £350k budget. Testing the data submission element with clinics will begin in September 2017.
- 7.3.** Members agreed that this was a successful and important programme where an enormous amount has been achieved and the Authority is grateful for all the efforts of the staff in bringing this work to its conclusion.
- 7.4.** Members stated that the lessons learned exercise, always conducted after projects, should assess how useful the GDS process was as an external source of assurance. The Director of Compliance and Information confirmed that this would be part of the lessons learned process and that staffing priorities would be closely managed until final delivery.
- 7.5.** The Authority noted:
- The HFEA website GDS assessment and arrangements for launch.
  - Progress on the new data submission system.
  - The progress with data migration and assurance.
  - Budget update and spending to date.
  - Key risks and issues.

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## 8. Donor information requests

- 8.1.** The Donor Information Manager gave the Authority the annual update on donor information requests (or Opening the Register, OTR, requests). The requests are for information about donors and for donors themselves to remove their anonymity. This is an extremely important service that has a real, personal impact on the users.
- 8.2.** The Authority noted that the number of OTR requests received per year has increased by more than 100% between 2010 and 2016. A total of 165 donors have removed their anonymity to date, and 137 donor-conceived people have joined Donor Sibling Link (DSL) since it was launched.
- 8.3.** In a recent survey respondents rated the service highly. Members noted the positive feedback on the OTR service and some of the informal comments from service users.
- 8.4.** Members heard that the three-year pilot for the counselling support service is now in its second year. Demand is low so far but feedback has been positive so there are no concerns about the service being delivered. Further, post pilot there will be a full evaluation of the service offered, where feedback can be obtained from a larger group of users.
- 8.5.** Members commented that there could be a surge in requests in 2023 when donor conceived people born from 2005 onwards would start to turn 18, and this should be carefully planned for.
- 8.6.** Members thanked the Donor Information Manager for her dedication to delivering this excellent service and wished her well in her new role in a different organisation.
- 8.7.** Members noted:
- The update on OTR performance and figures
  - The timely and supportive way in which these requests are handled
  - The second-year evaluation of the pilot support service and the informal positive feedback received from service users
  - The need to decide on the future of the support service at an Authority meeting in 2018.

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## 9. Improving embryo research

- 9.1.** The Policy Manager overseeing this project introduced a paper explaining that improving embryo research is a key element of the new strategy. She highlighted that, although many patients would be willing to donate their embryos to research, only a small proportion of them actually do so. Following research, stakeholder engagement and a survey of patients, the Policy Manager had identified a number of actions that could improve this:
- improved literature and website pages to inform patients and increase awareness
  - increasing collaboration between clinics and research projects - only one in five clinics are involved in a research project
  - a review of the consent process to make it simpler and increase donation rates.
- 9.2.** The Policy Manager informed members that a survey of patients (188 responses) showed that 83% did or would consider donating embryos, so the appetite for this piece of work was reflected in patients' attitudes.



- 9.3.** Members heard that it was recommended that better patient information and improving co-ordination between clinic and research centres should be pursued in the first instance, to see if that approach alone improved the numbers of embryos being donated. Following that, this should be evaluated to decide whether a change to the consent regime should be considered.
- 9.4.** Members welcomed this proactive approach to match up clinics and researchers. Because around 60% of IVF takes place in the independent sector, there will be a resource implication in establishing collaborations in these clinics. However, members hoped that private clinics could receive kudos from being involved with important research.
- 9.5.** Members agreed that these are individual decisions that are challenging and complex for patients. Indeed, for some, the difficulty in making a decision about allowing their embryos to be disposed of shows that some patients are unable to make a decision they are morally comfortable with. Good support for patients in enabling them to make these difficult decisions is crucial.
- 9.6.** It was mentioned that research teams could help improve understanding of their research by describing their projects in a clearer way when applying to the Authority for a licence. Members heard that new guidance was being developed to encourage research centres to describe their projects in a much more 'lay' way so that patients could look at this information on our website, and understand the benefits that can arise from these projects.
- 9.7.** Members felt that improving collaboration between clinics and researchers should take place first before increasing patients' awareness so expectations can be managed and patients' generosity can therefore be maximised.
- 9.8.** Members felt our goal should be to give patients more opportunity to donate to research, rather than to have high donation rates. The whole process should not be rushed and patients should have the freedom to decide not to take part in research.
- 9.9.** On reviewing the consent process, members heard that patients were broadly in favour of generic consent rather than having to consent to specific projects. One member observed that 33% of the survey respondents had donated embryos, which is a much higher proportion than all patients, and therefore the views about generic consent are not necessarily representative. If a change to generic consent is to be considered in the future, there should be a bigger sample surveyed to confirm this.

### Decision

- 9.10.** Members agreed:
- To improve the information and support available to patients when making decisions about what to do with their embryos.
  - To encourage better collaboration between treatment clinics and research centres using the new clinic portal facility and via annual workshops.
  - To leave the consent policy unchanged at the moment.

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## 10. Guidance on treating transgender patients

- 10.1.** The Policy Manager leading this work informed Members that transgender issues are growing in prominence and the workshop at the HFEA annual conference confirmed that although the

number of patients is small, clinics have a real desire to treat patients sensitively, whilst complying with the law. Although our Code of Practice refers to gender reassignment, and we remind clinics of their obligation not to discriminate, the HFEA does not yet have adequate information, guidance for the sector, or a way for a trans patient to record their consent. An internal working group had begun to consider how to address this.

- 10.2.** Members received a paper setting out proposed changes to the Code of Practice to add guidance for clinics, building on the gender-neutral consent forms released in April 2017.
- 10.3.** The members thanked the Policy Manager for the very detailed paper, which set out clearly the issues and the legislation that surrounded the treatment of transgender patients. They agreed that clinics really want to care and support these patients well, so it is important for the Authority to assist them to do this. The Chair suggested another workshop at the next conference, or indeed a separate one, to inform and enable clinics on approaching the emotional support they want to offer these patients.
- 10.4.** Members raised concern over disclosing highly personal information about the donor around transitioning, which could be inferred by a female name given for a sperm donor, for example. Members heard that clinics will be encouraging trans patients via the counselling process to disclose this information in their pen portrait. In addition, donor conceived people will only be given a name, with no commentary from the HFEA, to ensure that there is no breach of confidentiality.
- 10.5.** Members heard that part of the criteria to obtain a Gender Recognition Certificate (GRC) is demonstrating an intention to be legally considered their acquired gender until death. This effectively means gender can be changed and legally recognised once, as this is how it is set out in the Gender Recognition Act 2004. This rules out the concept of gender fluidity, but members appreciated that this was how the law was drafted, even if some might now view this as out of date.
- 10.6.** One Member raised a question about how we can ensure that donor-conceived people have access to up-to-date information about their donor, including whether he or she had changed gender. Members noted that when there is a request for information about a donor, the HFEA does not contact the donor but the information held in the Register is supplied. This system relies upon the clinic and the donor keeping the information up to date.
- 10.7.** Members heard that should a donor not decide to inform the clinic where the donation was made, the original information in the Register will be disclosed. This means there is always a chance the Register will be at variance with the current situation.
- 10.8.** Members agreed that whilst this is unavoidable, the counselling process in the clinic touches on the importance of issues like keeping in contact and information held for the donor conceived. Further, when we receive a request for identifying donor information, the OTR team lets the donor know that such a request has been made, hopefully triggering them to report any significant change to their situation if they had not reported it before. If a change is reported, the donor-conceived person can be warned that there is a change to the non-identifying information they were given. This has typically occurred when a donor conceived person has requested information on their anonymous donor, who has later made the decision to be identifiable.

### Decision

- 10.9.** Members agreed to all the proposed amendments to the Code of Practice as set out in the paper and these changes will be effective from October 2017.

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## 11. Updates to the Code of Practice 2017

- 11.1.** Members considered a paper with detailed changes, clarifications and updates for the update to the Code of Practice in October 2017. In addition to the new guidance on treating trans patients and donors, the proposals included new guidance on embryo research ethics approval, and other minor amendments and corrections relating to mitochondrial donation and medicines management.

### Decision

- 11.2.** Members considered and agreed all the changes to the Code of Practice as set out in the paper, for implementation on 2 October 2017.

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## 12. Any other business

- 12.1.** The Chief Executive announced to members that in the Queen's birthday honours, Sally Cheshire was awarded a CBE for her services to the NHS and infertility patients. Members congratulated Sally on the award.
- 12.2.** The Chair stated that nothing is more important than services to patients and she is delighted that work is being recognised. She also added the CBE reflects well on the HFEA as an organisation, the staff working within it and the sector as a whole.

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 (28/06/17) 848
Meeting date	13 September 2017
Author	Helen Crutcher, Risk and Business Planning Manager

## Output:

For information or decision?	For information
Recommendation	The Authority is asked to note and comment on the latest performance report.
Resource implications	In budget
Implementation date	Ongoing
Communication(s)	<p>CMG reviews performance in advance of each Authority meeting, and their comments are incorporated into this Authority paper.</p> <p>The Department of Health reviews our performance at each DH quarterly accountability meeting (based on the CMG paper).</p> <p>The Authority receives this summary paper at each meeting, enhanced by additional reporting from Directors. Authority's views are fed back to the subsequent CMG performance meeting.</p>
Organisational risk	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High
Annexes	Annex 1: Performance report

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## 1. Introduction

- 1.1. The attached paper summarises our performance up to the end of July 2017.
- 1.2. We have committed to reviewing all indicators to identify more measures of quality and performance, as opposed to quantity. At the last CMG meeting, we focussed on the Communications indicators, which have been reviewed in the light of the communications strategy and new website analytics.
- 1.3. There is one proposed change to the Authority dashboard and key performance indicators, this is to include a new indicator: the number of website sessions to reflect the importance of the new website to the delivery of our strategic goals. This indicator would replace the OTR indicator in the dashboard, but information on OTR performance would remain in the body of the performance report. If approved, this new indicator will be introduced in the next performance report. More detailed communications measures will also be presented to the Authority in future communications reports.

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## 2. Reviewing performance

- 2.1. The Corporate Management Group (CMG) reviewed the May, June and July data at its August performance meeting.
- 2.2. Overall performance remains good.

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## 3. Recommendation

- 3.1. The Authority is asked to approve the proposed change to the Authority dashboard to include the number of website sessions measure instead of the OTR measure, and to note the latest performance report.

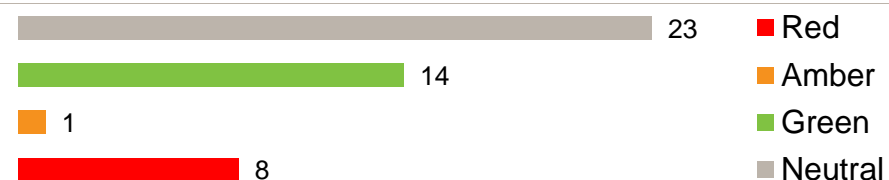
### Dashboard – July data

#### People – capacity

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

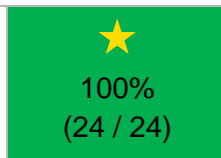


#### Overall performance – RAG status (all indicators)



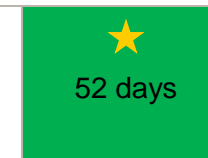
#### Information – OTR efficiency

**Opening the Register requests responded to within 20 working days**  
(Number on time/ number due)  
KPI: 100%



#### Licensing end-to-end

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



#### Money – budget

	Year to Date			Full Year		
	Actual £'000	Budget £'000	Variance £'000	Forecast £'000	Budget £'000	Variance £'000
Income	2,002	1,980	22	6,263	6,230	33
Expenditure	1,740	2,149	409	5,975	6,062	(87)
<b>TOTAL Surplus / (Deficit)</b>	<b>262</b>	<b>(169)</b>	<b>430</b>	<b>288</b>	<b>168</b>	<b>120</b>

#### Commentary

Our year to date position shows a surplus compared to budget of £262k. Our income is up by 1% against budget and includes the first tranche of grant in aid drawn down in June.

Our expenditure in the first four months of the year is lower than budget. Areas of significance are staff costs where we still have unfilled vacancies but expect these to be recruited to by Q3; Legal costs are always difficult to plan for and currently show an underspend. Our facilities costs are also below budget but this may change in Q4.

The year end forecast has been amended to reflect information received from directorates.

## Overall performance – July 2017

We reviewed the overall performance picture at the CMG meeting on 30 August. Most indicators are on track, which demonstrates the ongoing commitment of our staff during a continuing busy period. We noted an increase in the number of red indicators since the last CMG review in June, and consequently discussion focused on these areas. A full discussion of these red indicators is below.

CMG noted that we are approaching a watershed in the implementation of the new organisational structure, with colleagues leaving under a voluntary redundancy scheme in August and new colleagues joining in September. This presented both challenges and opportunities, but in the short term an already stretched staff are having to cope with the additional pressure of covering from colleagues and inducting new colleagues into the organisation. This also presents an additional risk in terms of loss of expertise and corporate memory.

When discussing performance in July, CMG acknowledged the hard work of all staff over several very busy months. The ongoing support of members has also been greatly appreciated, particularly given the large and often complex agendas of our committees and the need to expedite certain minutes. The licensing team reported an unprecedented workload in July, with 41 items considered across the committees. This is more than double the usual workload. CMG noted that this bulge may not be an ongoing trend, early indications suggest that the volume of business will decrease somewhat in August. We will continue to monitor workload and other factors affecting licensing business, to ensure that we can continue to deliver our core function to a consistently high standard. The result of this increased workload is reflected in the red rated licensing indicators discussed below.

In addition to the performance report, we received a paper on proposed changes to communications performance indicators. These changes were proposed in the light of the publication of the new website and Portal and the availability of new analytics. These changes will also bring the indicators more in line with the Comms strategy. The main proposed change to Authority indicators is the inclusion of the number of sessions statistic on the Authority dashboard. 'Sessions' are website visits which may include several pages. CMG discussed how this indicator compared to the old 'number of visits' indicator. CMG were of the view that the number of sessions indicator should replace the OTR one on the dashboard, as although we continue to care about this indicator, and it will be in the Authority performance and volume indicators, the website metric is an indicator of broader engagement with the Authority and so seems like a better top-line metric. The new detailed indicators will be used in future for reporting to CMG and the Authority will receive further information on these metrics and indicators when it receives periodic communications reports.

The 8 red key performance indicators (KPIs) shown in the 'overall status - performance indicators' pie chart on the dashboard are as follows (it should be noted that four of the red indicators relate to different elements of licensing and PGD authorisation):

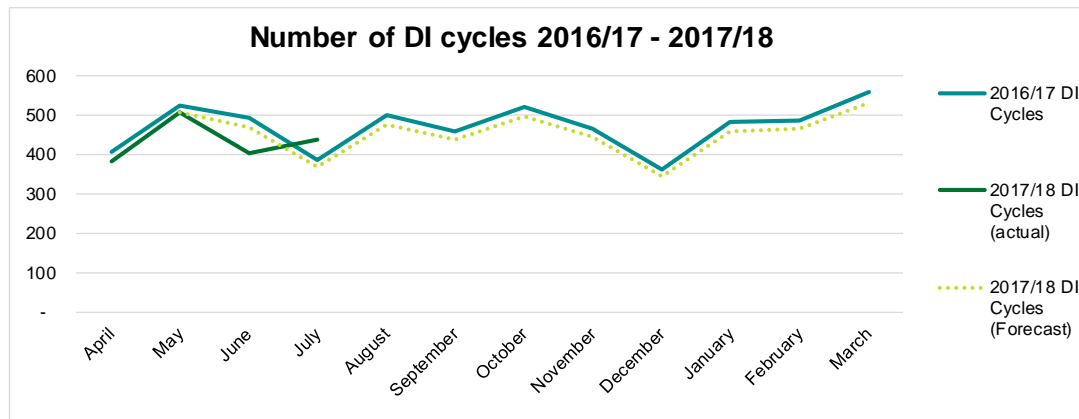
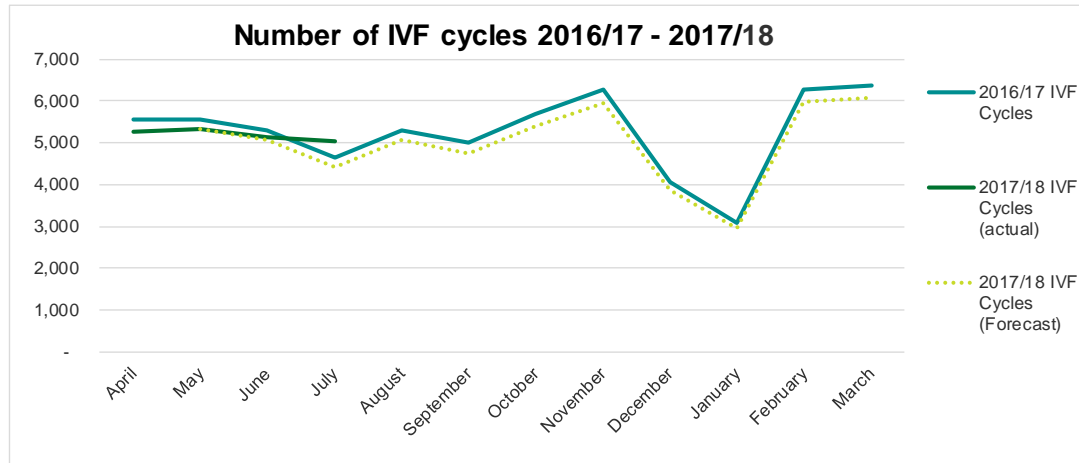
- Establishment ('unplanned') leavers per month. Our target is to remain within 5 - 15% establishment turnover for the year. There were 3 leavers in July and current performance is 20.9 % establishment turnover for the year. Looking ahead to August, an additional three colleagues took voluntary redundancy as part of our organisational change programme. New colleagues will join the organisation in September as part of the same change programme.
- 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. Current performance is an increase of 7% in July to 3,135 errors that are 2-14 months old. The persistently increasing rate of 'outstanding errors' reflects the fact that the Register team no longer has the resource necessary to proactively chase centres in addition to day to day support and other tasks. A generic approach has been initiated for dealing with clinic enquiries and errors so clinics no longer have a named Register team contact. Register team resource was reassigned to other related tasks such as verification and the data submission project, the risk of doing so was understood and is accepted to move to an improved future system.

- Average number of working days between ELP/LC/SAC date and minutes being finalised (signed by the Chair). Our target is for 100% of ELP/LC/SAC minutes to be finalised within 10 working days. In July, our performance was 50% completed in 10 working days, with an average of 14 days. Various factors meant that some minutes took a long time to finalise. The factors were: large agendas; complex LC and SAC items; items associated with additional legal processes; further legal requests in relation to the May LC meeting; staff leave and member leave and availability.
- Average number of working days between ELP/LC date and minutes being finalised (signed by the Chair). (Subset of Data). Our target is for 100% of ELP/LC/SAC minutes to be finalised within 10 working days. 66% of minutes were finalised within 10 working days with an average of 14 days. The reason is the same as for the above, this is the subset of data, for those items arising from an inspection.
- Average number of working days taken between committee meeting date at which PGD decision is made, and decision being finalised (ie, minutes signed off by SAC Chair). Our target is for 100% of minutes to be finalised within 10 working days. Performance in July was 28% within the target, with an average of 16 working days for decisions to be finalised. The same reasons apply to this indicator as those above. In addition, the timing of the SAC meeting, directly after the full LC meeting had a direct impact on this, as it was supported by the same committee secretary.
- Percentage of PGD applications processed within three months. Our target is 100% to be processed (i.e. considered by SAC) within three months (66 working days) of receipt of completed application. Current performance is 57%, although the average was only just above the target at 67 working days. This KPI was affected by delay to the SAC minutes this month, for reasons above.
- Annualised rolling average figure – Percentage of all PGD applications processed within 3 months for the year to date. Our target is 100% processed (ie, considered by SAC) within three months (66 working days) of receipt of completed application, in the rolling year to date. July performance was 73%. The negative impact of the period of temporary cover in Business Support from from Dec 2016 – Mar 2017 will continue to be seen for several months and this will have an ongoing impact over the rolling year until 2018.
- % debts collected within 60 days. Our target is 85% of debts collected in the month being within 60 calendar days from billing. Performance in July was slightly outside of the KPI at 84%. There were five clinics with debts over 100 days unpaid. At least three out of those five are repeat offenders and are being closely monitored.



## Budget status – July data

### 2017/18 Income



#### IVF Cycles

	YTD		YE / Forecast	
	Volume	£	Volume	£
2016/17 IVF Cycles	21,063	1,685,014	63,111	5,048,854
2017/18 IVF Cycles	20,752	1,660,160	60,781	4,862,485
Variance	311	24,854	2,330	186,369

YTD volumes for IVF cycles in the four months of this financial year are 1% below those undertaken in 2016/17. This is a drop from the 4% reported at the end of Q1. Extrapolating that position across the financial year would see a fall in income, compared to 2016/17, of c£186k, a drop of £50k from that reported in Q1. The 2017/18 income budget was prudently predicated on a reduction in volume of 3%.

It is too early to suggest whether this indicates a likely trend for the remainder of this financial year, we will review the position at the end of Q1 before making any amendments to the overall income forecast.

#### DI Cycles

	YTD		YE / Forecast	
	Volume	£	Volume	£
2016/17 DI Cycles	1,811	67,913	5,651	211,913
2017/18 DI Cycles	1,733	64,988	5,389	202,073
Variance	78	2,925	262	9,839

DI cycles have followed the pattern of IVF cycles for the first quarter of this financial year. At the end of period 4 (July), the difference to 2016/17 remains at 4%.

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

## People – key performance and volume indicators

Indicator	Score	RAG	Recent trend <sup>1</sup>	Notes																		
<b>Current headcount by month</b> Headcount/ establishment	61/67	↔	<p>Headcount vs establishment</p> <table border="1"> <caption>Headcount vs establishment data</caption> <thead> <tr> <th>Month</th> <th>Headcount</th> <th>Establishment</th> </tr> </thead> <tbody> <tr> <td>Mar</td> <td>61</td> <td>67</td> </tr> <tr> <td>Apr</td> <td>61</td> <td>67</td> </tr> <tr> <td>May</td> <td>61</td> <td>67</td> </tr> <tr> <td>Jun</td> <td>62</td> <td>67</td> </tr> <tr> <td>Jul</td> <td>61</td> <td>67</td> </tr> </tbody> </table>	Month	Headcount	Establishment	Mar	61	67	Apr	61	67	May	61	67	Jun	62	67	Jul	61	67	Overall volume (capacity) indicator. See commentary above for full discussion about headcount.
Month	Headcount	Establishment																				
Mar	61	67																				
Apr	61	67																				
May	61	67																				
Jun	62	67																				
Jul	61	67																				
<b>Turnover: Establishment ('unplanned') leavers per month</b> (% establishment turnover for the year).	20.9%	↑	<p>Turnover vs target range (5-15%)</p> <table border="1"> <caption>Turnover vs target range data</caption> <thead> <tr> <th>Month</th> <th>Turnover (%)</th> </tr> </thead> <tbody> <tr> <td>Mar</td> <td>14.1%</td> </tr> <tr> <td>Apr</td> <td>15.8%</td> </tr> <tr> <td>May</td> <td>19.2%</td> </tr> <tr> <td>Jun</td> <td>17.7%</td> </tr> <tr> <td>Jul</td> <td>20.9%</td> </tr> </tbody> </table>	Month	Turnover (%)	Mar	14.1%	Apr	15.8%	May	19.2%	Jun	17.7%	Jul	20.9%	KPI range: 5-15% turnover for the rolling year  The public sector average is 10% (Expert HR & CIPD research 2013) which therefore forms the basis of our target. This is worked out on a rolling basis each month.						
Month	Turnover (%)																					
Mar	14.1%																					
Apr	15.8%																					
May	19.2%																					
Jun	17.7%																					
Jul	20.9%																					
<b>Staff sickness absence rate (%) per month.</b>	1.56%	★	<p>Sickness absence</p> <table border="1"> <caption>Sickness absence data</caption> <thead> <tr> <th>Month</th> <th>Sickness absence (%)</th> </tr> </thead> <tbody> <tr> <td>Mar</td> <td>1.1%</td> </tr> <tr> <td>Apr</td> <td>1.5%</td> </tr> <tr> <td>May</td> <td>2.35%</td> </tr> <tr> <td>Jun</td> <td>1.17%</td> </tr> <tr> <td>Jul</td> <td>1.56%</td> </tr> </tbody> </table>	Month	Sickness absence (%)	Mar	1.1%	Apr	1.5%	May	2.35%	Jun	1.17%	Jul	1.56%	KPI: Absence rate of ≤ 2.5%.  Public sector sickness absence rate average is eight days lost per person per year (3.0%).						
Month	Sickness absence (%)																					
Mar	1.1%																					
Apr	1.5%																					
May	2.35%																					
Jun	1.17%																					
Jul	1.56%																					

<sup>1</sup> 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 (cw same month last year)	156	↓	<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>March</td> <td>208</td> <td>242</td> </tr> <tr> <td>April</td> <td>200</td> <td>224</td> </tr> <tr> <td>May</td> <td>196</td> <td>261</td> </tr> <tr> <td>June</td> <td>186</td> <td>263</td> </tr> <tr> <td>July</td> <td>156</td> <td>242</td> </tr> </tbody> </table>	Month	This year	Last year	March	208	242	April	200	224	May	196	261	June	186	263	July	156	242	Volume indicator.						
Month	This year	Last year																										
March	208	242																										
April	200	224																										
May	196	261																										
June	186	263																										
July	156	242																										
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>March</td> <td>19</td> <td>100%</td> </tr> <tr> <td>April</td> <td>13</td> <td>100%</td> </tr> <tr> <td>May</td> <td>23</td> <td>100%</td> </tr> <tr> <td>June</td> <td>17</td> <td>100%</td> </tr> <tr> <td>July</td> <td>24</td> <td>100%</td> </tr> </tbody> </table>	Month	Number of requests	% within 20 days	March	19	100%	April	13	100%	May	23	100%	June	17	100%	July	24	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																										
March	19	100%																										
April	13	100%																										
May	23	100%																										
June	17	100%																										
July	24	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 dealt with</th> <th>No. re mitochondria</th> <th>Same month last year</th> </tr> </thead> <tbody> <tr> <td>March</td> <td>8</td> <td>4</td> <td>14</td> </tr> <tr> <td>April</td> <td>0</td> <td>0</td> <td>7</td> </tr> <tr> <td>May</td> <td>0</td> <td>0</td> <td>11</td> </tr> <tr> <td>June</td> <td>0</td> <td>0</td> <td>3</td> </tr> <tr> <td>July</td> <td>0</td> <td>0</td> <td>3</td> </tr> </tbody> </table>	Month	PQs dealt with	No. re mitochondria	Same month last year	March	8	4	14	April	0	0	7	May	0	0	11	June	0	0	3	July	0	0	3	Volume indicator. Last year's numbers were notably high, for a period. Many of those PQs related to the work we were then doing on the mitochondria scientific review.
Month	PQs dealt with	No. re mitochondria	Same month last year																									
March	8	4	14																									
April	0	0	7																									
May	0	0	11																									
June	0	0	3																									
July	0	0	3																									

Indicator	Score	RAG	Recent trend	Notes
Number of Freedom of Information (FOI), Environmental Information Regulations (EIR) and Data Protection Act (DPA) requests	5	↓		Volume indicator. There does not appear to be any trend or predictability in the volume or focus of our FOI (and other) requests.

### Inspection and licensing process – key performance and volume indicators

Indicator	Score	RAG	Recent trend <sup>2</sup>	Notes
<b>Recommendations met by clinics following earlier inspections</b> (No. met that month / No. due to be met that month)	100%	★		KPI: 80% of recommendations due that month, completed on time by clinics.
<b>Average number of critical/major recommendations at clinics in inspection reports that were considered by ELP/LC that month</b>	3	↓		Volume indicator  Although the volume of recommendations is high, this is as a result of the number of reports. The average number per report has decreased.

<sup>2</sup> 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 <sup>2</sup>	Notes												
Average number of working days taken for the whole licensing process, from the day of inspection to the decision being communicated to the centre.	52	★	<table border="1"> <caption>Working days (March to July)</caption> <thead> <tr> <th>Month</th> <th>Working days</th> </tr> </thead> <tbody> <tr> <td>March</td> <td>53</td> </tr> <tr> <td>April</td> <td>63</td> </tr> <tr> <td>May</td> <td>76</td> </tr> <tr> <td>June</td> <td>47</td> </tr> <tr> <td>July</td> <td>52</td> </tr> </tbody> </table>	Month	Working days	March	53	April	63	May	76	June	47	July	52	KPI: Less than or equal to 70 working days.
Month	Working days															
March	53															
April	63															
May	76															
June	47															
July	52															
Monthly percentage of PGD applications processed within three months (66 working days).	57%	↓	<table border="1"> <caption>Performance (March to July)</caption> <thead> <tr> <th>Month</th> <th>Performance</th> </tr> </thead> <tbody> <tr> <td>March</td> <td>45%</td> </tr> <tr> <td>April</td> <td>100%</td> </tr> <tr> <td>May</td> <td>75%</td> </tr> <tr> <td>June</td> <td>100%</td> </tr> <tr> <td>July</td> <td>57%</td> </tr> </tbody> </table>	Month	Performance	March	45%	April	100%	May	75%	June	100%	July	57%	KPI: 100% processed (i.e. considered by SAC) within three months (66 working days) of receipt of completed application.
Month	Performance															
March	45%															
April	100%															
May	75%															
June	100%															
July	57%															
Average number of working days taken.	67	↑	<table border="1"> <caption>Working days (March to July)</caption> <thead> <tr> <th>Month</th> <th>Working days</th> </tr> </thead> <tbody> <tr> <td>March</td> <td>67</td> </tr> <tr> <td>April</td> <td>0</td> </tr> <tr> <td>May</td> <td>63</td> </tr> <tr> <td>June</td> <td>63</td> </tr> <tr> <td>July</td> <td>67</td> </tr> </tbody> </table>	Month	Working days	March	67	April	0	May	63	June	63	July	67	Performance in July was affected by SAC minute delays, see commentary below.
Month	Working days															
March	67															
April	0															
May	63															
June	63															
July	67															

Indicator	Score	RAG	Recent trend <sup>2</sup>	Notes												
Annualised (rolling year) percentage of PGD applications processed within three months (66 working days)	73%	↓	<table border="1"> <caption>Performance Data</caption> <thead> <tr> <th>Month</th> <th>Performance (%)</th> </tr> </thead> <tbody> <tr> <td>March</td> <td>77%</td> </tr> <tr> <td>April</td> <td>75%</td> </tr> <tr> <td>May</td> <td>74%</td> </tr> <tr> <td>June</td> <td>80%</td> </tr> <tr> <td>July</td> <td>73%</td> </tr> </tbody> </table>	Month	Performance (%)	March	77%	April	75%	May	74%	June	80%	July	73%	<p>KPI: As above.            (Annualised score).            Dips in monthly performance across the preceding year will have an impact on the annualised figure.</p>
Month	Performance (%)															
March	77%															
April	75%															
May	74%															
June	80%															
July	73%															
Average number of working days taken.	64	★	<table border="1"> <caption>Working days Data</caption> <thead> <tr> <th>Month</th> <th>Working days</th> </tr> </thead> <tbody> <tr> <td>March</td> <td>59</td> </tr> <tr> <td>April</td> <td>60</td> </tr> <tr> <td>May</td> <td>60</td> </tr> <tr> <td>June</td> <td>61</td> </tr> <tr> <td>July</td> <td>64</td> </tr> </tbody> </table>	Month	Working days	March	59	April	60	May	60	June	61	July	64	
Month	Working days															
March	59															
April	60															
May	60															
June	61															
July	64															

# Data submission project: update

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

## Details:

Meeting      Authority

Agenda item      7

Paper number      HFEA (13/09/17) 849

Meeting date      13 September 2017

Author      Nick Jones, Director of Compliance and Information

## Output:

For information or decision?      For information

Recommendation      The Authority is asked to note:

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

Resource implications      The budget for data submission work has been established at £350,000

Implementation date      During 2017–18 business year

Communication(s)      Regular, range of mechanisms

Organisational risk       Low       Medium       High

Annexes:      None

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## 1. Background

- 1.1.** The Information for Quality Programme has now closed, following the launch of the new HFEA website. With the Clinic Portal, our digital communications channels are now established and working well (always a few teething issues) and we are now evolving the way we work – the next step to realising the benefits of the investment – to maximise their impact.
- 1.2.** That leaves the remaining work to complete on the data submission project. It was agreed that work towards completion of the data submission system and associated infrastructure will continue as a defined project, with progress reported to Authority.
- 1.3.** By way of background, the project encompasses:
  - A revised dataset and data dictionary which will be submitted for approval by the Data Coordination Board (DCB) - part of NHS Digital. This is to ensure data collection arrangements that affect NHS organisations are applied consistently and are not burdensome.
  - A revised Register of treatments, which will include the migration of historical data contained within the existing Register

The redesign of the system that many clinics use to record and submit treatment data to the HFEA enhancing the experience and speeding it up; and enabling clinics using their own (or third party) patient record systems to plug-in, or link, to the HFEA Register.
- 1.4.** This paper updates Members on:
  - Work in progress
  - Programme budget
  - Risks and issues

---

## 2. Work in progress

- 2.1.** The Authority meeting in June 2017 received a positive report on progress. It was expected that the system would be released to users – for testing and feedback in September. This commitment will be met with a comprehensive programme of user testing set up for later this month for 8 clinics to test aspects of the system – including the experience, navigation between screens, design, and fit with clinic business processes.
- 2.2.** Work has also now been completed on the technical environment by which third party suppliers (this includes clinic groups that have designed their own patient record system) can interact with the new system. In short, those systems need to be able to send to us the data, and in the format we specify, and we need those systems to be able to receive information back from us as to the accuracy or otherwise of those transmissions.
- 2.3.** We have been greatly aided in this aspect of the work by support and advice provided by colleagues in HMRC, used to dealing with many hundreds of such suppliers. This has



been invaluable in providing pointers and lessons learned from their experiences and also confirming the approach adopted by our team is a robust one. This is important given that most treatments are now reported to us via third party systems.

- 2.4.** Subject to the testing with clinics and suppliers being reasonably positive we will then expose the system to a wider audience for further feedback and an iterative programme of testing and improvement – likely to conclude in November 2017.
- 2.5.** This is an important milestone, as clinics will see the very real improvements to the system and they will be reassured that the (promised) benefits to them are now in sight – rather than a slightly theoretical promise that things will be better.
- 2.6.** That signals the completion of the majority of development effort and the task then becomes one of implementation, and roll-out.

#### **Data migration**

- 2.7.** As we have reported previously to the Authority, there is a key dependency. Until we have completed the migration of existing Register data to the new design we are unable to launch the new data submission system. Moreover, until we have greater certainty as to the completion of this important work we are wary of committing to a schedule for the launch of the new data submission system.
- 2.8.** We have adopted a consistently cautious and careful approach to the migration task. We had expected to have concluded by now. The work has been slow over the Summer as a consequence of organisation change, holiday period, and capacity constraints. We are reliant on a small number of colleagues who are working hard, and making progress; a next tranche of work is about to complete as we progress to ‘trial load three’ of five.
- 2.9.** Given the progress made on the new data submission system there is now a risk that progress on data migration will delay the launch of the new data submission system. Our focus now, and in the coming period, is to explore how we can address this.

---

### **3. Data submission/Data migration budget**

- 3.1.** The budget for completion of the data submission project has been established at £350,000 for the 17/18 financial year.
- 3.2.** The budget is in line with capital expenditure expectations - such expenditure is on investment, or development, of the IT system estate provided by contractors on short-term contracts, and some programme management resource (delivered by internal secondment).
- 3.3.** There was a slight variance for the July period, but overall, the current spend is in line with forecasts.

Budget this F/Y	Planned spend	Actual to date	Monthly Variance
	£124,764 (Jul 17)	£125,890 (Jul 17)	£1,125

## 4. Risks and issues

**4.1.** Risks are reviewed regularly, with several new risks to the project identified since the last reporting period. The main area of risk relates to staffing, particularly given the departure of colleagues from the organisation further to the organisational change programme.

**4.2.** The top five risks to the project have been identified as:

- Workload and lack of resources
- Loss of knowledge within the IT team, with knowledge transferred to contractors on a transitional basis
- Data migration supported by only a few people, often diverted to other work
- Reliance on external contractors, which means there is a risk of contractors leaving at short notice

**4.3.** The principal mitigation activities relate to:

- Retaining our existing external contractors by close monitoring, support and documenting procedures and processes
- The recruiting of additional (short-term) expertise to provide extra capacity during the period of organisational change
- Institute new ways of working, better balancing business as usual and project priorities
- The new posts of Chief Information Officer and Head of Intelligence and postholders starting imminently

## 5. Recommendation

The Authority is asked to note:

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

# Draft business plan 2018-2019

## Strategic delivery:

Safe, ethical effective treatment

Consistent outcomes and support

Improving standards through intelligence

## Details:

Meeting	Authority
Agenda item	8
Paper number	HFEA (13/09/17) 850
Meeting date	13 September 2017
Author	Paula Robinson, Head of Planning and Governance

## Output:

For information or decision?	For decision
Recommendation	To approve the outline objectives for 2018/19, as the basis for drafting the next business plan.
Resource implications	In budget (to be agreed with DH in the usual way).
Implementation date	Across the 2018/19 business year
Communication(s)	The HFEA's business plans, once approved by the Department of Health, are published on our website.
Organisational risk	<input checked="" type="checkbox"/> Low <input type="checkbox"/> Medium <input type="checkbox"/> High
Annexes	Annex 1: outline business plan content for 2018/19

---

## 1. Introduction

- 1.1. The strategy for 2017-2020 has been in place since April this year, and the current business plan sets out year one of delivery.
- 1.2. CMG has previously agreed an outline three year delivery plan for the strategy, and has recently begun to discuss the business plan for 2018/19, which will describe year two of delivery.

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## 2. 2018/19 business plan outline

- 2.1. The outline business plan flows from discussions at CMG, and consists of a delivery plan for year two of the strategy, alongside our usual range of statutory work and other 'business as usual'. The focus in our second year of the strategy will be on making the most of the new tools and capabilities introduced this year, as a result of the Information for Quality Programme and our organisational restructuring. Key pieces of strategic work will include:
  - Working with the sector to develop greater consistency in compliance standards between clinics, and throughout the inspection cycle.
  - Refining the information published on our website to ensure that it meets users' needs.
  - Monitoring the impact of the embryo research project completed in 2017/18.
  - Improving research data consent information and consent rates.
  - Working with clinics, sperm banks and voluntary organisations to improve the availability of donor sperm and eggs.
  - Analysing our data on success rates, with a view to increasing birth rates while avoiding adverse outcomes.
  - Making use of new benchmarking information on price, working in collaboration with NHS England.
  - Ensuring best practice in clinics on the emotional experience of care.
  - Publishing more and better data.
  - Making use of our data to inform targeted regulatory interventions.
  - Analysing patient feedback obtained from our website (including Choose a Fertility Clinic ratings) and through social media.
  - Ensuring we are an efficient and responsive regulator.
- 2.2. The full list of activities proposed for inclusion is presented in Annex 1 in a very summarised form – there will be more descriptive detail in the ensuing draft business plan, which will come to the Authority in November.

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### 3. Planning timetable for 2018/19

#### Key dates

- 3.1.** The business plan for 2018/19 will take shape over the next few months. The table below lists the main milestones in the process.

Date	Item
August 2017	Initial CMG discussion (done)
September 2017	Authority approval for outline BP for 2018/19
October 2017	2018/19 BP drafted
November 2017	Authority approval for full draft BP for 2018/19
December 2017	Submission of approved draft to DH; budget discussions
January 2018	DH considers draft; budget discussions continue
February 2018	DH comments on draft; budget near-final
March 2018	Near-final draft submitted to DH; budget confirmed
April 2018	Year-end figures added as relevant. Approval and publication.

---

### 4. Recommendation

- 4.1.** The Authority is asked to approve the outline business plan for 2018/19, for further development.

# Annex 1

## Strategy area | Business plan 2018/19

### Safe, ethical, effective, treatment

<b>Standards</b>	Regulation of clinics
	Good governance of licensing decisions
	Processing applications for PGD and mitochondrial donation
	Policy project on the list of PGD conditions.
	Major revision of the Code of Practice (in October 2018).
	Work on encouraging and supporting leadership in clinics, with the aim of improving standards and consistency over time.
<b>Evidence</b>	Annual horizon scanning and Scientific and Clinical Advances Advisory Committee work, including ongoing review of add ons.
	Responding to new developments and media reports.
	Refine the way we publish information about the evidence base on our website, based on feedback from users.
<b>Research</b>	Further work on embryo research, following the project in 2016/17 to produce better information about embryo research, streamline the application process and encourage collaboration between clinics and research centres. In 2018/19 we will monitor the impact of this work.
	Focus on ensuring clinics explain research data consent adequately, record such consent properly, and report consents accurately to the HFEA.
	Information provision for researchers requesting access to Register data.

### Consistent outcomes and support for patients and donors

<b>Access</b>	Advice and information about accessing services.
	Collaborate with professional stakeholders to put new patients in touch with better information about services.
	Working with clinics, sperm banks and voluntary organisations to improve the availability of donor sperm and eggs.
<b>Outcomes</b>	Focus on consistency and success rates on inspection.
	Analyse Register data on success rates and explore with professionals the key factors behind success at the clinic level.
	Review the outcomes information on clinics' websites information and incorporate revised guidance into the new Code of Practice.

<b>Strategy area</b>	<b>Business plan 2018/19</b>
	Evaluate areas of regulatory concern.
	Annual fertility trends report
	Improved Register data quality, as a result of work done earlier under the Information for Quality (IfQ) programme.
	Further work with commercial groups of clinics (on a group-wide basis), to improve the quality of their data.
<b>Value</b>	Make use of benchmarking information on price, working in collaboration with NHS England.
<b>Support</b>	Evaluation of the third and final year of the pilot of counselling support services for Register applicants.
	Managing the contract for running the pre-1991 donor-conceived Register.
	Improving the emotional experience of care in clinics, by defining and encouraging best practice in clinics, and focusing on support at inspection.
	Ensuring that best practice is applied to donors and donor conceived people as well as to patients. (This will be implemented in the October 2018 Code of Practice update).
<b>Improving standards through intelligence</b>	
<b>Data</b>	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.
<b>Regulation</b>	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.
<b>Feedback</b>	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) and social media, and establish additional channels and methods for obtaining patient experience information and sharing it with professional stakeholders.
<b>Efficiency</b>	Ensure that we retain the staff we need in order to operate a good quality service, and implement our People Strategy for 2017-2020.
	Make best use of our limited resources.

Strategy area	Business plan 2018/19
	Ensure our infrastructure and central systems are efficient and responsive.
	Review of records management and information governance arrangements.
	Ensure the HFEA is easy to deal with and offers a professional service.
	Comply with government requirements, including the new General Data Protection Regulation from May 2018 onwards.
	Collaborative work and shared services.
	Survey stakeholders about our performance as a regulator.



# Fertility sector report: 2016-17

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

## Details:

Meeting	Authority
Agenda item	9
Paper number	HFEA (13/09/17) 851
Meeting date	13 September 2017
Author	Peter Thompson + Nick Jones, Director of Compliance and Information; Juliet Tizzard, Director of Strategy and Corporate Affairs; Hannah Verdin, Head of Regulatory Policy; Sharon Fensome-Rimmer, Chief Inspector

## Output:

For information or decision?	For information
Recommendation	<p>The Authority is invited to:</p> <ul style="list-style-type: none"> <li>• Endorse the decision to move away from a narrow discussion about clinic non-compliances</li> <li>• Comment on the proposed scope and coverage of the draft report</li> <li>• Agree that the report be embargoed until publication in the Autumn.</li> </ul>

Resource implications	None
Implementation date	Autumn 2017
Communication(s)	National publication, with press release
Organisational risk	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High
Annexes:	Draft report – State of the fertility sector 2016-17

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## 1. Background

- 1.1. In recent years we have used the September meeting of the Authority to reflect on the level of compliance of the fertility sector. That consideration has usually involved an analysis of the number and type of non-compliances identified by HFEA inspectors in a given business year and the publication of a report on the number and type of incidents reported in the same period.
- 1.2. Though such analysis has been undoubtedly of value it does present a rather skewed picture of the state of the sector. Viewed through the lens of non-compliances the discussion inevitably focusses on what clinics do badly rather than what they do well.
- 1.3. We think we need to move to a position where we are facilitating a broader and more even handed discussion of the fertility sector, focussing not just on the performance of licensed clinics, but also on essential characteristics of the sector itself; its size, public private split, geographical concentration and much else. The attached draft report entitled State of the fertility sector: 2016-2017 (annex A) is a first attempt at such a wider ranging report.

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## 2. Suggested scope

- 2.1. The draft report is divided into 13 sections under five headings. The headings are:
  - Context – which looks at key features of the sector including the number, type and ownership of clinics
  - Leadership and staffing – which looks at the Person Responsible and staffing
  - Safety of services – which looks at multiple births and incidents
  - Regulatory compliance – which at what clinics do well and the number and type of non-compliances
  - Patient experience – which looks at patient feedback, the provision of counselling, information for patients and clear pricing
- 2.2. It should be noted that the data in the report is of variable quality. This is primarily because in the year in question, 2016-17, our data on patient experience, in particular, is limited. Members will recall that we are currently trialling the patient feedback mechanism on our new website but early signs are very encouraging. We have already seen a marked increase in the quantity of patient feedback since the new site came on line.
- 2.3. We could decide not to include any material on patient feedback at this stage until we have a richer source of data. In our view this would be a mistake as patient experience is central to any assessment of the quality of services provided. It is also central to our new regulatory model where the quality of care is driven by both our regulatory standards (embodied in the Code of Practice and supported by inspections and licensing) and by better information for patients, which enables them to become more demanding and discerning users of services. The data on patients is more limited than we would wish at this stage but we believe that it is better to acknowledge those limitations and improve the position over time, than omit discussion of patient experience altogether.

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### 3. Publication

- 3.1.** The draft report is intended for publication within the next few weeks. In the future, we envisage an annual report each Autumn which will complement our annual fertility trends report. As incidents are now covered in this draft report we propose not publishing a separate annual incidents report in future.

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### 4. Discussion

- 4.1.** The Authority is invited to discuss the draft report. In particular, we would welcome views on:
- The broad direction of travel and scope of the report
  - The balance between the individual sections
  - The tone of voice and level of detail.

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### 5. Recommendation

- 5.1.** The Authority is invited to:
- Endorse the decision to move away from a narrow discussion about clinic non-compliances
  - Comment on the proposed scope and coverage of the draft report
  - Agree that the report be embargoed until publication in the Autumn.

# Investigation into fertility clinics

## Strategic delivery

Safe, ethical, effective treatment

Consistent outcomes and support

Improving standards through intelligence

## Details

Meeting Authority

Agenda item 11

Paper number HFEA (13/09/2017) 852

Meeting date 13 September 2017

Author Sharon Fensome-Rimmer, Chief Inspector and Hannah Verdin, Head of Regulatory Policy (section 8 only)

## Output

For information or decision? Decision

Recommendation

- For egg sharing and egg donation (paragraphs 4.15 – 4.17)
- For success rates from egg freezing (paragraphs 5.15 – 5.16)
- For the promotion of loans to pay for treatment (paragraph 6.7)
- For drug pricing (paragraphs 7.4 – 7.5)
- For OHSS (paragraph 8.9)

Resource implications Within budget

Implementation date Over time, dependent on issue

Communication(s) Over time. Tied in part to the review of the Code of Practice

Organisational risk  Low  Medium  High

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## 1. Introduction

- 1.1. In May 2017, the Daily Mail published several stories (on subsequent days) alleging failures in care at five private UK fertility clinics. The detail of the allegations varied from clinic to clinic, as did the seriousness of the non-compliances. Much of the information for the stories came from reporters operating undercover, posing as potential patients at clinic open events.
- 1.2. We investigate all potentially serious allegations relating to the clinics we regulate. In undertaking such investigations, we have reference to the HFEA Compliance and Enforcement Policy. We describe that action in the 'regulatory action' section below. Those matters are considered by a licensing committee of the HFEA, and have been mostly concluded.
- 1.3. However, it is important that we also consider whether the allegations raise wider issues; perhaps they are indicative of more widespread failings of UK licensed clinics, or raise issues that we need to consider further – particularly in the light of our strategy intentions, high quality care for people affected by fertility treatment.
- 1.4. This report considers those policy implications, which are not a matter for a HFEA licensing committee, but quite properly are a matter for the Authority. The suggested policy responses are indicated in bold text throughout. Nothing in this report should be considered as additional evidence relating to the identified clinics' performance, and no inference should be drawn as to whether individual clinics have breached any HFEA requirements. Those matters have been dealt with elsewhere.

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## 2. Background

- 2.1. The five clinics identified in the Daily Mail investigation were: the Centre for Reproductive Genetic Health; Create St Pauls; Herts and Essex Fertility Clinic; the Lister Fertility Clinic; and the London Women's Clinic Darlington. In summary, these clinics were alleged to have done one or more of the following:
  - Encouraged egg sharing / donation for financial reward
  - Inflated the likely success rates for treatment with frozen eggs
  - Encouraged patients to take out loans to pay for treatment with little or no credit checks
  - Overcharged for drugs without explaining that the same drugs were readily available for less elsewhere
- 2.2. In addition, the Daily Mail suggested that there was widespread under-reporting in the fertility sector of ovarian hyperstimulation syndrome (OHSS), a potentially serious side effect of fertility treatment.

- 2.3.** We published a statement at the time saying that we treat any allegations of poor care seriously and would investigate. Sally Cheshire said:

*“We are very concerned by the allegations made in this investigation. At the HFEA our priority is the best possible treatment and care for patients and donors. If any patients at these clinics have worries about their care, they should contact us while we investigate further. We have already contacted the clinics involved and our inspectors will investigate each allegation. If we find poor practice in a clinic, we will take regulatory action.”*

- 2.4.** We also gave statements to the Daily Mail about some of the specific areas of practice covered in its investigation. These are included in the relevant sections below.

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### **3. Regulatory action**

- 3.1.** We followed a standard process in investigating the concerns raised by the Daily Mail. This can be summarised as follows:
1. The Daily Mail provided a few days’ notice of the nature of the allegations together with the identity of the clinics involved. Before publication we contacted the ‘Person Responsible’ (PR) of each clinic mentioned to seek their reaction to the allegations.
  2. The PRs responded promptly and forwarded the communication they had with the Daily Mail, having been invited to comment.
  3. Following the publication of the allegations, we analysed the issues highlighted and considered each in the light of the requirements placed on licensed clinics as set out in the Code of Practice – the standards in place by which licensed clinics’ compliance is assessed.
  4. Arrangements were made to visit each clinic by way of a scheduled inspection involving members of the inspection team and key members of the clinic team including the PR.
  5. The inspection team considered a range of evidence and supporting information – including our analysis of the allegations and the PRs initial response, together with evidence from previous inspection findings. At the inspection, we held a meeting with the PR; undertook interviews and meetings with members of the clinic team, where appropriate, and where they were identified within the article(s); and reviewed a range of material, for example marketing material visible in the clinic – posters and banners, together with written information provided to patients – such as leaflets.
  6. A report was prepared reviewing the allegations relevant to each licensed clinic; the HFEA requirements in place relevant to each issue; the purpose of the inspection; the main evidence put forward by the licensed clinic; our findings; conclusions, together with any recommendations relating to sanctions or identifying where improvements by the clinic are necessary.
  7. As noted above, it is HFEA policy that reports of non-compliance at clinics are considered by a licensing committee rather than the full Authority. HFEA Standing Orders set out the scheme of delegation in respect of the Authority’s licensing functions, but the broad principle is that more serious

matters of non-compliance are considered by the Licence Committee with more routine matters considered by the Executive Licensing Panel. With this scheme of delegation in mind, five separate investigative reports on the allegations made were prepared and considered by the following licensing committee:

- London Women's Clinic Darlington – considered by the Licence Committee on 13 July 2017
- Centre for Reproductive Genetic Health – considered by the Executive Licensing Panel on 25 August 2017
- Create St Pauls – considered by the Executive Licensing Panel on 25 August 2017
- Herts and Essex Fertility Clinic – considered by the Executive Licensing Panel on 25 August 2017
- Lister Fertility Clinic – considered by the Executive Licensing Panel on 25 August 2017

**3.2.** All regulatory decisions made by the Licence Committee or Executive Licensing Panel are published on our website.

**3.3.** As the allegation regarding the incidence of OHSS did not refer to specific clinics, instead implying that this is a sector-wide issue, our commentary here is dealt with separately at section 8 below.

**3.4.** The remainder of this report focusses on the wider policy issues raised by these allegations. They are:

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

**3.5.** The question we are asking is: are these isolated incidents or do they give rise to concerns about performance in the fertility sector more widely?

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## **4. Egg sharing and egg donation**

### **Allegation**

**4.1.** The allegations centred on what was described as the exploitation of women, some on low incomes, with the clinics targeting them to donate their eggs for financial reasons and using financial incentives to convince those women to donate eggs to allow the clinic to maximise its profits. For example, the article claimed that there could be as many as 10 recipients for each egg donor. The article also alleged that lesbian couples were targeted for egg sharing, even though they may only need treatment to enable them to access donor sperm.

- 4.2.** We gave the following statement at the time:

*“We have clear rules in our code of practice, enforced by inspectors, that clinics must explain the risks and chance of success of treatment to each patient and donor, and avoid encouraging people to donate eggs and sperm with the promise of financial gain. This investigation highlights potential breaches of our code and our inspectors will be investigating each allegation presented to us. If we find that a clinic is in breach of our code, we will take regulatory action.”*

### Current requirements

- 4.3.** In the UK, egg donation and compensation of donors is permitted under the Human Fertilisation and Embryology Act 1990 (as amended) (the Act). Requirements and best practice guidance are set out in our Code of Practice (CoP) and general directions. The CoP also allows patients to receive treatment services in exchange for donation of their gametes (eggs and sperm) to treatment or research, the policy is known as ‘benefits in kind’ or, more commonly, egg sharing.
- 4.4.** The parameters regarding compensation to donors are set by the European Union Tissues and Cells Directive (EUTCD) and egg sharing arrangements fall within these parameters as they support the objective of increasing tissue and cell availability for donation.
- 4.5.** HFEA policy allows clinics to offer both sperm and egg donors undergoing fertility treatment, the option of having free or reduced treatment in exchange for donation to research or another patient (General Directions 0001).
- 4.6.** There has been much debate about the ethics of donating eggs or sperm in exchange for a benefit, especially as that benefit may exceed the compensation available to ‘altruistic’ donors (those that are not undergoing any fertility treatment, and only wish to donate their gametes), which is currently up to £35 per visit for sperm donors and up to £750 per egg donation cycle. However, evidence suggests that there are positive outcomes for both the recipient and the donor in egg sharing arrangements and the practice is widespread across the fertility sector, with many patients benefiting from receiving donated gametes. CoP guidance states that if benefits in the form of licensed services are offered to an egg provider (including a mitochondrial donor), they should be given in connection with the cycle in which eggs are supplied for a recipient’s treatment unless providing treatment to the egg provider at this stage could be harmful, or there is a clinical reason(s) to defer treatment to the egg provider.
- 4.7.** Moreover, it is crucial that people considering egg donation, including egg sharing, are fully aware of the implications of their decision, which have the potential to be lifelong and profound. As such, the Act requires counselling to be offered when patients seek treatment with donated gametes or embryos; wish to donate or store their gametes or embryos or wish to nominate, or be nominated as, a legal parent. We consider that the offer and provision of counselling is an important part of the decision-making process for any potential donor. It is important that donors take this opportunity to explore and discuss the wider implications of donating, such as the potential impact on the donor;



their family (including any future children), and the potential for a future contact from a person(s) born following that donation.

- 4.8.** Section 13.1 of the CoP states that advertising or publicity aimed at recruiting gamete or embryo donors, or at encouraging donation, should not refer to the possibility of financial gain or similar advantage, although it may refer to compensation permitted under relevant HFEA Directions.

#### What we found

- 4.9.** We saw some evidence of an overly informal culture about the provision of information to patients in relation to donation treatment.
- 4.10.** We saw a distinction between information within internal procedures and written information provided to patients, and what was reported was said by some clinic staff – suggesting that there is a mismatch between policy and practice.
- 4.11.** Some clinic staff did not have satisfactory explanations for some of the words they agreed they had said, and were apologetic. Several staff said that their comments were taken ‘out of context’ – and we saw some evidence to support this.
- 4.12.** Moreover, we saw evidence that information provided to prospective patients on clinics’ websites do refer to an advantage to the patient (financial or similar) if they share/donate some of their eggs – for example in references to *free fertility treatment* or a low-cost treatment option which goes against the principle of altruistic donation – where the donor is making a gift to others and receiving treatment which might not otherwise be available.
- 4.13.** One of the clinics concerned in fact did very little egg-sharing – none or one or two cases per year (although their egg donation activities were higher). This suggests that they may have been unused to dealing with the questions and issues raised by the reporters and this may account for the poor practice. To say this is not to excuse the actions of some staff, but does indicate that although we found evidence that this clinic could be seen to be exploiting women on low incomes, given the low volume of egg sharing the financial benefit to the clinic was minimal.
- 4.14.** We saw good evidence of the effectiveness of clinics’ counselling service at the two clinics involved, and that patients and donors have opportunities to discuss and fully understand the implications of their decision(s). We are satisfied in every case that counselling services are suitable and compliant with regulatory requirements.

#### Are our requirements fit for purpose?

- 4.15.** There are always limitations with an inspection and regulatory process that is episodic in nature – and which cannot see what happens at open days and patient consultations. Like other regulatory bodies, we must place reliance on the role played by our guidance, the professionalism of staff to implement it, and other mechanisms to promote compliance. The evidence we found here

suggests that **there is work to do to further emphasise the special nature of egg donation and egg sharing** – to promote the important role played by altruism and ensure that the rules of the market place do not impinge. **That is a communication and influencing task.**

- 4.16.** We are committed to scrutinising clinics’ websites more frequently, to ensure their claims are evidence-based and factual. Where clinics are seen to be making extravagant claims about their performance or the effectiveness of services they offer, it may inform conclusions that a clinic may be losing sight of the importance of the ethical framework in which assisted reproduction should be provided.
- 4.17.** The role played by patient feedback is an important one. **Our new website provides new opportunities for patients to feedback their experiences of clinics.** Already we are getting useful information to prompt conversations with clinics and focus our interactions.

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## 5. Success rates from egg freezing

### Allegation

- 5.1.** The allegations principally relate to two clinics who were accused of exploiting women by targeting them to freeze their eggs, on the grounds that it is an insurance policy to preserve fertility for many years. That in doing so, the clinics overstated the success rates of the treatments and at the same time underplayed the risks of subsequent treatment with those eggs being unsuccessful. Further to this, some of the information on clinics’ websites relating to egg sharing is potentially misleading. The allegations also reference those clinics offering ‘free’ consultations and open evenings to market specific techniques such as egg freezing.
- 5.2.** We gave the following statement at the time:

*“Egg freezing has become more widely available over recent years, though the numbers are still too low for us to publish clinic-by-clinic data. Our latest national data on egg freezing shows that the pregnancy rate is around 22%, but this is for women of all age groups and is likely to include eggs frozen using older techniques. We require clinics to give an accurate prediction of the chance of success from any fertility treatment and we check patient information on inspection.”*

### Current requirements

- 5.3.** First, some context here is necessary. Since 2005, the number of women storing their eggs has increased, with the most rapid growth occurring further to the introduction of egg ‘vitrification’ which became widely available around 2010. Vitrification is a cooling technique allowing the water inside and surrounding the egg to quickly cool into a solid state with no ice crystal formation, a problem with earlier, slow freezing, techniques. Despite growth of 25-30% year-on-year, egg storage cycles are still a relatively small proportion of

fertility treatment performed in the UK. The live birth rate per thaw cycle started for women using their own thawed frozen eggs was 20.8% in 2012 and 13.9% in 2013 – albeit the actual difference is represented by only a small change in the number of births due to the small numbers involved. This is a lower rate of success than for fresh eggs or frozen embryo transfers. In short, the evidence available to provide to prospective patients as to the efficacy of egg freezing is not yet robust. In any event our requirements focus around two areas – information provision; and free consultations.

### **Information provision**

**5.4.** We expect fertility patients to be given appropriate information before giving consent to licensed activities. This is required by the Act (schedule 3,3,1b) and by licence condition T58: ‘Prior to giving consent gamete providers must be provided with information about:

- a) the nature of the treatment
- b) its consequences and risks
- c) any analytical tests, if they are to be performed
- d) the recording and protection of personal data and confidentiality
- e) the right to withdraw or vary their consent, and
- f) the availability of counselling.’

**5.5.** We consider that ‘proper’ information is accurate, complete and easily understood. Specific information on success rates on clinic’s websites is covered by CoP guidance 4.5, and a further related requirement relating to the consent to store (eggs) at 17.13b states that to extend storage beyond 10 years a medical practitioner must find that the gamete provider is at risk of, or exhibits, premature infertility and the gamete provider must consent to the added storage period. In short, patients must be made aware that their options may not be indefinite.

### **Free consultations**

**5.6.** Our powers are limited with regards to costs and financing of treatments including the costs of consultations or services provided in support of the provision of treatment. However, we have considered this aspect of the allegation, as patients can be vulnerable, by their circumstances, and we are committed to ensuring high quality care for fertility patients.

### **What we found**

**5.7.** Our main findings here relate to the evidence provided to patients about the efficacy of egg freezing more generally, and individual clinic’s claims as to their efficacy in freezing and then treating the patient and leading to a successful pregnancy. The presentation of reliable data in this area is complex.

**5.8.** A major factor here is the lack of statistically reliable data, due to the relatively low numbers of egg freezing, and then thawing and treatment, activity. Last year we published information on treatments in 2013 and 2014; and it is noted

that some clinics are relying on published information (following a Freedom of Information request) about treatments in 2009-11.

- 5.9.** To provide more current and (potentially) statistically reliable data, the clinics highlighted were relying on data drawn from their own (increasing) activity levels. This is to be encouraged, particularly if the volumes of activity support reliable statistically valid conclusions.
- 5.10.** Some of the evidence gathered by clinics has also been published in reputable scientific journals, and other evidence was provided to us openly. As such, we found that the clinics were making efforts to gather evidence which would be helpful to patients.
- 5.11.** That said, we also found that the use made of official data, and the data produced locally, was not always conveyed as carefully, or with the necessary caveats, as we would wish. Equally, we saw no evidence of attempts made to deliberately mislead patients – but some of the information conveyed could be misleading. This is a subtle but important distinction.
- 5.12.** Considering this, we found that insufficient efforts were made to follow up verbal claims – made in open sessions (at open evenings, say) or individual and necessarily brief ‘free’ individual patient consultation sessions – with written information. Given the complexity of this area, the costs involved, and the decisions that prospective patients must weigh up, it is important that patients are provided with information for them to read and consider further. Whether a session is free of charge, or not, is less relevant than patients being provided with accurate information.
- 5.13.** Of concern, we noted that prospective patients were not consistently appraised of the rules relating to the permitted time for the storage of a patient’s eggs, which is usually 10 years – unless other conditions are satisfied. It is imperative that a patient is fully aware of these limitations. At the point by which a patient commences treatment to store, we are content that the clinics involved would discuss these implications with the patient (for example a consent form must be signed by the patient that makes this clear) but it is important that prospective patients are appraised of this as early as possible.
- 5.14.** Again, we found that the claims made on clinics’ websites as to the efficacy of egg freezing activity was not always supported by the evidence.

#### **Are our requirements fit for purpose?**

- 5.15.** As noted above, the low level of activity in egg freezing and thawing means that it is not possible to draw firm conclusion from the data, whether clinic level data or national data. As more treatment take place with frozen eggs that picture will change. **We have already produced some data on egg freezing in our annual fertility trends report and we continue to include it in future editions.**
- 5.16.** In the meantime, we expect clinics to provide accurate information to patients making it clear that pregnancy success rates should be treated with caution.

**We will strengthen guidance about success rate information on clinics' website as part of our review of guidance on information for patients.**

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## **6. The promotion of loans to pay for treatment**

### **Allegation**

- 6.1.** The focus of the allegation related to one clinic promoting a payment plan for self-funded patients via a third party, in this case Zebra Finance. The loans were intended for couples unable to finance their treatment by other means, with little or no credit checks made by the clinic. The interest rates for such arrangements can be higher than the costs of financing secured elsewhere. The allegation implied that clinics may have a conflict of interest in such cases.

### **Current requirements**

- 6.2.** We have no powers with regards to costs and financing of treatments and we cannot set prices for treatments or the rules relating to financial services. However, we wanted to explore this aspect of the allegation given patients' potential vulnerability.
- 6.3.** The Financial and Conduct Authority (FCA) has strict guidelines and codes of conduct governing how personal financial services providers conduct their business in relation to advertising and promotion. Only certain authorised personnel are permitted to engage in introductory activities, within the terms of an Introducer Appointed Representative (in this case a licensed clinic) who must follow strict guidelines relating to advertising and promotion. Failure to meet these requirements is a criminal offence under the Consumer Credit Act 1974.

### **What we found**

- 6.4.** We found evidence of a casual approach taken by the clinic as to the importance of effective arrangements being in place to safeguard patients' interests. We contacted the finance provider itself and the company was sufficiently concerned about its compliance with FCA requirements that it decided to end the agreement.

### **Are our requirements fit for purpose?**

- 6.5.** We do not have powers here and therefore we do not know the extent of clinics' arrangements with third-party financial service companies, nor are clinics required to inform us.
- 6.6.** Some patients are made more vulnerable by their circumstances and may therefore be susceptible to entering into financial (or other arrangements) that may not be to their advantage. However, this is an unfortunate feature of an increasingly commercial sector. And further, if it is a patient's only option that to access treatment they must enter in to a financing agreement then, even if we had the powers, it might not be appropriate for us to intervene.

- 6.7.** However, patients must be fully informed. **We therefore plan to work with the FCA to make clinics aware of their responsibility not to engage in financial activities in breach of FCA requirements.** We believe that this will reduce the likelihood of patients entering in to disadvantageous financial credit agreements.

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## 7. Drug pricing

### Allegation

- 7.1.** It was alleged that three clinics offered medications necessary for IVF treatments directly to patients at prices that were higher than from other sources, for example from national and local pharmacy groups. This could lead to perceptions that patients are being taken advantage of, and who may understandably believe the clinic is not acting in their best interests given the medical relationship they have with their clinic.

### Current requirements

- 7.2.** The Code of Practice requires that patients are given certain information before they can give informed consent. It also requires that, before treatment, storage or both are offered, the clinic should give the patient a personalised costed treatment plan. We do not require clinics to inform patients about their options for buying their medication.

### What we found

- 7.3.** We found evidence in the three clinics that patients were not fully informed about the costs of medication or that the medication could be obtained elsewhere, although in one case, we found the costs of medication were lower than is often found elsewhere.

### Are our requirements fit for purpose?

- 7.4.** Our inspectors check compliance with Code of Practice requirements around information to be given to patients and across the sector as whole compliance is generally good. However, we have separate feedback from patients that they have not received sufficient information about the price of their treatment. We have therefore included **a question in the new patient feedback feature on Choose a Fertility Clinic about whether self-funded patients were charged what they expected to pay.**
- 7.5.** We do not have statutory powers in respect of the cost of medication, so could not introduce guidance in this area. However, we have started **a review of guidance relating to information to be provided to patients and will consider adding more specific information about pricing information to that guidance.**

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## 8. Ovarian hyperstimulation syndrome

### Allegation

**8.1.** It was alleged that there is under-reporting by clinics of ovarian hyperstimulation syndrome (OHSS), a condition that some patients develop in reaction to the drug treatment necessary for IVF. We require licensed clinics to report all severe and critical cases of OHSS – they report approximately 60-80 each year. We know from data provided to the Daily Mail from NHS Digital that, in 2015-16 there were 865 admissions to hospital for OHSS in England, 836 of which were emergency admissions.

**8.2.** We gave the following statement at the time:

*“We are very concerned about the allegation of under-reporting of OHSS, which can in rare cases be life-threatening. Our figures include only severe and critical cases of OHSS which clinics must report to us immediately. Mild or moderate cases, which are less serious but still very worrying for patients, may also involve a hospital admission and are therefore included in the NHS data. We believe that we do have a good picture of the severe and critical cases. However, we will investigate this and if any evidence of intentional under-reporting by clinics is found, we will take action against those responsible.”*

### What we found

**8.3.** Clinics must report severe and critical cases of OHSS to us immediately. Sixty cases of severe/critical OHSS were reported to us in 2015 and 38 were reported to us in 2016. HFEA inspectors review incident reporting on inspection. This includes reviewing the clinic’s internal incident log to ensure all appropriate incidents (including severe and critical OHSS) are reported.

**8.4.** Some mild and moderate cases are reported to us, although we do not require this. Therefore, the data we hold on mild and moderate cases will not reflect the true number of cases. In 2015, 140 mild/moderate cases of OHSS were reported and 90 mild/moderate were reported to us in 2016. All these cases resulted in a hospital admission.

**8.5.** We have discussed this data with NHS Digital who will be providing us with further analysis and information regarding what falls under their category/definition of ‘hyper-stimulation of ovaries’ which may allow us to deduce how many of these cases were severe and critical OHSS because of IVF treatment.

**8.6.** The criteria for assessing and classifying the severity of OHSS cases are set out in the Royal College of Obstetricians and Gynaecologists (RCOG) Green-top guideline no.5, ‘The Management of Ovarian Hyperstimulation Syndrome’ (February 2016). Hospital admissions and the length of time spent in hospital is not part of this classification system and is therefore not an indicator of severity.

- 8.7.** Although the RCOG guidelines only recommend hospital admission for severe and critical OHSS, a patient with mild or moderate symptoms may be admitted to hospital as a precaution, especially as the guideline also states that:

*“Hospital admission should be considered for women who:*

- *are unable to achieve satisfactory pain control*
- *are unable to maintain adequate fluid intake due to nausea*
- *show signs of worsening OHSS despite outpatient intervention*
- *are unable to attend for regular outpatient follow-up”.*

- 8.8.** It is therefore likely that the number of hospital admissions are significantly higher than the number of severe and critical cases of OHSS related to IVF, for the following reasons:

- It is likely that the majority of the reported 865 hospital admissions in 2015-16 would have been mild or moderate cases, where patients are admitted as a precaution, and therefore not reported to us.
- It is likely that some IVF patients are admitted to hospital for post-egg retrieval symptoms (pain, nausea, diarrhoea and/vomiting) and hospital staff may presume the patient is suffering from OHSS and labelled as such without verification of the diagnosis before discharge (or if the diagnosis is later changed the categorisation/reason for admission may remain unchanged).
- Patients are often admitted to hospitals not associated with their IVF clinic, either because they have attended a stand-alone private clinic or because they do not live close to their clinic. It is possible that their IVF clinic may be unaware of the admission and may disagree with the diagnosis or classification of severity.
- It is possibly the case that Accident and Emergency staff would not refer to the green top guidelines/HFEA definitions regarding incidents, or have a good understanding of OHSS. There may therefore be misclassifications in the NHS Digital data.
- It is also possible that some cases arise because of stimulation of ovaries without IVF treatment (i.e., clomid), which would not be reported to us because we do not regulate this area of fertility services.

### Proposed actions

- 8.9.** From our investigations so far, there seems to be valid reasons for the difference between the number of severe and critical OHSS cases reported to us and the number of patients admitted to hospital with OHSS of any category. However, we have further work to do before to be sure that IVF clinics are not under-reporting. We plan to take the following actions:

- **Work with NHS Digital to:**
  - analyse the data to establish, as far as possible, how many of the 865 hospital admissions were severe and critical OHSS because of IVF treatment



- set up an arrangement to receive regular updates on hospital admissions relating to OHSS, to check whether the number of cases reported to us is in line with those figures (while acknowledging that the different statistical definitions employed means that the figures are unlikely to be identical) and in relation to their proportion of the overall number of cases.
- **Meet with the RCOG and the British Fertility Society** to discuss:
  - what proportion of mild, moderate, severe and critical cases we should expect to see, bearing in mind there are no reporting requirements for mild and moderate OHSS
  - whether there is any room for improvement/update of our definitions (definitions in guidance note 27 – Adverse incidents, taken from the RCOG Green-top guideline), and how RCOG promotes its guideline to ensure it reaches the appropriate clinicians
  - whether implementation of a specific OHSS incident form would be useful, or if the information we glean from our reviews of severe and critical cases is sufficient
  - the possibility of requiring clinics to have procedures for the prevention and management of OHSS.
- As part of the **review of Code of Practice guidance** regarding information which clinics are required to provide patients, we will consider **what information clinics should provide patients on OHSS**, including reporting requirements and information which patients should give an Accident and Emergency clinician or any other clinician involved with their care. This should encourage patients to alert their treating centre if they suffer from OHSS (and are admitted to hospital).
- Depending on the outcomes of the actions above we may wish **to review what inspectors ask clinics about their application of the OHSS/adverse incident definitions** (guidance note 27) and/or the **information clinics provide patients about OHSS**.

# Leadership in clinics

## Strategic delivery:

Safe, ethical effective treatment

Consistent outcomes and support

Improving standards through intelligence

## Details:

Meeting Authority

Agenda item 12

Paper number HFEA (13/09/17) 853

Meeting date 13 September 2017

Author Nick Jones, Director of Compliance and Information  
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## Output:

For information or decision? For information

Recommendation The Authority is asked to:

- Note and comment on our proposed approach to leadership in the sector
- Comment on the proposals for progressing this agenda

Resource implications This work is integrated within policy resourcing

Implementation date Dialogue in 2017 and through 2018 with Code of Practice version 9 publication October 2018

Communication(s) Various channels

Organisational risk  Low  Medium  High

Annexes: None

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## 1. Introduction

- 1.1.** It is increasingly understood that leadership is central to the delivery of high quality services in healthcare, and indeed elsewhere – think of the focus on leadership in schools in recent years. Our strategy for 2017-20 has three ambitions:
- Safe, ethical, effective treatment
  - Consistent support and outcomes
  - Improved standards through intelligence
- 1.2.** And we know that raising the quality of leadership in the clinic will be vital to achieving those goals.
- 1.3.** This is not a new concern for us. Our Chair, Sally Cheshire, highlighted the importance of leadership in her speech at our last annual conference in March this year. In it, she challenged representatives of the sector to reflect on the leadership skills in their own clinics.
- 1.4.** This paper considers what more we might do to encourage and support leadership in the fertility sector. The aim is not to set out a range of detailed initiatives but rather a direction of travel to better enable us to regulate for leadership. As such we welcome Members' views to shape our next steps here.

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## 2. Context

- 2.1.** Any consideration of leadership in the fertility sector needs to pay attention to several contextual factors.
- 2.2.** We need, first, to acknowledge that many clinics are well led. That is not to say there is no room for improvement – indeed an indicator of good leadership is a recognition that improvement is a continuous process - but we are not starting from the assumption that leadership in the sector is particularly lacking. Equally, it would be a mistake to be complacent and any consideration of leadership in the fertility sector needs to recognise several recent developments:
- 2.3.** Poor practice - there have been concerns over the past year about specific examples of poor practice in a small minority of clinics. We have seen media coverage about clinics offering so-called treatment add ons without proper advice and, more recently, coverage about egg sharing and egg donation schemes which did not follow our guidance. We are acting on both these fronts, but such stories give the impression that some clinics are not adopting ethical practices in relation to patients in their care. Some clinics performing to these standards might otherwise be well-led – but pushing at the boundaries at what is acceptable.

- 2.4.** Legal parenthood – the consent errors, though small when compared to the total number of consents, had a profound impact on the patients involved and some clinics were slow to take full responsibility and recognise that it is how you respond to errors that matters as much as not making them in the first place. Our experience in providing advice to clinics over the last few years reinforces the conclusion that consent is not just about good processes but also about leadership – staff will only truly understand the importance of consent when it is promulgated at all levels in the clinic.
- 2.5.** Clinic ownership – the growth of groups of private clinics, the array of partnerships emerging between NHS services and essentially private partners, and the influx of private capital seeking a return on investment and with it the distinction between ownership and management, has all raised tricky questions of ‘who’s really in charge?’

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### **3. Legal and policy requirements**

- 3.1.** The Human Fertilisation and Embryology Act 1990 (as amended) - ‘the Act’ - has little to say about leadership. It is agnostic about organisational form, or the management and leadership of clinics. Under the law all of our regulatory focus is placed upon the ‘person responsible’ (PR). So the law requires licensable activity to take place only under the supervision of the PR, as named on the centre’s licence. The Act (section 16 (1) and (2)) allows us to ‘on application grant a licence to any person’ if ‘the application is for a licence designating an individual as the person under whose supervision the activities to be authorised by the licence are to be carried on’.
- 3.2.** A licence can only be granted if a number of requirements are met in relation to the PR, including:
- the Authority is satisfied that the applicant is a suitable person to hold a licence
  - the individual possesses a diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences, awarded on completion of a university course of study, or other course of study recognised in the United Kingdom as equivalent, or is otherwise considered by the Authority to be suitably qualified on the basis of academic qualifications in the field of nursing, and has at least two years’ practical experience which is directly relevant to the activity to be authorised by the licence
  - the Authority is satisfied that the character of that individual is such as is required for the supervision of the activities and that the individual will discharge the duty under section 17 of the Act.

**3.3.** Section 17 of the Act then goes on to spell out broad expectations of the PR, which are to secure:

- that the other persons to whom the licence applies are of such character, and are so qualified by training and experience, as to be suitable persons to participate in the activities authorised by the licence,
- that proper equipment is used,
- that proper arrangements are made for the keeping of gametes, embryos and human admixed embryos and for the disposal of gametes, embryos or human admixed embryos that have been allowed to perish,
- that suitable practices are used in the course of the activities,
- that the conditions of the licence are complied with,
- that conditions of third party agreements relating to the procurement, testing, processing or distribution of gametes or embryos are complied with, and
- that the Authority is notified and provided with a report analysing the cause and the ensuing outcome of any serious adverse event or serious adverse reaction.

**3.4.** As these legal requirements are fairly broad we have long used our Code of Practice to spell out our policy requirements of the PR, although it must be admitted that those are limited. The main requirements, outlined in guidance note 1 of the Code of Practice, are:

- The person must complete the Persons Responsible Entry Programme (PREP) assessment before the HFEA can consider whether or not to approve them. (PREP is an online tool designed to assess the PR's understanding of the law and Code of Practice.)
- The person responsible is ultimately responsible for ensuring that all licensed activities are conducted with proper regard for the regulatory framework that governs treatment and research involving gametes or embryos.
- The role of the person responsible should include:
  - a) maintaining an up-to-date awareness and understanding of legal obligations
  - b) responding promptly to requests for information and documents from the HFEA
  - c) co-operating fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement, regulation or healthcare, and
  - d) informing the HFEA of any change to their professional registration.

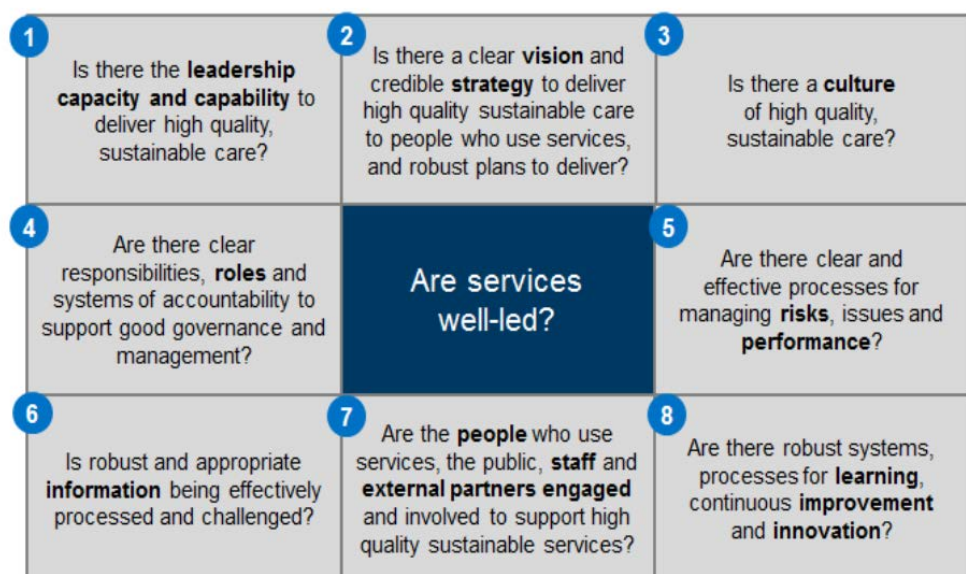
- 3.5.** As outlined at 3.2 the PR is required to have a medical or other qualification. There is not a requirement to be medically qualified as a doctor, although many are. Currently, of the 101 treatment and storage clinics (including donor insemination) the composition by professional category is as follows:
- Medically qualified doctor/consultant – 63
  - Nurse or other clinically qualified – 8
  - Scientist – e.g. embryologist/andrologist – 30
- 3.6.** We do not set out the fundamental requirements, or a job description, for our expectations of what being a PR means. Given the centrality of the PR to the law, the Code and leadership more generally, this seems like something worth doing.
- 3.7.** The PR, as the name suggests, is given prominence in compliance activities. The inspection report is directed towards the postholder; the PR is required to 'respond' to the recommendations made within the inspection report; and, in certain circumstances the 'suitability' of the PR in supervising licensed activities comes under question.
- 3.8.** From time to time we encounter clinics, at inspection or other form of intervention, where the nature, seriousness, extent and volume of non-compliances identified point towards the performance (or otherwise) of the leadership of the clinic – embodied under the terms of the Code by the PR.
- 3.9.** The Act at S.17 gives us the ability to make the case that the PR is unsuitable – and consequently the continuation of the licence cannot be recommended. We have not set out in explicit terms what the features of an unsuitable PR might be. Instead we have relied on the extent and type of the non-compliances to 'speak for themselves'. Given such circumstances are place and case specific it is often difficult for the licensing decision-makers to be assured that the recommendation is proportionate or consistent.
- 3.10.** On occasion, and more so recently, we have seen in the face of considerable performance concerns a few PRs step aside or retire or resign – in recognition that the proportionate sanction we might apply in such circumstances is to recommend the suspension or revocation of that licence.
- 3.11.** Further, as noted above, in some clinics we have been aware that the position of the PR and where the leadership sits within the clinic (or wider setting say in the case of a NHS Trust or a group of private clinics) is distinct – in other words the PR holds all the responsibility but none of the influence (or the ability to make decisions about the allocation of resources) – often uncomfortably so.
- 3.12.** This gets us into considerations about the nature of leadership and where it resides within the organisation; to an understanding as to the organisational forms of clinics such that we can understand those dynamics, and be sensitive to them (but at the same time not allowing ourselves to be distracted by them) –

such that our regulatory incentives and interventions are effective. To a greater or lesser degree, we do this now, but without an explicit leadership framework.

- 3.13.** Taking all this in consideration, we think there is now merit in being more specific as to the requirements of leadership in a modern assisted reproduction clinic (see section 5 below).

## 4. What do others do?

- 4.1.** In thinking about assessing leadership it is instructive to look at what others do. As noted above, improving the quality of leadership in healthcare is increasingly a common project. In their assessments of NHS and independent providers judging leadership in one way or another has been the feature the Care Quality Commission and NHS Improvement (and to a lesser extent the Healthcare Commission and Monitor before them). This work stems from a recognition that performance in terms of clinical areas, clinical governance and quality of care is all underpinned by the way a place is run.
- 4.2.** These frameworks have evolved over time and start from the observation that the board (both non-executive and executive) has a key role in setting strategy and developing and implementing action plans to achieve objectives; and monitoring performance and challenging the executive where that might be improved.
- 4.3.** CQC and NHSI have now alighted on a single framework in their assessment of whether a service is ‘well-led.’



- 4.4.** This assessment framework may be useful to consider – as we think about possible approaches. That said fertility clinics are, overall, small and medium size enterprises and any approach we take must be sensitive to this.

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## **5. New incentives to encourage and support leadership**

- 5.1.** Developing a regulatory framework that can encourage and support leadership will have greater impact if it is properly understood by the sector. We think there is merit in beginning this work with a dialogue with clinics and professional bodies about:

- What a well led clinic looks like
- What it means to be a suitable PR
- In what circumstances the aggregate charge sheet points to the failure of the PR to discharge their duties
- How we promote the notion of a cadre of leaders ready to lead clinics over the next 10 years – in the light of technological breakthrough and disruptive technology; NHS funding constraints; NHS models changing; and the requirement to provide a return to investors.

- 5.2. Is the Authority content with this approach?** If so, we will start a dialogue with the sector over the course of the Autumn alongside our engagement on the new version of the Code of Practice – for example through a planning group and workshops. We plan to publish a draft Code next year for comment.

- 5.3.** We see the components of the work as having three main elements:

- Inspiration – we need to find ways of identifying good leadership where we find it in the sector and sharing that good practice
- Guidance/training – we need to find ways of being clearer about what we expect of a PR. This will involve the preparation of a new guidance note 1 and subject to consultation, we would expect any new leadership requirements to be embodied in v.9 of the Code of Practice scheduled for October 2018. We would also look to develop a new PREP with a greater focus on the leadership requirements involved and a programme to put all extant PRs through the new PREP as part of their continuing professional development. This would be a way of emphasising to PRs the importance of leadership and we believe there would be good support for this. Lastly, we would work with the professions to develop a PR training programme.
- Encouragement/incentives – we need to find ways to connect the leadership agenda with what patients want; that a culture of continuous improvement is likely to improve success rates and the quality of care. Working with NHS England there may also be opportunities for direct incentives for those clinics providing NHS care.



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**5.4. Is the Authority content with these broad areas for action?**

- 5.5.** Alongside this work, we need also to develop the skills and tools of inspectors such that they are equipped to make connections between the quality of the service – evidenced in inspection reports in similar ways as now - and the quality of the leadership in the clinic. This is not straightforward and may require not just training but also changes to the summary section of inspection reports.
- 5.6.** The direction set out in this paper has the potential to make significant changes to the way we inspect and regulate. We have consistently inspected against the law and the Code of Practice and held the PR to account for a clinic's performance against those standards. But we haven't really held the PR's own performance to account, other than when it is so bad that we consider encouraging the PR to step down or even consider suspending or withdrawing the licence.
- 5.7.** This paper represents an attempt to get upstream a bit, to directly encourage/support better performance in PRs to improve the quality of care at source rather than only deal with very poor performance after the event. This is potentially a big prize. We are looking to PRs to set the tone in their clinic, develop their staff and be responsive to the needs of their patients. Some PRs are there already; our task is design a framework that can help all PRs to raise their leadership game.

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**6. Recommendation**

- 6.1.** The Authority is asked to:
- Note and comment on our proposed approach to leadership in the sector
  - Comment on the proposals for progressing this agenda