

# Authority meeting - agenda

**15 March 2017 Venue: Church House, 27 Great Smith Street, London SW1P 3NZ**

<b>Agenda item</b>	<b>Time</b>
1. Welcome, apologies and declaration of interests	12:45pm
2. Minutes of 18 January 2017 <a href="#">HFEA (15/03/17) 825</a> For decision	12:50pm
3. Chair's report (verbal)	12:55pm
4. Chief Executive's report (verbal)	1:05pm
5. Committee chairs' updates (verbal)	1:20pm
6. Strategic performance report <a href="#">HFEA (15/03/17) 826</a> For information	1:30pm
7. Information for Quality programme: update <a href="#">HFEA (15/03/17) 827</a> For information	1:45pm
8. Draft Information policy <a href="#">HFEA (15/03/17) 828</a> For information	2:05pm
9. Governance and transparency <a href="#">HFEA (15/03/17) 829</a> For decision	2.35pm
Break	2:50pm
10. A strategic approach to facilitating research and responsible innovation <a href="#">HFEA (15/03/17) 830</a> For decision	3.00pm
11. Choose a fertility clinic - patient rating trial and evaluation <a href="#">HFEA (15/03/17) 831</a> For decision	3:35pm
12. Strategic risk register <a href="#">HFEA (15/03/17) 832</a> For information	4:15pm



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13.	Business plan 2017/18 <b>HFEA (15/03/17) 833</b> For decision	4:30pm
14.	Any other business	4:45pm

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# Minutes of Authority meeting 18 January 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 (15/03/17) 825

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Meeting date                15 March 2017

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Author                        Erin Barton, 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 18 January 2017 held at Church House, 27 Great Smith Street, London SW1P 3NZ

Members present	Sally Cheshire (Chair) Dr Andy Greenfield Kate Brian Dr Anne Lampe Anthony Rutherford Bishop Lee Rayfield	Yacoub Khalaf Margaret Gilmore Anita Bharucha Ruth Wilde Bobbie Farsides
Apologies	None	
Observers	Jeremy Mean (Department of Health)	
Staff in attendance	Peter Thompson Nick Jones Juliet Tizzard Paula Robinson	Anjeli Kara Richard Sydee Joanne McAlpine Erin Barton

### Members

There were 11 members at the meeting, 7 lay members and 4 professional members

## 1. Welcome, apologies and declarations of interest

- 1.1.** The Chair opened the meeting by welcoming Authority members and members of the public to the first 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.** Declarations of interest were made by:
- Anthony Rutherford (Person Responsible at a licensed centre)
  - Kate Brian (Regional organiser for London and the South East for Infertility Network UK)
  - Yacoub Khalaf (Person Responsible at a licensed centre)
  - Ruth Wilde (Senior Fertility Counsellor at a licensed centre)

## 2. Minutes of Authority meeting held on 15 December 2016

- 2.1.** Members agreed the minutes of the meeting held on 15 December, subject to one minor amendment, for signature by the Chair of the meeting.

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### 3. Chair's report

- 3.1.** The Chair provided members with a summary of events that she attended with organisations in the IVF sector and the wider health and care system since the Authority meeting on 16 November 2016.
- On 18 November, the Chair participated in the Philomathia Symposium 2016 in Cambridge, on the theme of 'body politics'. She then attended the Royal College of Obstetricians and Gynaecologists annual dinner.
  - On 7 December, she chaired a session on the 14-day rule at the Progress Educational Trust conference.
  - On 15 December, she chaired the extraordinary Authority meeting on mitochondrial donation, and on 11 January she chaired the Multiple Births Stakeholder meeting.
  - Finally, the Chair informed members that later that day she, together with the Chief Executive, were to meet Clara Swinson, the HFEA's new senior sponsor at the Department of Health.

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### 4. Chief Executive's report

- 4.1.** The Chief Executive advised members that on 24 November he attended the Association of Chief Executives annual conference and on 7 December he attended the Audit and Governance Committee before going to the PET conference in the afternoon.
- 4.2.** On 6 January, the Chief Executive spoke at Fertility 2017 in Edinburgh, the joint conference of the British Fertility Society, Association of Clinical Embryologists and the Society for Reproduction and Fertility. The Chief Executive gave an overview of our strategic priorities for the coming year, focusing on the range of regulatory levers we have including the use of soft powers, like information, to bring about culture change in the sector.
- 4.3.** On 11 January, the Chief Executive attended the Multiple Births Stakeholder meeting and on 12 January he attended the quarterly Healthcare Leaders senior talent board meeting.

#### Organisational change

- 4.4.** On 29 November, the Chief Executive held a leadership away day for all of the department heads and senior management team (SMT) to reflect on the results of the annual staff survey and to prepare for the annual all staff away day, held on 13 December.
- 4.5.** The Chief Executive reported that the results of the staff survey suggested a significant decline in morale in most areas when compared to the previous year's survey, although 90 per cent of staff have a clear understanding of the organisation's purpose and objectives. The all staff away day provided an opportunity for frank discussion and, whilst it was recognised that there may be little scope for change in some areas, staff agreed to set up six 'task and finish' groups, with the aim to make recommendations for change within the next three months on the following issues:
- Resources and workload
  - Leadership and managing change
  - Line-management and performance

- Careers and recruitment
- Learning and development
- Engagement and action.

- 4.6.** Each group will be led by a member of the SMT and a Head of department, and will consist of volunteers from across the organisation. There will also be an overarching piece of work on pay and benefits led by the Director of Finance to address the impact of restrictions in public sector pay on staff morale.
- 4.7.** The Chief Executive said that, at the staff away day, he also told staff about the proposed organisational changes that need to be implemented as a result of the new strategy and the completion of the Information for Quality (IfQ) programme. These changes include:
- Forming a new Intelligence team with a Head to be located in the Strategy and Corporate Affairs Directorate
  - Bringing together the existing Governance and Licensing team with the Business Planning team under a single Head
  - Recasting the Information and IT functions under a new Chief Information Officer role in the Compliance and Information Directorate
- 4.8.** A formal, one-month consultation with all staff will shortly begin and will include 1:1 discussions with the staff directly affected by the changes. The new structure will be finalised in February or early March 2017. SMT planned to redeploy staff where possible but accepted that there could be a small number of staff without the necessary skills for a position within the new organisational structure. The Chief Executive assured members that the change would be handled properly and sensitively, and that any final proposals would be put before the Remuneration Committee.
- 4.9.** Some members were keen to receive further information and agreed that the information disseminated to staff will be available for those who were interested.

### Press coverage

- 4.10.** The Chief Executive informed members that there was a lot of high-profile coverage of both our work and fertility issues in general.
- 4.11.** The Authority's decision in December to permit the use of mitochondrial donation techniques in treatment was very well covered in the press at home and abroad. The Chair gave interviews to a number of different national and international broadcasters, which appeared on various news channels. There were hundreds of articles written in the following days. The coverage was almost universally favourable, both in terms of the decision and recognition for the work done by the panel and our staff over the numerous reviews.
- 4.12.** There were reports of a baby born in Ukraine following the use of mitochondrial donation. The Chief Executive reminded members that the use of these techniques to treat infertility is not permitted in the UK; it can only be used to avoid serious mitochondrial diseases.
- 4.13.** Treatment add ons: In late November, BBC Panorama broadcast a half hour show on the use of treatment add ons, the supplementary treatments given to patients to increase their chances of success. The programme was based on research by the Oxford Centre for Evidence-Based Medicine which concluded that many treatment add ons were either unproven or counterproductive. We gave a statement to Panorama and some interviews around the issue after

the show was broadcast including the Victoria Derbyshire show the following day. There was a mixed response to both the programme and the published research from the sector but both highlighted some essential truths: that many clinics are offering add ons, that the price of each add on varies significantly, that patients are confused and that the evidence base for most add ons is weak. This message was reiterated by the Chief Executive at the Fertility 2017 conference in January. These were all issues that we have been considering for a while, and which will be covered in more detail later in the meeting.

- 4.14.** The Chief Executive informed members that during the previous week, the BMJ Online published a study by Manchester University which suggested that clinics were 'cherry picking' the outcomes data published on their websites. We prepared a statement which was given to a few media outlets. The Chief Executive assured members that the inspection team check clinic websites on a regular basis, and that the duty for clinics to act responsibly in presenting data within certain parameters is part of the Code of Practice. However, the Chief Executive acknowledged the need to revisit current guidance on clinic websites in light of the proposed changes to Choose a Fertility Clinic.

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## 5. Committee Chairs' updates

- 5.1.** The Chair of the Statutory Approvals Committee (SAC) reported that the committee met on 24 November and 15 December. It considered five preimplantation genetic diagnosis (PGD) applications in November, all of which were approved, and two requests for Special Directions, one of which was approved and one adjourned for further information. At the December meeting, five PGD applications were considered, all of which were approved.
- 5.2.** The Chair of the Licence Committee advised members that the committee had met on 12 January to consider one research licence renewal application and one executive update. The minutes have not yet been published.
- 5.3.** The Director of Strategy and Corporate Affairs advised members that the Executive Licensing Panel (ELP) met four times since the Authority meeting on 16 November; on 18 November, 2 and 20 December, and 13 January. At the first three meetings, the panel considered one treatment and storage renewal application which was approved; one interim inspection report, where the licence was continued; three initial licence applications, all of which were granted; and eight licence variations, all of which were approved. At the meeting on 13 January, the minutes of which have not yet been published, the panel considered one treatment and storage renewal application, two interim inspections and four licence variations.
- 5.4.** The Chair of Audit and Governance Committee (AGC) advised members that the committee met on 7 December, and considered the following items:
- Updates from the Internal and External Audit teams
  - Register and Compliance Risks, and an update on the IfQ programme and managing risks, from the Director of Compliance and Information
  - Strategic risks, from the Head of Business Planning
  - The implementation of audit recommendations
  - Disclosure and barring service (DBS checks), from the Chief Executive

- Cyber security: information security and testing, from the Head of IT - a topic the committee felt it was important to revisit more regularly particularly as the IfQ programme nears completion
- Contracts and procurement, and the whistle blowing policy, from the Head of Finance
- An annual review of AGC's effectiveness, which was overall very positive; the committee were keen to take on board feedback and planned to distinguish clearly between items that were for information and items for decision.

**5.5.** Our internal auditors, PwC, interviewed members of the Authority on behalf of the Department of Health's internal audit group who are encouraging Arm's Length Bodies in the health sector to undergo a review of their board effectiveness. The Chair informed members that an early report presented to AGC was overwhelmingly positive and that the final report will highlight any recommendations.

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## **6. Strategic performance report**

- 6.1.** The Chair introduced this item, advising that the strategic performance report was a general summary of our performance measures, the progress towards implementation of the strategy, our programmes and their status, and generally the wider performance of the Authority.
- 6.2.** The Director of Strategy and Corporate Affairs summarised the activities within her Directorate, including recent work following on from the Multiple Births Stakeholder meeting. The Policy team is in the process of analysing five years of patient feedback relating to the provision of information and decision-making in clinics surrounding elective single embryo transfer (eSET). Early analysis shows that patients want more information from both their clinics and external sources, and this was fed into work on the relevant sections of the new website. It was evident that in some clinics patients were given inconsistent advice from different members of clinic staff and that often information was provided too late in the treatment pathway. It was noted that there was a common misconception amongst those women opting for a double embryo transfer against the advice of their clinic, that this would increase their chances of success, when recent publications have shown that this is not necessarily true. These misconceptions will be addressed through the One at a Time campaign.
- 6.3.** Further collaborative work is being done to collect data on the number of multiple births coming from licensed treatment in the UK, unregulated treatments or from treatment overseas. She advised members that, whilst performance in the sector is very good as a whole and has come a long way in five years, there are still a handful of clinics not achieving the target of less than 10% of all births being multiple births. The inspection team will work closely with those clinics to try to improve their services.
- 6.4.** Some members were particularly interested in the growing difference in the proportion of eSET between NHS funded cycles and privately funded cycles. It was decided that further analysis of eSET as a proportion of those eligible, rather than as a proportion of all cycles, could provide a better understanding of other factors such as potential differences in the culture of NHS and private clinics, or the attitudes of their respective patients.
- 6.5.** The Director of Strategy and Corporate Affairs reminded members that the annual conference will take place on 16 March, and that their participation on the day will be much appreciated.

Registration for the conference will be launched on 1 February in Clinic Focus. The Chair and Chief Executive have already agreed some of the themes for the day but the main focus will be the new Strategy for 2017-2020.

- 6.6.** The Director of Finance summarised the position towards the end of the financial year. At the end of December, there was a surplus of £590k. Actual income was consistently around 15% more than budgeted throughout the year, and this was not expected to change. At the end of December, we were under-spending against budget by around £40k. The Director of Finance advised members that, although it is difficult to accurately forecast income generated from treatment, this will be carefully monitored.
- 6.7.** The Director of Compliance and Information informed members that whilst the organisation performed well against most indicators, there were three which fell below target. The number of working days between an inspection and the draft report being sent to the Person Responsible (PR), and as a consequence the total number of days taken for the whole licensing process, were marginally outside of the KPI. This was due to the complexity of the report and an increased number of inspections during this period. There was also a higher rate of staff sickness absence, which was thought to be seasonal and heavily affected by the small size of the organisation.
- 6.8.** Following the discussion, members noted the latest strategic performance report.

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## 7. Strategy 2017-20

- 7.1.** The Head of Business Planning introduced the Strategy for 2017-2020 which, once approved by the Authority, will be finalised ready for the annual conference in March and subsequently published on the website in April 2017. The new strategy retains the existing vision of high quality care for everyone affected by fertility treatment but focuses on the following areas in order to meet patients' needs at various stages before, during and after treatment:
- safe, ethical, effective treatment
  - consistent support and outcomes
  - improving standards through intelligence.
- 7.2.** The Head of Business Planning set out the new strategic objectives in further detail:
1. Ensure that consistent high quality, safe, treatment is provided by all clinics.
  2. Publish clear information for patients about the efficacy and safety of treatments and treatment add-ons, while supporting innovation.
  3. Support and promote high quality embryo and data research.
  4. Use our data to improve access to donation and treatment.
  5. Increase consistency in treatment standards, outcomes, value for money and support for donors and patients.
  6. Use our data and feedback from patients to provide a sharper focus in our regulatory work and improve the information we produce.
- 7.3.** Members were advised that the new organisational structure and people strategy will ensure the skills and capacity required to deliver these strategic aims, and that a communications strategy will also be prepared to promote and influence particular issues.

- 7.4.** The Head of Business Planning summarised stakeholder feedback on an earlier draft of the strategy from the Professional Stakeholders Group, the Association of Fertility Patient Organisations and the Licensed Centres Panel, as well as a short survey of 28 patients, all of which was very positive and offered great insight.
- 7.5.** Members commended the new strategy and the aim to use regulatory powers, influence and collaborative working in combination to implement change.
- 7.6.** Members discussed the wording of the aim to promote research and encourage patients to consent to their data being used in research or to donate embryos for research purposes. The Chief Executive explained that patient information and the rate of consent, varies greatly between clinics. This strategic objective is to publish more consistent and digestible patient information across all clinics, and to raise awareness of the benefits of research with the aim to increase both the rate and quality of consents. The anticipated increase in the availability of embryos and data will facilitate high quality research with the potential to improve care and outcomes for patients.
- 7.7.** The Director of Strategy and Corporate Affairs added that more work could be done to promote participation in clinical trials that we do not license and to encourage clinics to embrace a culture of enquiry and treatment led by research. Some members suggested that the data we hold should be more easily accessible to researchers too.
- 7.8.** Some members suggested that the inspection team focus more closely on clinics' abilities to regularly monitor performance and outcomes, and to use training where appropriate to ensure their clinic is meeting the required standards.
- 7.9.** Some members were pleased that the new strategy aims to provide better patient information but wanted to explore ways in which we could use our 'soft powers' to monitor and influence the accuracy of patient information on clinics' websites.
- 7.10.** Many members supported the strategic aim to improve access to donor gametes but felt strongly that access to egg donation – as much as sperm donation - within the UK should also be a priority over the next three years.
- 7.11.** Some members were concerned about the emotional harm associated with fertility treatment and felt that our obligation to regulate safe treatment should also encompass patients' emotional wellbeing.

**Decision:** Members supported the Strategy for 2017-2020. The Director of Corporate Strategy and Affairs and the Head of Business Planning will continue to work with a sub group of members and the Chair to finalise the wording.

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## 8. Treatment add ons

- 8.1.** The Director of Strategy and Corporate Affairs introduced a paper on treatment 'add ons'. She informed members that, following a review of scientific literature, clinic websites and patient feedback, it was clear that:
- add ons are offered in around 70% of clinics, often at additional cost
  - most add ons do not have a strong evidence base to show effectiveness
  - many clinics are not making it clear to patients that the evidence of effectiveness is weak

- patients are confused about the merits of add ons and are not sure who to trust for information.

**8.2.** Members felt strongly about the issue of treatment add ons and discussed the next possible steps.

**8.3.** Members discussed the need for agreement on the way novel techniques or add ons are introduced into practice. Members noted the rigorous analysis of the safety and efficacy of mitochondrial donation techniques that was required before moving from research to treatment. It was felt that there should be more research into add ons before they can ethically be introduced and charged for.

**8.4.** Members acknowledged the limits of publishing patient information as a catalyst for change. However, they were concerned that add ons were so widely available that they were considered the norm and their efficacy remained unquestioned. Members noted the success of the One at a Time campaign, and felt that a similar approach to introduce cultural change across the sector would encourage patients to ask more questions and encourage clinics to innovate responsibly.

**Decision:** Following discussion, members noted the report and agreed to revisit treatment add ons following further work with stakeholders to develop a consensus around what responsible innovation might look like. The aim was to work with professional societies, patient groups and interested clinics to develop and commit to a consensus. Members also agreed to explore the range of regulatory powers that might be used to regulate treatment add ons, if there is not sufficient progress using softer powers.

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## 9. Code of Practice

**9.1.** The Regulatory Policy Manager gave an overview of the proposed amendments to the Code of Practice which sought to clarify guidance on the following areas:

- Mitochondrial donation; which had previously been approved in the meeting on 15 December 2016
- Legal parenthood
- Egg sharing arrangements
- Cases where consent to storage is not required
- Storage periods for eggs, sperm and embryos
- Legislation, professional guidelines and information
- Other minor amendments and corrections.

**9.2.** Members heard that, if approved, the changes will be incorporated in the April 2017 update to the Code of Practice. Members also noted the creation of a separate suite of gender neutral forms and patient information for transgender patients for 1 April 2017, and agreed to the development of guidance on this area for 1 October 2017.

**9.3.** Members who work in clinics were particularly supportive of the amendments and felt that they would be very beneficial in practice.

**9.4.** The Regulatory Policy Manager advised members that egg sharing is currently permitted in UK clinics, while egg giving is prohibited. This means that eggs collected in a cycle must be shared between the egg provider and recipient(s) unless there is a clinical and/or medical reason against doing so. The proposed amendments to the Code of Practice sought to clarify the exceptional circumstances where all of a patient's eggs can be given to the recipient - essentially, only where there would otherwise be a risk of harm to the egg provider.

**9.5.** Members felt that further clarification of the circumstances where there is a risk of harm to the egg provider was necessary in order to prevent clinics from misinterpreting the guidance.

**Decision:** Following discussion, members agreed to all other proposed amendments, which will be incorporated into the Code of Practice on 3 April 2017.

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## 10. Information for Quality: update

**10.1.** The Director of Compliance and Information reminded members that the IfQ programme was a comprehensive review of the information that we hold, the systems that govern the submission of data, the uses to which it is put and the ways in which the information is published. It includes:

- The redesign of our website and Choose a Fertility Clinic (CaFC) function
- The redesign of the 'clinic portal' used for interacting with clinics
- Combining data submission functionality
- A revised dataset and data dictionary which will be accredited
- A revised Register of treatments, which will include the migration of historical data contained within the existing Register
- The redesign of our main internal systems that comprise the Authority's Register and supporting IT processes.

**10.2.** The Director of Compliance and Information advised members that in mid December 2016 it was decided that the team should regroup and focus their efforts on the completion of the Clinic Portal which necessarily limited the progress made elsewhere. It was expected that the new Portal will launch the following day, on 19 January 2017.

**10.3.** Members noted that the launch of the treatment data submission system product for 31 March 2017 is no longer achievable and that we have sought from the Department of Health an extension to the budget of £90,000 in order to allocate additional resources to support the team and maintain pace.

**10.4.** Following a discussion, Members noted:

- The extension of £90,000 to the Programme budget, subject to Department of Health approval
- Progress since the last Authority meeting, noting the launch of the clinic portal, and plans as regards our website
- The delays to Release 2 – the new data submission system
- Steps in relation to a proposed Information Policy, for incentivising clinics to improve and maintain their performance. The policy and full suite of supporting Directions will be presented to the March 2017 Authority meeting

- Programme expenditure.

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## **11. Any other business**

- 11.1.** The Chair of the meeting confirmed that the next meeting will be held on 15 March at Church House, 27 Great Smith Street, London, SW1P 3NZ. Members were asked to confirm their attendance to the Executive Assistant to the Chair and Chief Executive as soon as possible.

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## **12. Chair's signature**

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

**Signature**

**Chair**

**Date**

# Strategic performance report

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

## Details:

Meeting	Authority
Agenda item	6
Paper number	HFEA (15/03/17) 826
Meeting date	15 March 2017
Author	Paula Robinson, Head of Business Planning

## Output:

For information or decision?	For information
Recommendation	The Authority is asked to note and comment on the latest strategic performance report.
Resource implications	In budget
Implementation date	Ongoing – strategic period 2014-2017
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 Update 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: Strategic performance report

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## 1. Introduction

- 1.1. The attached paper summarises the main performance indicators, following discussion by the Corporate Management Group (CMG) at its February performance meeting.
- 1.2. Most data relate to the position at the end of January 2017.
- 1.3. Overall performance is good, and we are making good progress towards our strategic aims. As soon as the new strategy has been launched, the existing document and indicators will be reviewed, so as to align them with the new strategy.

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## 2. Recommendation

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

### 1. Summary section

#### Dashboard – January data

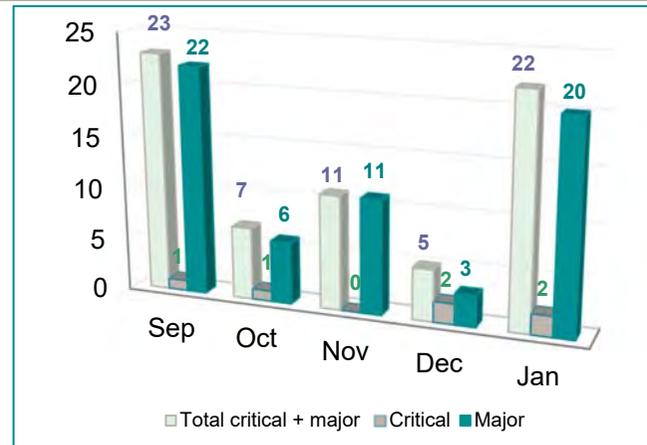
##### Strategic delivery totaliser

(see overleaf for more detail)



##### Setting standards:

critical and major recommendations on inspection

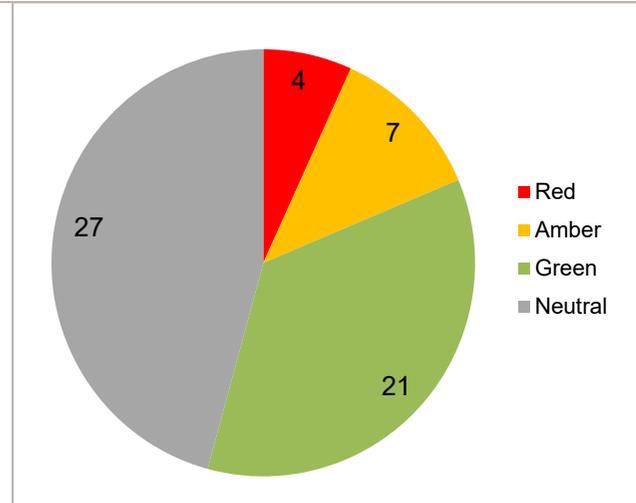


##### Increasing and informing choice:

public enquiries received (email)



##### Overall performance - all indicators:



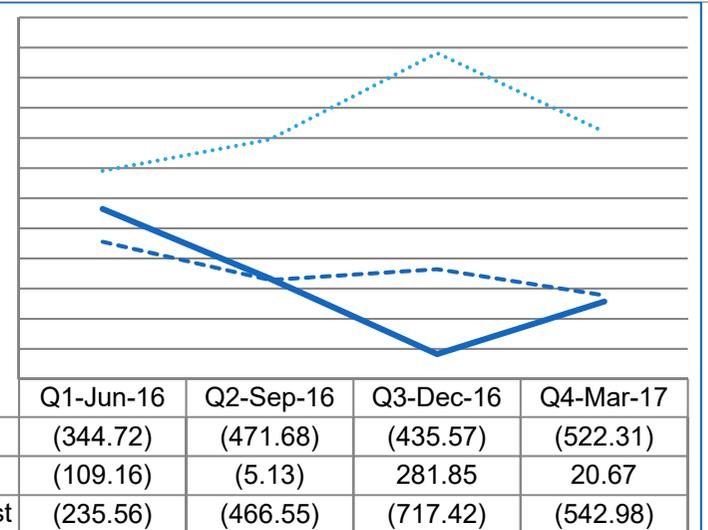
(See RAG status section for detail.)

##### Efficiency, economy and value: Budget status: cumulative surplus/(deficit)

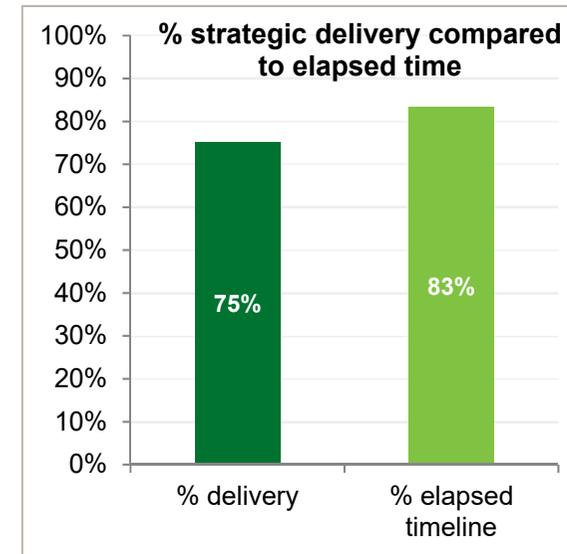
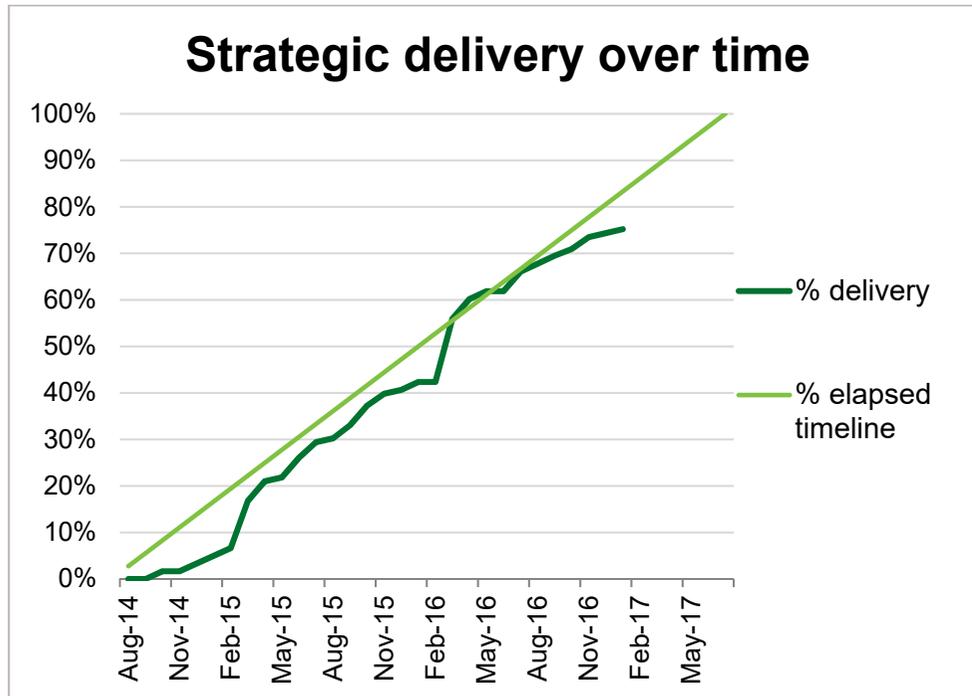
Net position over the year - how we perform against budget.

At the end of period 10 (January) we are showing a surplus of £203k, however for the month of January we were under budget by £82k. For the full year we are forecasting a surplus of £21k which is net of IfQ. With capitalisation of IfQ and the upward trend in our income, our surplus would be £80k.

Surplus / deficit £'000s



## Strategic delivery (to end of January) – summary:



The remaining items to be delivered are mainly IfQ milestones, with the exception of the project work to implement new EU Directives on the import and coding of donor eggs and sperm, which have been delayed by the Brexit vote and subsequent Department of Health consultation. Some of the IfQ milestones have been delayed by earlier issues such as limited supplier resources and diversions from business as usual. At present there are a total of 29 milestones still to be delivered by the end of July (the end date for our outgoing strategy). Of these, ten items are not yet due for delivery, and 19 are overdue items. Many of these are interdependent in that one follows from another. For example, until the CaFC delivery milestone is reached, we cannot complete the related milestone of our first 6 monthly update of the new CaFC; we can't go live with the website until we have passed the GDS live gateway assessment; and so on.

## **Strategic delivery in December and January:**

### **Setting standards**

Project work on the new EU requirements relating to the import and coding of donor eggs and sperm remains on hold pending further Department of Health advice in the wake of the Brexit vote. A consultation is expected to be released shortly. Meanwhile, detailed planning to enable us to manage the timeline for implementation has taken place.

### **Increasing and informing choice**

In this area there are six overdue milestones, all relating to IfQ work on the website and CaFC. Therefore all our efforts have been focused on preparing the website for a GDS service assessment in March, which will unlock the overdue milestones.

### **Efficiency, economy and value**

The new clinic portal went live in January.

Meanwhile, data cleansing has continued, but there has been some diversion of effort in order to assist clinics with the current data verification exercise, which is an essential part of the groundwork for achieving improved data quality.

In addition, work is in progress on our new organisational structure, with a staff consultation in February. The new structure has been designed to enable us to maximise the benefits of IfQ.

## Red/amber/green status of performance indicators – January 2017

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

Average number of working days from day of inspection to the day the draft report is sent to the PR

- In January, there were two reports due, and both were slightly delayed owing to the inspector's heavy workload that month. We achieved an average of 27 working days, compared to our target of 20 working days.

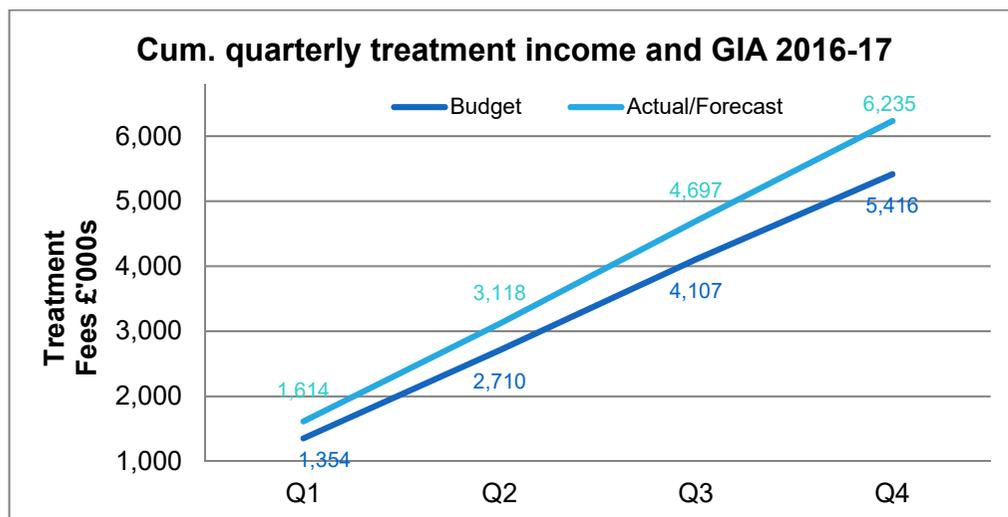
Average number of working days between minutes being finalised and decision communicated to clinic (minutes forwarded and licence issued or letter sent explaining refusal of licence).

- Seven of the 14 items minuted were circulated within three days, compared to our target of two days, due to a member of staff being still in training. This outcome is also reflected in another indicator which records performance on a sub-set of the items minuted, and so that indicator was in the red for the same reason.

The Information for Quality programme is also currently rated red, owing to resourcing issues, delays in finalising contract negotiations, and other delays in completing the website and CaFC. The Authority has a separate item on IfQ on the agenda for the March meeting.

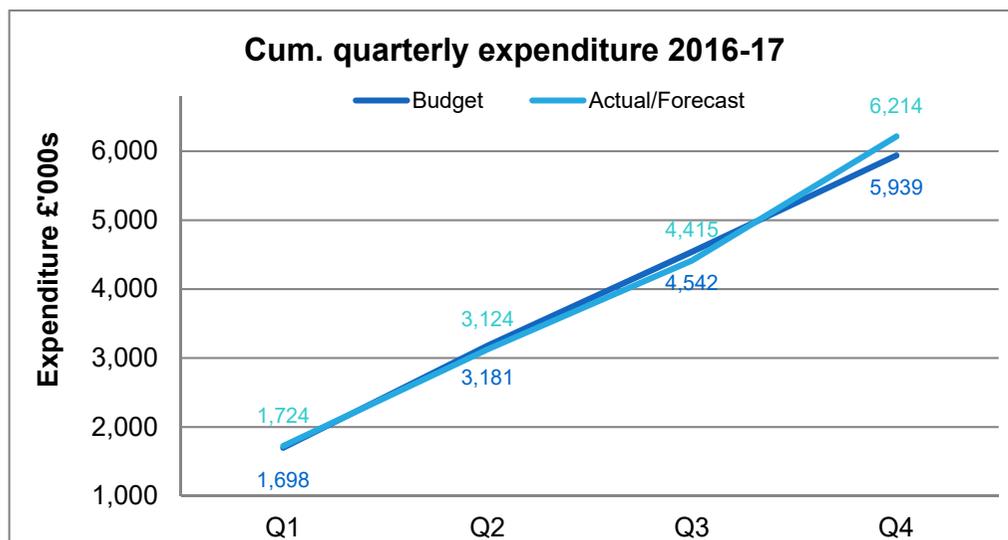
## Budget status – January data

The dashboard shows the overall surplus/deficit position. The graphs below show how the surplus or deficit has arisen. These figures are updated quarterly, approximately one month after the end of each quarter.



This graph shows our budgeted (planned) income including grant-in-aid (GIA) compared to actuals and our best forecast for the remaining two months.

As of month 10 (January 2017) we have exceeded our total budgeted treatment fee income by £636k.



This graph is the second component that makes up the surplus/deficit. This includes costs relating to IfQ, although they are being funded from reserves and will be transferred to the balance sheet at year end.

The year-to-date position shows we are under budget by £123k (2.5%). This includes costs for IfQ and accruals for legal spend.

Our year end forecast position prior to removing IfQ costs is an overspend against budget of £376k. This is due to our legal budget being different from our actual spend by £261k.

## Quality and safety of care

As agreed previously, the following items are most meaningful when reported on an annual basis and are presented to the Authority each year in October:

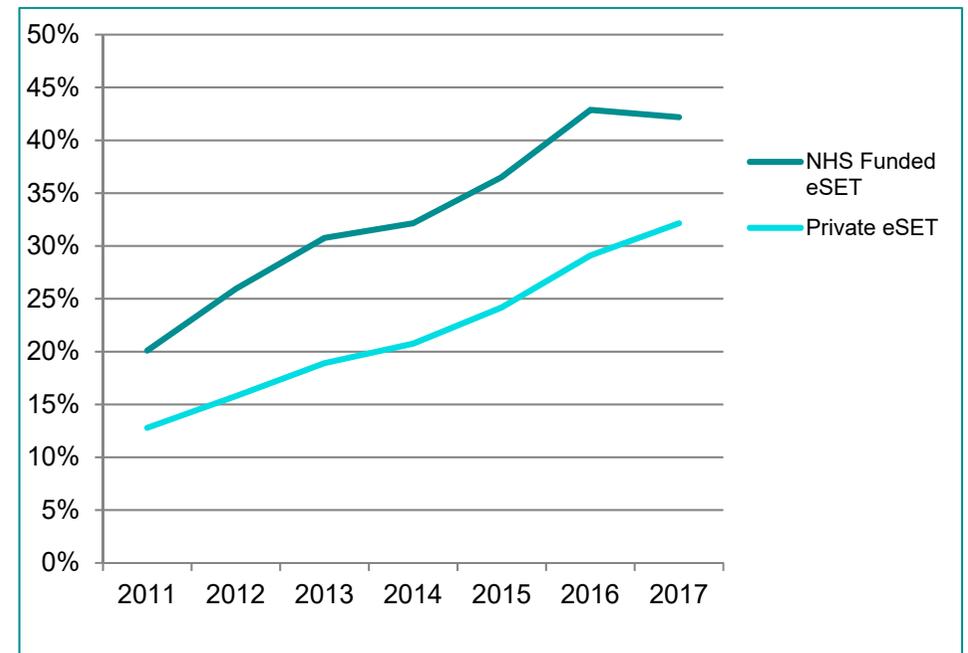
- number of risk tool alerts (and themes)
- common non-compliances (by type)
- incidents report (and themes).

The following figures and graphs were run on 22 February 2017.

### ESET split by private/NHS:

Funding	Year						
	2011	2012	2013	2014	2015	2016	2017
<b>NHS Funded:</b>							
Recorded as eSET	4903	6263	7871	8443	9749	11739	1443
	8%	10%	13%	13%	15%	17%	18%
Not recorded as eSET	19490	17869	17719	17823	16941	15636	1977
	32%	30%	29%	28%	26%	23%	25%
Relative eSET %	20%	26%	31%	32%	37%	43%	42%
<b>Private:</b>							
Recorded as eSET	4626	5698	6857	7734	9354	11626	1442
	8%	9%	11%	12%	14%	17%	18%
Not recorded as eSET	31550	30400	29392	29528	29339	28316	3044
	52%	50%	48%	46%	45%	42%	39%
Relative eSET %	13%	16%	19%	21%	24%	29%	32%

**Graph: eSet % trends NHS/private:**



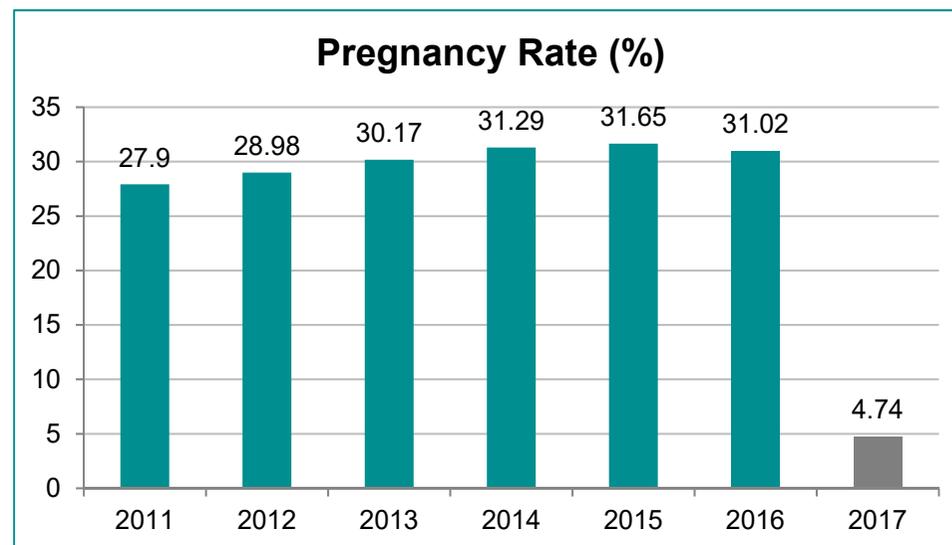
**Explanatory text:** Showing the total of all reported IVF treatment forms and counting those that the clinics recorded as eSET.

The graph above displays the relative percentages of eSET for NHS and privately funded cycles, rather than the percentage of all treatments. This relative approach gives a clearer picture, given that the number of overall cycles completed in the private sector is significantly higher than the number of NHS cycles. We have retained the raw figures in the table, however, so that the raw 'all treatment' numbers can still be seen as well.

Unfiltered success rates as % - pregnancies (rather than outcomes, since this provides a better real-time picture):

Years	All cycles	Pregnancies	Pregnancy rate %
2011	60570	16897	27.9
2012	60230	17455	28.98
2013	61839	18654	30.17
2014	63528	19878	31.29
2015	65383	20694	31.65
2016	67318	20884	31.02
2017	7906	375	4.74

Graph showing the pregnancy rate over recent years:



**Explanatory text:** Looking at all IVF treatment forms, and providing a count of pregnancies - as recorded on the early outcome form.

2017 figures are in grey since there is always a lag in reporting pregnancies, which means that the figure will not be meaningful until much later in the year. These figures were produced at only seven weeks into the new calendar year.

## 2. Indicator section

### Key performance and volume indicators – January data:

Indicator	Performance	RAG	Recent trend <sup>1</sup>	Aim <sup>2</sup>	Notes																		
<b>Setting standards: improving the quality and safety of care through our regulatory activities.</b>																							
<b>Licensing decisions made:</b> - By ELP - By Licence Committee	8 0	↑	<table border="1"> <caption>Licensing Decisions</caption> <thead> <tr> <th>Month</th> <th>ELP</th> <th>Licence Committee</th> </tr> </thead> <tbody> <tr> <td>Sep</td> <td>16</td> <td>3</td> </tr> <tr> <td>Oct</td> <td>7</td> <td>0</td> </tr> <tr> <td>Nov</td> <td>7</td> <td>0</td> </tr> <tr> <td>Dec</td> <td>8</td> <td>0</td> </tr> <tr> <td>Jan</td> <td>8</td> <td>0</td> </tr> </tbody> </table>	Month	ELP	Licence Committee	Sep	16	3	Oct	7	0	Nov	7	0	Dec	8	0	Jan	8	0	No KPI – tracked for workload monitoring purposes	Volume indicator (no KPI target).
Month	ELP	Licence Committee																					
Sep	16	3																					
Oct	7	0																					
Nov	7	0																					
Dec	8	0																					
Jan	8	0																					
<b>Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.</b>																							
<b>Percentage of Opening the Register requests responded to within 20 working days</b>	100% (14)	★	<table border="1"> <caption>OTR Requests Performance</caption> <thead> <tr> <th>Month</th> <th>Number of requests</th> <th>% OTR requests within 20 days (KPI = 100%)</th> </tr> </thead> <tbody> <tr> <td>Sep</td> <td>23</td> <td>100%</td> </tr> <tr> <td>Oct</td> <td>21</td> <td>100%</td> </tr> <tr> <td>Nov</td> <td>22</td> <td>100%</td> </tr> <tr> <td>Dec</td> <td>25</td> <td>100%</td> </tr> <tr> <td>Jan</td> <td>14</td> <td>100%</td> </tr> </tbody> </table>	Month	Number of requests	% OTR requests within 20 days (KPI = 100%)	Sep	23	100%	Oct	21	100%	Nov	22	100%	Dec	25	100%	Jan	14	100%	Maintain at 100%	KPI: 100% of complete OTR requests to be responded to within 20 working days (excluding counselling time)
Month	Number of requests	% OTR requests within 20 days (KPI = 100%)																					
Sep	23	100%																					
Oct	21	100%																					
Nov	22	100%																					
Dec	25	100%																					
Jan	14	100%																					

<sup>1</sup> Blue dashed line in graphs = KPI target level. This line may be invisible when performance and target are identical (eg, 100%).

<sup>2</sup> Direction in which we are trying to drive performance. (Are we aiming to exceed, equal, or stay beneath this particular KPI target?)

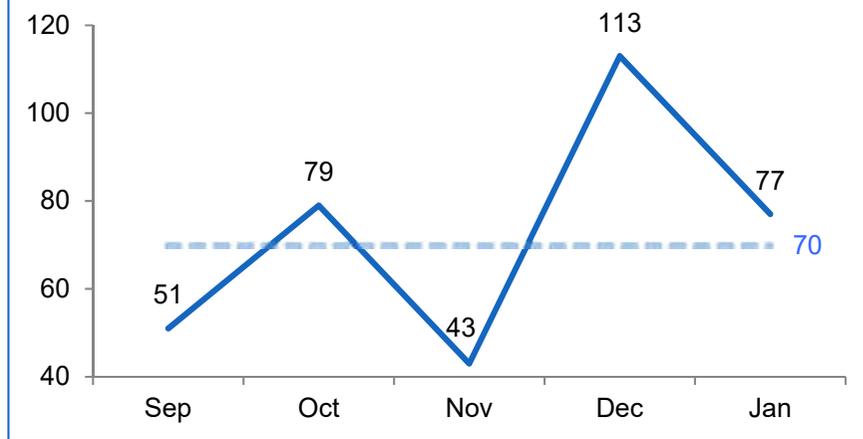
Indicator	Performance	RAG	Recent trend <sup>1</sup>	Aim <sup>2</sup>	Notes
Increasing and informing choice: using the data in the Register of Treatments to improve outcomes and research.					

See graphs relating to quality and safety of care – previous section.

**Increasing and informing choice: ensuring that patients have access to high quality meaningful information.**

<p><b>Number of visits to the HFEA website (compared with previous year)</b> (trend arrow indicates movement since previous month)</p> <p>110,065 (122,644)</p>		 <table border="1"> <caption>Number of visits to the HFEA website</caption> <thead> <tr> <th>Month</th> <th>This year</th> <th>Last year</th> </tr> </thead> <tbody> <tr> <td>Sep</td> <td>110512</td> <td>124171</td> </tr> <tr> <td>Oct</td> <td>107709</td> <td>125613</td> </tr> <tr> <td>Nov</td> <td>118336</td> <td>120456</td> </tr> <tr> <td>Dec</td> <td>91008</td> <td>97490</td> </tr> <tr> <td>Jan</td> <td>110065</td> <td>122644</td> </tr> </tbody> </table>	Month	This year	Last year	Sep	110512	124171	Oct	107709	125613	Nov	118336	120456	Dec	91008	97490	Jan	110065	122644	<p>No KPI – tracked for general monitoring purposes.</p> <p>Volume indicator showing general website traffic compared to the same period in previous year. Measured on the basis of ‘unique visitors’.</p>
Month	This year	Last year																			
Sep	110512	124171																			
Oct	107709	125613																			
Nov	118336	120456																			
Dec	91008	97490																			
Jan	110065	122644																			

**Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.**

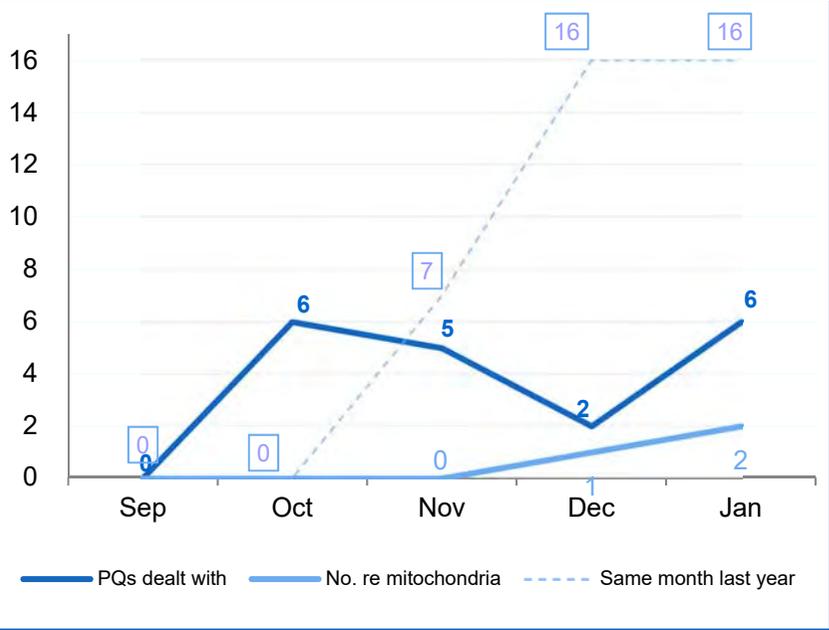
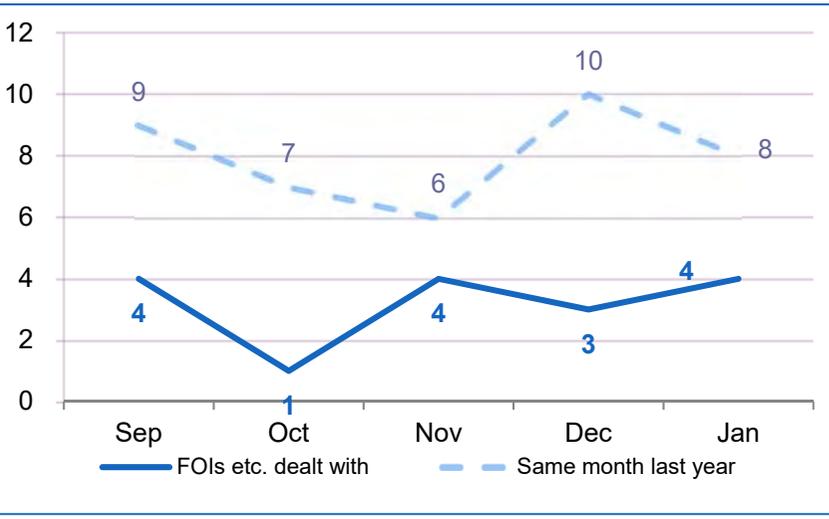
<p><b>Average number of working days taken for the whole licensing process, from the day of inspection to the decision being communicated to the centre.</b></p> <p>77 working days</p>		 <table border="1"> <caption>Average number of working days for licensing process</caption> <thead> <tr> <th>Month</th> <th>Working days</th> </tr> </thead> <tbody> <tr> <td>Sep</td> <td>51</td> </tr> <tr> <td>Oct</td> <td>79</td> </tr> <tr> <td>Nov</td> <td>43</td> </tr> <tr> <td>Dec</td> <td>113</td> </tr> <tr> <td>Jan</td> <td>77</td> </tr> </tbody> </table> <p>Target: 70 working days</p>	Month	Working days	Sep	51	Oct	79	Nov	43	Dec	113	Jan	77	<p>KPI: Less than or equal to 70 working days.</p> <p>Return to 70wd or less</p>
Month	Working days														
Sep	51														
Oct	79														
Nov	43														
Dec	113														
Jan	77														

**Commentary:** In December, one report was inadvertently not scheduled for a committee in a timely way, due to a combination of issues. The centre’s licence was never at risk of lapsing. Since that time, there has been an improvement in the overall performance on this indicator.

Indicator	Performance	RAG	Recent trend <sup>1</sup>	Aim <sup>2</sup>	Notes
Monthly percentage of PGD applications processed within three months (66 working days).	100%	★		Maintain 100%	KPI: 100% processed (i.e. considered by SAC) within three months (66 working days) of receipt of completed application.
Average number of working days taken.	52	★			

**Commentary:** In December, two applications were processed in 68wd and 69wd respectively, which is only slightly longer than the target. Both were complex applications involving multi-type conditions and requiring specialist peer review.

Annualised (rolling year) percentage of PGD applications processed within three months (66 working days)	90%	↓		Maintain 100%	KPI: As above. (Annualised score). Dips in the monthly performance will have an impact on the annualised figure.
Average number of working days taken.	54	★			

Indicator	Performance	RAG	Recent trend <sup>1</sup>	Aim <sup>2</sup>	Notes																								
<b>Number of requests for contributions to Parliamentary questions</b>	Total = 6		 <table border="1" data-bbox="801 132 1630 762"> <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>Sep</td> <td>0</td> <td>0</td> <td>0</td> </tr> <tr> <td>Oct</td> <td>6</td> <td>0</td> <td>0</td> </tr> <tr> <td>Nov</td> <td>5</td> <td>0</td> <td>7</td> </tr> <tr> <td>Dec</td> <td>2</td> <td>1</td> <td>16</td> </tr> <tr> <td>Jan</td> <td>6</td> <td>2</td> <td>16</td> </tr> </tbody> </table>	Month	PQs dealt with	No. re mitochondria	Same month last year	Sep	0	0	0	Oct	6	0	0	Nov	5	0	7	Dec	2	1	16	Jan	6	2	16	No KPI – tracked for general monitoring purposes.	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																										
Sep	0	0	0																										
Oct	6	0	0																										
Nov	5	0	7																										
Dec	2	1	16																										
Jan	6	2	16																										
<b>Number of Freedom of Information (FOI), Environmental Information Regulations (EIR) requests and Data Protection Act (DPA) requests</b>	4		 <table border="1" data-bbox="801 770 1630 1289"> <caption>Number of Freedom of Information (FOI), Environmental Information Regulations (EIR) requests and Data Protection Act (DPA) requests</caption> <thead> <tr> <th>Month</th> <th>FOIs etc. dealt with</th> <th>Same month last year</th> </tr> </thead> <tbody> <tr> <td>Sep</td> <td>4</td> <td>9</td> </tr> <tr> <td>Oct</td> <td>1</td> <td>7</td> </tr> <tr> <td>Nov</td> <td>4</td> <td>6</td> </tr> <tr> <td>Dec</td> <td>3</td> <td>10</td> </tr> <tr> <td>Jan</td> <td>4</td> <td>8</td> </tr> </tbody> </table>	Month	FOIs etc. dealt with	Same month last year	Sep	4	9	Oct	1	7	Nov	4	6	Dec	3	10	Jan	4	8	No KPI – tracked for general monitoring purposes.	Volume indicator. There does not appear to be any trend or predictability in the volume or focus of our FOI (and other) requests.						
Month	FOIs etc. dealt with	Same month last year																											
Sep	4	9																											
Oct	1	7																											
Nov	4	6																											
Dec	3	10																											
Jan	4	8																											

Indicator	Performance	RAG	Recent trend <sup>1</sup>	Aim <sup>2</sup>	Notes												
Staff sickness absence rate (%) per month.	1.4%	★	<table border="1"> <caption>Staff Sickness Absence Rate (%)</caption> <thead> <tr> <th>Month</th> <th>Rate (%)</th> </tr> </thead> <tbody> <tr> <td>Sep</td> <td>0.3%</td> </tr> <tr> <td>Oct</td> <td>3.5%</td> </tr> <tr> <td>Nov</td> <td>2.3%</td> </tr> <tr> <td>Dec</td> <td>1.0%</td> </tr> <tr> <td>Jan</td> <td>1.4%</td> </tr> </tbody> </table>	Month	Rate (%)	Sep	0.3%	Oct	3.5%	Nov	2.3%	Dec	1.0%	Jan	1.4%	 Maintain 2.5% or less	KPI: Absence rate of ≤ 2.5%. Public sector sickness absence rate average is eight days lost per person per year (3.0%).
Month	Rate (%)																
Sep	0.3%																
Oct	3.5%																
Nov	2.3%																
Dec	1.0%																
Jan	1.4%																
Cash and bank balance	£2,357k	↓	<table border="1"> <caption>Cash and Bank Balance (£k)</caption> <thead> <tr> <th>Month</th> <th>Balance (£k)</th> </tr> </thead> <tbody> <tr> <td>Sep</td> <td>£2,363</td> </tr> <tr> <td>Oct</td> <td>£2,243</td> </tr> <tr> <td>Nov</td> <td>£2,205</td> </tr> <tr> <td>Dec</td> <td>£2,578</td> </tr> <tr> <td>Jan</td> <td>£2,357</td> </tr> </tbody> </table>	Month	Balance (£k)	Sep	£2,363	Oct	£2,243	Nov	£2,205	Dec	£2,578	Jan	£2,357	 Reduce	KPI: To move closer to minimum £1,520k cash reserves (figure agreed with DH).
Month	Balance (£k)																
Sep	£2,363																
Oct	£2,243																
Nov	£2,205																
Dec	£2,578																
Jan	£2,357																

**Management  
accounts**

**Income & Expenditure Account**

**Jan-2017**

Accounting Period  
Cost Centre Name  
Department Name

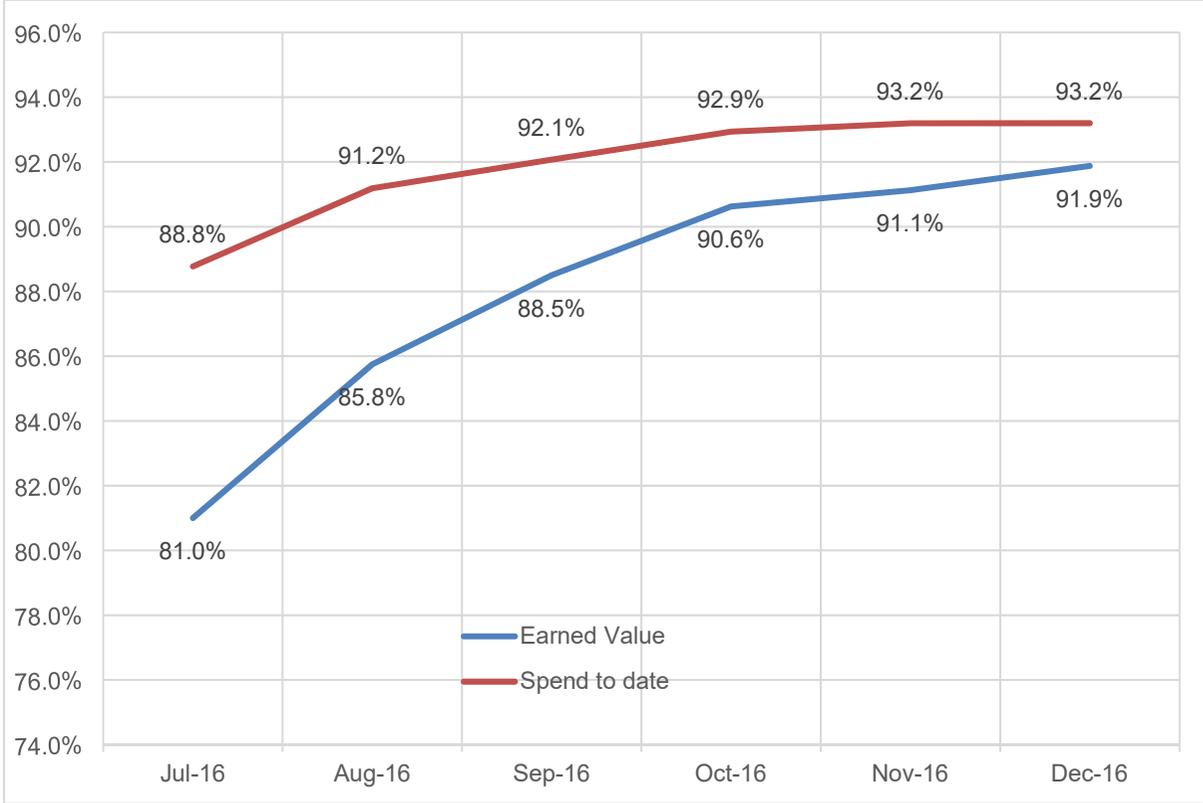
[Period 10 16-17](#)  
[All Cost Centres](#)  
[All Departments](#)

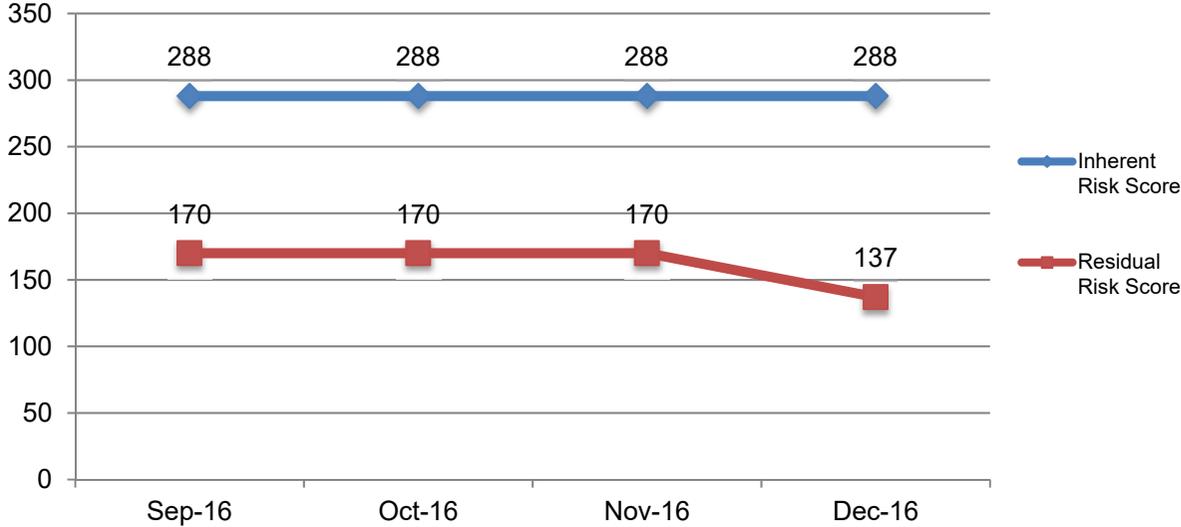
	Year to Date				Full Year		
	Actual YTD	Budget YTD	Variance YTD	% Variance YTD	Forecast	Budget	Variance
	£	£	£	%	£	£	£
Grant-in-aid	703	704	1	0	933	938	(5)
Licence Fees	4,304	3,668	(636)	(17)	5,298	4,472	826
Other Income	3	5	2	35	4	6	(2)
<b>Total Income</b>	<b>5,010</b>	<b>4,376</b>	<b>(634)</b>	<b>(14)</b>	<b>6,235</b>	<b>5,416</b>	<b>819</b>
<b>Revenue Costs - Charged to Expenditure</b>							
Salaries (excluding Authority)	2,153	2,232	79	(4)	2,580	2,679	(99)
Shared Services	54	69	15	(22)	60	81	(21)
Employer's NI Contributions	220	206	(13)	7	246	247	(2)
Employer's Pension Contribution	465	477	12	(3)	551	573	(22)
Authority salaries inc. NI Contributions	121	121	0	(0)	145	146	(1)
Temporary Staff costs	100	-	(100)		138	-	138
Other Staff Costs	191	223	31	(14)	249	265	(15)
Other Authority/Committee costs	101	130	29	(22)	148	156	(8)
Other Compliance Costs	15	24	10	(40)	16	28	(12)
Other Strategy Costs	44	86	42	(49)	109	142	(33)
Facilities Costs incl non-cash	373	415	42	(10)	475	488	(22)
IT costs Costs	88	77	(11)	14	110	93	17
Legal Costs	386	339	(48)	14	661	400	261
Professional Fees	58	56	(2)	4	69	67	2
<b>Total Revenue Costs</b>	<b>4,368</b>	<b>4,455</b>	<b>87</b>	<b>(2)</b>	<b>5,555</b>	<b>5,361</b>	<b>183</b>
<i>Total Surplus/(Deficit) before Capital &amp; Project costs</i>	<i>642</i>	<i>(79)</i>	<i>(720)</i>	<i>(915)</i>	<i>680</i>	<i>55</i>	<i>636</i>
IFQ & Other Project Costs - Reserves funded	439	475	36	(8)	659	477	182
<b>TOTAL NET ACTIVITY</b>	<b>203</b>	<b>(554)</b>	<b>(757)</b>		<b>21</b>	<b>(422)</b>	<b>454</b>
<i>Other Capital Costs</i>	<i>49</i>	<i>75</i>	<i>26</i>	<i>(35)</i>	<i>100</i>	<i>100</i>	<i>-</i>

Indicator	Performance	RAG	Recent trend <sup>1</sup>	Aim <sup>2</sup>	Notes
<b>Commentary:</b>	<b>Summarised management accounts – commentary for January 2017</b>				
	<b>Income</b>				
	As at the end of period 10 (January) we are exceeding our total income budget by £634k (14%). By the end of January, our treatment fee income for the year has increased by a total of £636k (17.3%). Subject to any corrections from clinics in the last two months of this financial year, we will finish this year around £800k over budget.				
	<b>Expenditure</b>				
	Reporting by exception:				
	There is an over-spend within staff costs for the year-to-date of 0.2% (slightly less than reported in Q3). This small amount relates to contingent labour costs (temporary staff) incurred to back-fill key staff working on the IfQ programme. The forecast year end position is expected to be 0.2% below budget. This is based on information received at our Q3 finance meetings. This position may change. Our legal spend is the area that remains a point of focus. For the year-to-date we are overspending on the legal budget by £48k (14%). Our forecast outturn in legal spend is £261k above budget. Legal costs are always difficult to predict and budget for. There are no other areas of significant over or underspends.				
	<b>IfQ and other project costs</b>				
	For the year-to-date, IfQ is showing an underspend against budget of 7% (£34k) and is forecast to overspend by 39% (£182k). This takes into account extra budget agreed by SMT. This overspend will reduce by £90k at the end of March, because the additional budget was subsequently declined by DH. The year-to-date position looks different to that being forecast due to the timing of invoices, which will come at the end of the programme. The increase in spend by year end is due to delays and the requirement to complete the programme by Q1 of 2017/18. A thorough review of required resource is being undertaken.				

## IfQ indicators: January update for beta project phase

Frequency / trigger point	Metric	Purpose	Latest status:																				
At programme set-up / major reorganisation / new tranche	MSP health check overall score achieved / maximum score as a %	Is the programme set up to deliver?	<p><b>December to January update:</b>                      A security audit for the IS project has been completed, and the outcomes confirmed the previous report done during penetration testing. Our security systems are sound. The recommendations from the audit will be addressed by the team and incorporated into release two (R2) or business as usual (BAU) work. Overall the programme has been delayed due to several factor including a complex contractual relationship over resources with Reading Room (RR), lack of internal resources owing to frequent diversions to manage BAU, and priorities at key milestone points, like the portal going live and the CaFC verification exercise. These challenges continue to delay R2, impacting the programme as a whole. The organisational restructuring is a further risk factor for IfQ, and could potentially impact performance and/or capacity over the next few months.</p>																				
Monthly	Timescales: we changed the burndown chart showing remaining estimate of work to a chart showing percentage of works complete.	Is there scope creep/over-run?	<p><b>December to January update:</b>                      The clinic portal has now gone live, although remaining bugs will have to be addressed by RR and the IS project team, as they come to light. The full implementation of portal support into BAU is also to be done. The website work was being seriously delayed due to the lack of RR resources, extended negotiations relating to contract completion, and support for the portal going live. The GDS live assessment will take place on 8 March and RR have now allocated resources accordingly.</p> <div style="display: flex; justify-content: space-around;"> <div data-bbox="779 901 1339 1404"> <table border="1"> <caption>Percent complete - clinic portal R1 to January 2017</caption> <thead> <tr> <th>Total Beta Sprint</th> <th>Percent Complete</th> </tr> </thead> <tbody> <tr> <td>Total Beta Sprint 19</td> <td>92.5%</td> </tr> <tr> <td>Total Beta Sprint 21</td> <td>93.5%</td> </tr> <tr> <td>Total Beta Sprint 23</td> <td>94%</td> </tr> <tr> <td>Total Beta Sprint 27</td> <td>96%</td> </tr> </tbody> </table> </div> <div data-bbox="1348 901 1937 1404"> <table border="1"> <caption>Percent complete - website R1 to January 2017</caption> <thead> <tr> <th>Total Beta Sprint</th> <th>Percent Complete</th> </tr> </thead> <tbody> <tr> <td>Total Beta Sprint 19</td> <td>70%</td> </tr> <tr> <td>Total Beta Sprint 21</td> <td>80%</td> </tr> <tr> <td>Total Beta Sprint 23</td> <td>80%</td> </tr> <tr> <td>Total Beta Sprint 27</td> <td>85%</td> </tr> </tbody> </table> </div> </div>	Total Beta Sprint	Percent Complete	Total Beta Sprint 19	92.5%	Total Beta Sprint 21	93.5%	Total Beta Sprint 23	94%	Total Beta Sprint 27	96%	Total Beta Sprint	Percent Complete	Total Beta Sprint 19	70%	Total Beta Sprint 21	80%	Total Beta Sprint 23	80%	Total Beta Sprint 27	85%
Total Beta Sprint	Percent Complete																						
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Total Beta Sprint 27	85%																						

Frequency / trigger point	Metric	Purpose	Latest status:																					
Monthly	Cost: earned value (% complete * estimated spend at completion)	Is the spend in line with milestone delivery?	<p>There are four things we can attribute value to: websites and CaFC; Clinic Portal; the Register and internal systems; defined dataset, discovery, stakeholder engagement etc. 25% of the value of the 1.8m programme cost at completion has been attributed to each project.</p>  <table border="1" data-bbox="763 368 1966 1171"> <caption>Chart Data: Earned Value vs Spend to date</caption> <thead> <tr> <th>Month</th> <th>Earned Value (%)</th> <th>Spend to date (%)</th> </tr> </thead> <tbody> <tr> <td>Jul-16</td> <td>81.0%</td> <td>88.8%</td> </tr> <tr> <td>Aug-16</td> <td>85.8%</td> <td>91.2%</td> </tr> <tr> <td>Sep-16</td> <td>88.5%</td> <td>92.1%</td> </tr> <tr> <td>Oct-16</td> <td>90.6%</td> <td>92.9%</td> </tr> <tr> <td>Nov-16</td> <td>91.1%</td> <td>93.2%</td> </tr> <tr> <td>Dec-16</td> <td>91.9%</td> <td>93.2%</td> </tr> </tbody> </table> <p>Note: this metric will be discontinued once the beta phase is finished and billed.</p> <p><b>December to January update:</b> The spend to date has risen slightly compared to last month and is now again joining the earned value. As we reach the end of beta (and thus most of the expenditure on the contract) and complete the live phase we expect the earned value to reach its peak reflecting the beta work being finished.</p>	Month	Earned Value (%)	Spend to date (%)	Jul-16	81.0%	88.8%	Aug-16	85.8%	91.2%	Sep-16	88.5%	92.1%	Oct-16	90.6%	92.9%	Nov-16	91.1%	93.2%	Dec-16	91.9%	93.2%
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Frequency / trigger point	Metric	Purpose	Latest status:															
Monthly	Stakeholder engagement: combined score (internal plus external events or communications)	Are we keeping stakeholders with us? Is it getting better or worse?	<p><b>December to January update:</b> The focus of the IfQ communications work over the last 2 months has been around the clinic portal. Actions have included emails to PRs and Clinic Focus articles related to the launch of the new portal.</p> <p>Engagement score = 4</p>															
Monthly	Risks: sum of risk scores (L x I)	Is overall risk getting worse or better (could identify death by a thousand cuts)?	<p><b>December to January update:</b> The line graph below represents the overall IfQ risk score, which combines the perceived impact and likelihood of the current risks on hand each month. The overall risk score for the IfQ Programme decreased slightly in December 2016 following a review of the risk register, in which the mitigation actions for a small number of the risks were updated. The risk register will continue to be monitored and reviewed throughout the next few months.</p>  <table border="1"> <caption>Risk Score Data</caption> <thead> <tr> <th>Month</th> <th>Inherent Risk Score</th> <th>Residual Risk Score</th> </tr> </thead> <tbody> <tr> <td>Sep-16</td> <td>288</td> <td>170</td> </tr> <tr> <td>Oct-16</td> <td>288</td> <td>170</td> </tr> <tr> <td>Nov-16</td> <td>288</td> <td>170</td> </tr> <tr> <td>Dec-16</td> <td>288</td> <td>137</td> </tr> </tbody> </table>	Month	Inherent Risk Score	Residual Risk Score	Sep-16	288	170	Oct-16	288	170	Nov-16	288	170	Dec-16	288	137
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			<p>The major risks are associated with resources, timescales, regulatory monitoring, quality, financial, development, patient information, data security and business continuity.</p> <p>In addition, a risk relating to organisational change has been added to the strategic risk register, and this could entail delivery risks for IfQ. This is also being managed closely.</p> <table border="1"> <caption>Risk Level Data from Chart</caption> <thead> <tr> <th>Category</th> <th>1-Insignificant</th> <th>2-Minor</th> <th>3-Moderate</th> <th>4-Major</th> <th>5-Critical</th> </tr> </thead> <tbody> <tr><td>Timescales</td><td>0</td><td>0</td><td>4</td><td>2</td><td>0</td></tr> <tr><td>Stakeholder Engagement</td><td>1</td><td>0</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>Service transition</td><td>0</td><td>1</td><td>1</td><td>0</td><td>0</td></tr> <tr><td>Resources</td><td>0</td><td>0</td><td>5</td><td>5</td><td>1</td></tr> <tr><td>Reputation</td><td>0</td><td>0</td><td>2</td><td>0</td><td>0</td></tr> <tr><td>Regulatory monitoring</td><td>0</td><td>0</td><td>0</td><td>1</td><td>0</td></tr> <tr><td>Quality</td><td>1</td><td>0</td><td>5</td><td>6</td><td>0</td></tr> <tr><td>Patient information</td><td>0</td><td>0</td><td>0</td><td>1</td><td>0</td></tr> <tr><td>Operational</td><td>0</td><td>0</td><td>1</td><td>2</td><td>0</td></tr> <tr><td>Financial</td><td>0</td><td>0</td><td>1</td><td>1</td><td>0</td></tr> <tr><td>Development</td><td>0</td><td>0</td><td>1</td><td>2</td><td>0</td></tr> <tr><td>Design</td><td>1</td><td>0</td><td>1</td><td>0</td><td>0</td></tr> <tr><td>Data security</td><td>0</td><td>0</td><td>0</td><td>1</td><td>0</td></tr> <tr><td>Clinic Costs</td><td>0</td><td>1</td><td>0</td><td>0</td><td>0</td></tr> <tr><td>Business Continuity</td><td>0</td><td>0</td><td>0</td><td>1</td><td>0</td></tr> </tbody> </table>	Category	1-Insignificant	2-Minor	3-Moderate	4-Major	5-Critical	Timescales	0	0	4	2	0	Stakeholder Engagement	1	0	0	0	0	Service transition	0	1	1	0	0	Resources	0	0	5	5	1	Reputation	0	0	2	0	0	Regulatory monitoring	0	0	0	1	0	Quality	1	0	5	6	0	Patient information	0	0	0	1	0	Operational	0	0	1	2	0	Financial	0	0	1	1	0	Development	0	0	1	2	0	Design	1	0	1	0	0	Data security	0	0	0	1	0	Clinic Costs	0	1	0	0	0	Business Continuity	0	0	0	1	0
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Quarterly	Benefits: value (£) of tangible benefits planned to be delivered by the programme	Is the value of the benefits increasing or decreasing (could trigger a review of the business case.)	<p><b>December to January update:</b></p> <p>The benefits realisation value should be reviewed based on the business case. No issues have been raised regarding benefits realisation to date.</p> <p>A full benefits realisation review will be conducted once the programme has been completed.</p>																																																																																																

# Information for Quality programme: update

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

## Details:

Meeting      Authority

Agenda item      7

Paper number      HFEA (15/03/17) 827

Meeting date      15 March 2017

Author      Nick Jones, Director of Compliance and Information

## Output:

For information or decision?      For information

Recommendation      The Authority is asked to:

- Note the Clinic Portal is now in live
- Note the intention to launch the HFEA website and choose a fertility clinic as live, in April 2017
- Note the intention to 'close' the programme at the end of March 2017
- Note the arrangements for securing completion of the programme components in 2017/18

Resource implications      The Programme budget has now been committed.

Implementation date      During 2016–17 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 (IfQ) programme encompasses:
- The redesign of our website and Choose a Fertility Clinic (CaFC) function
  - The redesign of the 'Clinic Portal' (used for interacting with clinics) and combining it with data submission functionality (Release 2) that is currently provided in our separate system (used by clinics to submit treatment data to us)
  - A revised dataset and data dictionary which will be submitted for approval by the Standardisation Committee for Care Information (SCCI)
  - A revised Register of treatments, which will include the migration of historical data contained within the existing Register
  - The redesign of our main internal systems that comprise the Authority's Register and supporting IT processes.
- 1.2.** Given the importance of IfQ to our strategy, we update the Authority on progress at each meeting and seek approval for direction and actions.
- 1.3.** This paper updates Members on:
- The programme
  - Work in progress
  - Completing the programme
  - Programme budget

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## 2. The IfQ programme

- 2.1.** The IfQ programme is scheduled to conclude in March this year. This paper brings members up to date with progress and sets out the path to conclusion.
- 2.2.** The programme is progressing according to 'agile' principles required by the Government Digital Service (GDS).
- 2.3.** Our attention is now focussed on completing the work necessary to move the HFEA website from Beta to live and producing a Beta version of the treatment submission system (Clinic Portal R2) – see below.
- 2.4.** The Clinic Portal was launched on 19 January 2017, the day following the last Authority meeting. That launch went reasonably well, albeit with some clinics getting in touch about getting access to the portal – given the enhanced security requirements. Most queries were dealt with quickly and effectively but there were frustrations felt by a few clinics. The queries were mostly categorised as 'user error' a frequently misused term: any new system will take some getting used to. Attention now is turning to the transition of the portal to business as usual status and, of course, maximising the potential of the portal as a communication channel and to drive improvements and efficiencies.

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## 3. Work in progress

### Website and choose a fertility clinic

- 3.1.** Since the launch of the Clinic Portal, the primary focus of activity has been on completing the website. Intensive activity has been underway leading to the GDS gateway assessment for authority to live stage, which took place on 8 March 2017. We hope to be able to report the outcome of that assessment at the Authority meeting.
- 3.2.** The team has been working very hard on creating new rich content for the website including video clips and animations as well as a home page news feed and a listings feature. We hope to demonstrate these features at the meeting.
- 3.3.** As outlined to the Authority at the previous meeting, we had been expecting the judgment on the judicial review relating to proposals for publishing performance measures within CaFC, by the end of January 2017. To date, this has not been received, and it is still unclear when this might be received. This is obviously frustrating and at this stage we simply do not know what impact this will have on plans to launch the website.
- 3.4.** Due to the delay to the website, and in anticipation of launch (in March/April 2017), we asked clinics (in December 2016) to undertake a verification exercise relating to their performance data in respect of CaFC. This differs from previous years' exercises (due to the new focus on cumulative birth rates) but is necessary to ensure that we can start the new CaFC with a high quality dataset (subsequent verification exercises will be more straightforward). We extended the deadline a month to the end of March 2017, to ease the burden on clinics.
- 3.5.** Until we receive the court judgment we cannot assess the extent of any changes necessary to meet any requirements; we need to complete the CaFC verification exercise; we need to undertake security penetration testing; and we require GDS clearance. However, it is still our hope and intention to launch in April 2017.

### Release 2 – data submission component

- 3.6.** Progress on this element of IfQ has slipped because of the additional work required on the launch of the portal and the website. Section four, sets out the implications of this further. However, it is important to emphasise the foundations that have been put in place to enable us to proceed to completion over the summer.

Over the last 12 months, the Register has been subject to a thorough overhaul, and cleansing exercise. Critical data fields have been reviewed for error, absence or duplication and resolved, wherever possible. The most serious errors – so-called 'severity 1' errors – which would have prevented data migration to take place have all been resolved, thanks to the hard work of the team and clinics.

### Register data migration

- 3.7.** Data migration is planned to take place over five stages (or 'trial loads') – each 'test' migration reports on anomalies, which are fixed in advance of progression to the next test. Trial load 1 took place last year and trial load 2 has just been completed. The gaps between each get progressively shorter as the anomalies are dealt with. As expected, a number of issues were identified, and the data migration team is working productively in clearing the backlog.
- 3.8.** As highlighted to Authority previously, we have engaged Northdoor PLC, a specialist in large-scale data migration exercises, to audit our process. The two-stage audit aims to assure the Senior Responsible Owner, the Senior Management Team and the Authority that our approach to data migration conforms with our data migration strategy and that all steps have been taken to ensure the integrity of the data being migrated.
- 3.9.** Northdoor's preliminary audit was completed at end January 2017 and gave positive feedback on our processes. Their scrutiny was thorough and detailed, and we draw comfort from this. The second phase of Northdoor's audit is scheduled for May 2017, as we move to trial load 3 - with a final check just prior to migration.
- 3.10.** Further detail will be presented to the Audit and Governance Committee later this month.

### Treatment data submission system

- 3.11.** The submission system (to be integrated within the Clinic Portal) is awaited eagerly by clinics, together with clinics using third party suppliers to link to it.
- 3.12.** Much foundation work has taken place – including substantial user requirements' feedback; detailed mapping of all processes such that the sequencing for questions on the users' screen have been mapped; front-end designs in line with the design of the website and portal; and development activity. We are over half way towards completion but there is still much to do.

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## 4. Completing the programme

- 4.1.** By the end of March (the official end of the programme) a very substantial amount of our overall ambition will have been achieved. The data submission system requires completion, as noted above, and there is ongoing work to do to realise the benefits of a new system to derive intelligence.
- 4.2.** A feature of the Programme to date has been the challenging nature of balancing so many complementary activities – the portal, website, cleansing, migration; with many components dependent on the involvement of the same individuals and skills. Since late last year our focus has been very much on completing one or more aspects to make the overall task more manageable – an approach that has been largely welcomed.

- 4.3.** We are of the view that we need to recognise the problems of the past and configure the remainder of the work differently. To that end we will close the formal aspects of the Programme on 31 March and scope the outstanding work as a project of activity – albeit a very important one – within our business plan commitments for 2017-18. It will be very important that we do not conflate the closure of the programme with any dilution of our commitment to deliver the final elements. Our stakeholders will demand nothing else.
- 4.4.** Such an approach also fits with our plans for organisational change currently being discussed with staff, and with our expectations as regards budget and capital allowances – both consistent with our longer-term expectations to support a new IT estate.

## 5. Programme budget

- 5.1.** Our IfQ budget this year 2016-17 was £527,000 (revised upwards to £619,00 in May 2016) within an overall revised budget for 2015-17 of £1.227m. Projections to year end are that expenditure will be slightly below this.
- 5.2.** We have now concluded our contractual commitments to Reading Room, our principal external supplier. We spent a little time in January and February agreeing the final schedule of work, which resulted in our requiring them to complete a slightly smaller amount of work, resulting in a contract underspend of just under £30,000 – which we have reallocated to other priorities – to ensure that we complete as much work as possible relating to R2 the data submission system, this financial year. To this end we have secured the services of three independent contractors to the end March 2017.
- 5.3.** The earned value and spend to date have progressed slightly, this is reflecting the final stage of the programme for both portal and websites, although the portal has gone live critical work remain to be done for the website.

Period	Aug-16	Sep-16	Oct-16	Nov-16	Dec-16	Jan-17
Earned Value	86%	88.5%	90.6%	91.1%	91.9%	92.3%
Spend to date	91%	92.1%	92.9%	93.1%	93.2%	93.2%

## 6. Recommendation

- 6.1.** The Authority is asked to:
- Note the Clinic Portal is now in live
  - Note the intention to launch the HFEA website and choose a fertility clinic as live, in April 2017
  - Note the intention to ‘close’ the programme at the end of March 2017
  - Note the arrangements for securing completion of the programme components in 2017/18.

# Draft information policy

<b>Strategic delivery:</b>	<input checked="" type="checkbox"/> Setting standards	<input checked="" type="checkbox"/> Increasing and informing choice	<input checked="" type="checkbox"/> Demonstrating efficiency economy and value
<b>Details:</b>	Draft information policy		
Meeting	Authority		
Agenda item	8		
Paper number	HFEA 15/03/2017 828		
Meeting date	15 March 2017		
Author	Nick Jones, Director of compliance and Information		
<b>Output:</b>			
For information or decision?	For information		
Recommendation	N/A		
Resource implications			
Implementation date	N/A		
Communication(s)	Consultation will be run with the sector. When the policy is finalised this will be communicated to all stakeholders.		
Organisational risk	<input type="checkbox"/> Low	<input type="checkbox"/> Medium	<input checked="" type="checkbox"/> High
Annexes	Annex A: Policy on collection, confirmation and publication of register data (current policy)		

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## 1. Background

- 1.1. As the statutory body, we are required by law to collect data from licensed clinics and research establishments and to make that data available to the public. Our position on such matters is set out in a mixture of policy ('Policy on collection, confirmation and publication of Register data' that was last updated in 2012), directions (Generals Directions 0005) and guidance in the Code of Practice. Taken together, these documents set out the rules and expectations both for clinics and for us.
- 1.2. With the Information for Quality (IfQ) programme drawing to a close, we have an opportunity to revisit those rules and expectations; to agree a new information 'bargain' between ourselves and the bodies we regulate. The new IT systems we are putting in place will allow for a much better 'bargain' with a more stretching set of rules and expectations for both sides and better services for patients, donors and the public.
- 1.3. This paper sets out our proposed approach to agreeing this new information 'bargain'. The scope of the work is wide and we propose a series of consultations, taking different form depending on the issue, to establish a consensus on the best way forward.

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## 2. Policy objectives

- 2.1. Our policy objectives on this topic are both narrow and wide. Our primary interest is to ensure that clinics hold treatment information safely and securely, and submit high quality information to us on time. This is vital: without it we cannot meet our statutory or strategic intentions and clinics cannot run high quality services either.
- 2.2. But our policy objectives are about more than the process by which clinics submit treatment data. We believe that high quality information:
  - can drive better performance - we have a unique role in receiving information; storing it; analysing it; and enabling others – such as clinic staff, researchers and others to analyse it and bring about improvement and change.
  - can allow our inspectors to have conversations with clinics about performance - including variance from the norm, and trends relating to incidents and non-compliant areas and so on. And the HFEA also has a role in disseminating such information in the form of reports, discussion papers and through choose a fertility clinic.
  - can enable patients and donors to make more informed choices about their options – our new choose a fertility clinic (CaFC) tool will be the primary means for achieving this aim, but we also need to be mindful of the quality of information on clinics' own websites.

- 2.3.** We want to create the right climate so that clinics are aware of their responsibilities and what will happen where these responsibilities are not met. Our new submission systems are being developed to be intuitive, sympathetic to clinics' processes, and to save time.
- 2.4.** Our policy intentions must be aimed at incentivising clinics to improve and maintain their performance regarding information submission in all its forms. This is the conversation we wish to have with the sector over the next few months, and the rest of this paper sets out those aspects where we require focused engagement and dialogue. Having gathered views and evaluated the feedback we expect to consolidate that within a draft information policy covering the scope set out within this paper, later this year.

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### 3. Scope

- 3.1.** Our starting point is that information submitted by clinics enables us to fulfil our statutory functions.
- 3.2.** We collect information from licensed clinics:
- because it is required by law, to enable us to provide donors, donor-conceived people and their parents with the information they are entitled to;
  - to provide prospective and current patients and donors with sufficient, accessible and up-to-date information to allow them to make informed decisions
  - to provide information that enables us to assess compliance of individual clinics against agreed standards
  - to provide information that enables us to alert clinics of performance changes
  - to obtain information about current practice that is considered by the professional groups and other relevant stakeholders to be useful and beneficial
  - to provide identifying information that enables linkage studies about children conceived as a result of licensed treatment
  - to enable ethically and scientifically approved data research.
- 3.3.** As noted above, we already have an information submission policy. This new work will update that policy also involve consequential amendments to General Directions 0005 and the Code of Practice. There may also be a need to amend the Compliance and enforcement policy – for example if we wish to make more explicit the consequences of non-compliance with information submission requirements.
- 3.4.** In summary, the areas under review are as follows:
1. The foundations of the Register
  2. Register data submission: quality and timeliness
  3. Publishing data – choose a fertility clinic

4. Clinics' websites and marketing
5. Information security
6. Accessing anonymised and identifying HFEA register data for research and understanding
7. Opening the Register

**3.5.** In taking this work forward we propose a 'mixed-model' approach to consultation, using a range of approaches to gather views, some more structured than others. This might include:

- gathering feedback from users on the new data dictionary and submission system further to 'user testing;'
- seeking the views of stakeholder using our existing framework of licensed centres' panel; professional stakeholder organisation group; and so on;
- focused pieces in Clinic Focus, including links to e-survey tools;
- engagement through the new Clinic Portal – which now provides the mechanism for gathering views more quickly;
- possibly some face-to-face events, for example workshops.

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## 4. The foundations of the Register

**4.1.** It is now some time since we first consulted on IfQ and its associated components and there is merit in surfacing where we are now on a range of fronts. For example, the components of the finalised data dictionary; how we might go about making changes to it (in response to requests from the sector; researchers and so on); and how we relate to third party suppliers of IT systems – be that NHS central IT functions or firms that clinics contract with. Our starting point for this conversation is as follows:

**4.2.** Our role and responsibilities are to:

- provide clear definitions and justifications for the data to be submitted and ensure it is consistent with the Standardisation Committee for Care Information (SCCI) UK ART information standard;
- consult sector representatives before changing data elements and carefully consider the balance of the additional benefit changes confer to users of the data collected and the impact of changes on the sector who supply it;
- subject to statutory, regulatory and provision of information requirements to consult the sector prior to setting or changing data submission timeframes;
- monitor and enforce compliance with submission requirements in accordance with the HFEA's Compliance and enforcement policy;List bullet;
- minimise the administrative consequences of register data submission;
- clearly specify the minimum technical/software requirements for register data submission;

- respond to requests for technical and non-technical support within 48 hours where requested via official support channels;
- promote technical interoperability and wherever appropriate adopt open standards;
- provide suppliers of third-party data submission systems with at least 6 months' advance notice of changes they may need to make to their software to maintain compatibility with changing data submission requirements and to provide them with the information necessary to make the changes.

#### 4.3. Clinics' responsibilities are to:

- submit register data in the form and at intervals specified by the HFEA in Directions;
- correct erroneous submissions within the period specified in Directions;
- confirm and verify the completeness and accuracy of submitted data at intervals specified in Directions (please see data publication below);
- in extremis (i.e. if the situation were to arise) where a centre is unable to supply required data, the PR must inform the HFEA in writing detailing the actions taken to obtain the data (i.e. prior to HFEA notification) and how they will respond to requests from patients, donors and donor conceived people for this data. The register record will be appropriately annotated.

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## 5. Data quality and timeliness

**5.1.** Our data submission requirements are informed by the needs of its statutory duties (ie, licensing, inspection and regulation, and information provision). Data submitted to us needs to be of a quality appropriate to the use it is put. In short, this is where we are clear(er) as to the consequences of submitting, or attempting to submit, sub-standard quality data or data that is not timely.

**5.2.** A principal focus here will be consulting on the timeliness of submission. Currently clinics notify us when there is an intention to treat, and at key stages along the treatment journey up to the point of notifying us of outcomes. There are choices for us (and clinics) along the way as to this approach, for example if clinics would like us to *prompt* them for updates there will be a need for them to input predecessor stages. Our starting point for this conversation is as follows:

**5.3.** Our role and responsibilities are to:

- promote data quality by provision of mechanisms to: reject data and require re-submission where it fails to meet the minimum quality standards; minimise input error; identify error in a timely way; and ease of error correction;
- provide transparency with respect to data held by the HFEA to the licensed centres that have submitted it along with the ability to extract and use the data submitted in a common format;

- disclose the status/quality of the data published to licenced centres and users of register information via use of status messages; caveats; data quality metrics;
- review and report on information performance as part of our overall inspection assessment; and where data quality issues give rise to particular concern and/or remain unaddressed, to take corrective action in accordance with the HFEA's compliance and enforcement policy.

**5.4.** Clinics' responsibilities are to:

- correct error identified in submissions within the period specified by the Authority in Directions;
- apply the quality management requirements detailed in licence conditions to data submission processes.

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## **6. Data publication**

**6.1.** For the data to have utility we must make the most of it, particularly with a view to informing improvements to the quality of care. Our principal route for so is Choose a Fertility Clinic (CaFC) on our website. The Authority will know the version to be launched soon will benefit from substantial research and development.

**6.2.** The published data extracts in CaFC generate considerable interest from the sector, and are the subject of media and public scrutiny. The Authority therefore considers it important to state clearly the procedures and timelines that it expects to be followed in respect of the collection, confirmation and publication of that data. Our starting point for this conversation is as follows:

**6.3.** Our role and responsibilities are to:

- disclose to a licensed clinic in advance of publication the data to be published about it along with the basis and reasons for any processing of the data. There is an open question as to whether we require the 'checking and sign-off' of that data, as now;
- allow a reasonable time between notification of data to be published for centre review, update, and feedback to the Authority to ensure the published data is complete and accurate. Again, there is an open question as to whether we might expect a sign off of that data;
- disclose the status/quality of the data published to users (e.g. published as clinic confirmed data, data unconfirmed by clinic, caveated and/or with data quality metrics). In other words, if we do require sign-off - and it is not forthcoming - we publish that the clinic's data cannot be relied upon;
- refuse to publish data where in the HFEA's judgement deficiencies mean the data may mislead/is not suitable for decision making (e.g. where data cannot be compared on a similar basis or where data is unavailable for the whole period covered by publication etc.).

- publish statistical analyses for use by the sector and the public (eg, Fertility trends, donation data, historical analyses etc).

**6.4.** The role and responsibilities of clinic Persons Responsible (see also data quality above) are to:

- review the data to be published and to correct it/inform the HFEA of any inaccuracies within the timeframe specified in Directions;
- confirm/verify that the data to be published is complete and accurate by the date required by the HFEA.

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## 7. Clinic websites

**7.1.** This aspect of clinics' activities is one where we may seek to exert greater influence. The assisted reproduction sector is increasingly competitive and the role of websites in clinics' marketing strategies plays an understandably important role.

**7.2.** Equally, we are aware that some of the claims made in those websites relating to performance – notably success rates, and the benefits of certain types of treatments (add ons) have the potential to mislead and bring about harm to the overall reputation of the sector. In both aspects of performance and services we have a legitimate interest in, where necessary, influencing the behaviour of clinics.

**7.3.** Currently, the Code of Practice sets out expectations in relation to claims made in clinics' websites mainly regarding their performance. These include:

- The information should include the most recent data available from the past three years.
- The website should provide the live birth rate per treatment cycle, and not highlight a high success rate that applies only to a small, selected group of patients.
- The data should show split by maternal age and, if appropriate, by treatment type.
- The website should provide raw numbers rather than just percentages.
- The website should provide the national rate and like-for-like comparisons (the same year, maternal age, treatment type, etc.).
- The centre's published success-rate data should refer to the HFEA as the source of national information.
- The website must state clearly that information on success rates is of limited value in comparing centres and choosing where to seek treatment. It should include a link to the HFEA's advice on success rates: <http://www.hfea.gov.uk/fertility-clinics-success-rates.html>
- If the website refers to comparative costs, it should indicate the likely total cost for a typical cycle, based on the actual costs for recent patients, not individual items in tariffs.

- 7.4.** Most clinics comply with some, if not all these requirements at any given time. At the same time, the websites are fast-moving and it can be difficult (and somewhat time-consuming) to monitor changes.
- 7.5.** Nevertheless, as we launch our new website and Choose a Fertility Clinic (together with new metrics and headline measures) it is timely that we look again at our approach to clinics' compliance with our expectations here. It is clear to us that prospective patients are not well served faced with some of the claims made. If we are to address this, we will need to devote more time and effort - something we believe it is necessary and important to do. That is our starting point. We now wish to begin a dialogue with the sector as to what are the barriers to it behaving responsibly and what our regulatory response will be in the circumstances.
- 7.6.** Our role and responsibilities are to:
- Set out our clear expectations regarding the standards expected of clinics' websites
  - Monitor compliance with those expectations on a regular basis
  - Set out the sanctions to be applied regarding licensing and/or other measures.
- 7.7.** Clinics' responsibilities are to:
- Maintain the reputation of the sector in publishing websites;
  - Comply at all times with HFEA requirements in publishing information regarding performance and services on their website.

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## **8. Information integrity and security**

- 8.1.** An effective information security management regime, ensures that information is properly protected and is reliably available. Along with other partners in the health and care system the extent to which (we ensure) information is secure is a key component of whether patients and the public trust health and care professionals with it. In other words, high profile health information security breaches corrode trust and impede sensible attempts at information sharing (intended to be in patients' interests). Information, whether in paper or digital form, is of its critical importance to support:
- patient choice
  - patient care/safety and continuity of care;
  - evidence-based clinical practice and research;
  - day-to-day business processes that underpin the delivery of care and sound administrative and managerial decision making and support clinical or other types of audit;
  - meet legal requirements, including requests from patients under the the Data Protection Act and/or the Freedom of Information Act.

**8.2.** The HFE Act makes specific amendments to the Data Protection Act and also places restrictions on the access to data that we hold, specifically an employee or member of the HFEA may not disclose any information held in the Register Database or any other information held in confidence by the HFEA. We will wish to consider our role in ensuring that clinics' arrangements for information security meet the highest possible cyber security and other security standards. The Care Quality Commission and NHS Improvement are turning their attention to these issues and so must we. As members of the National Information Board it is incumbent on us to maintain and drive up the standards of information security. Our starting point for this conversation is as follows:

**8.3.** Our role and responsibilities are to:

- ensure personal data held on a computer is only be used or disclosed for the purpose for which it was intended and for which registration exists. All staff must maintain the confidentiality of any personal data held on HFEA systems. Personal data must always be accurate and relevant in accordance with the Data Protection Act 1998;
- comply promptly with 'subject access requests' made under the Data Protection Act 1998. The centre must check the identity of the person making the request and may also request written consent and proof of identity from the partners of applicants if the medical record contains information relating to them.

**8.4.** Clinics' responsibilities are to:

- inform patients, partners and donors about uses of their personal information and offer appropriate choices about the uses of their personal information and explain the circumstances in which confidential information may be used or disclosed; and the opportunity to give or withhold consent to disclosure of information;
- protect confidential information and ensure access to medical records and data is restricted to persons authorised by the PR and to employees of the Authority (for the purpose of inspection);
- ensure personal data held on a computer is only be used or disclosed for the purpose for which it was intended and for which registration exists.
- ensure personal confidential data is handled, stored and transmitted securely, whether in electronic or paper form;
- ensure personal confidential data is only shared for appropriate and lawful purposes;
- investigate and deal with any breach of confidentiality and submit a full explanation to the HFEA in the form of an incident report. If it appears that a criminal offence has been committed, the centre should inform the police;
- ensure staff understand their responsibilities to handle information respectfully and safely, according to the Caldicott Principles;
- ensure personal data held on a computer is only be used or disclosed for the purpose for which it was intended and for which registration exists. All staff must maintain the confidentiality of any personal data held on centre

IT systems. Personal data must always be accurate and relevant in accordance with Data Protection Act 1998.

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## 9. Accessing anonymised, and identifying HFEA register data, for research and understanding

- 9.1.** In order to allow professionals in the sector and the wider research community to make good use of the data, we make available an anonymised version of the Register – a large and rich data set, but one that does not identify any patients, or children born as a result of treatment. The version is dated and would benefit from the wider participation of potential users as a revised version is prepared.
- 9.2.** Only recognised research institutions may apply for access to potentially identifiable Register data. Applicants will need to have secured research ethics committee approval for their proposed projects through the Health Research Authority (HRA) prior to submission to the HFEA Register Research Panel. In addition, all medical research projects will also be considered by the National Information Governance Board (which is part of the HRA). Researchers wishing to link HFEA data to Scottish or Northern Irish medical datasets will need to seek approval from the Privacy Advisory Committees (PACs) in those countries.
- 9.3.** This arrangement means that clear safeguards are in place: researchers will be bound by the same confidentiality restrictions as the HFEA and licensed clinics; they will need to meet a number of tests set out in statute to demonstrate why their research will be in the public interest and why such research cannot be carried out without access to information that identifies patients, partners and children born as a result of treatment.
- 9.4.** We seek to begin a conversation to reinvigorate the use made of the Register by researchers, generally, and in encouraging a dialogue with those interested in research to make the process of application more straightforward and the potential for collecting additional data items to maximise its potential. Our starting point for this conversation is as follows:
- 9.5.** Our role and responsibilities are to:
- Promote the benefits of high quality research, particularly the benefit of linking the information within the Register to other health datasets;
  - satisfy itself of the following prior to granting access to data if:
    - planned research is of high quality and is approved by an ethics committee;
    - consent to disclosure has effectively be obtained;
    - the research is not possible using anonymised data.
  - ensure where data release is approved, it will only be:
    - for the smallest possible number of patients;

- for the smallest possible number of identifiers (date of birth or name, for example);
- for the shortest time period possible (i.e. identifiers have to be removed once data from our Register has been linked to another dataset).
- authorise/refuse to authorise, suspend, revoke or place conditions upon authorisation to access via the HFEA's Register Research Panel which work closely with the Health Research Authority and the Privacy Advisory Committees in Scotland and Northern Ireland as required, as well as experts in the field of social science research;
- oversee the work of the Register Research Panel, it will monitor the granting of authorisations and appeals against the decisions of the Panel via an Oversight Committee which will receive regular updates from the Panel, as well as annual reports from authorised research establishments;
- publish lay summaries of all approved research projects to the HFEA web site and receive and review annual reports from all research establishments authorised to access Register data.

**9.6.** Researchers' roles and responsibilities are to:

- submit applications in the form the HFEA specified;
- provide application supporting evidence of ethics approval of the research project from a properly constituted research ethics committee; copies of all information provided to patients and/or donors relating to the proposed research project; and copies of the consent forms to be used to authorise use of gametes, embryos or human cells in the research project;
- submit to the Authority an annual update.

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## **10. Opening the Register**

**10.1.** The Human Fertilisation and Embryology Act provides donor-conceived individuals and donors with a statutory right of access to information held on the Register.

**10.2.** Depending on their age, donor-conceived individuals have a right to access information about their donor; donor-conceived genetic siblings; removal of their donor's anonymity; and whether they might be related to an intended spouse or partner.

**10.3.** Donors have a right to access information on the number, sex and year of birth of any children conceived from their donation and the right to remove their anonymity – if they donated before 1 April 2005.

**10.4.** Parents of donor-conceived individuals were granted discretionary access rights by the Authority to the non-identifying information about their donor; the number, sex and year of birth of any donor-conceived genetic siblings; and if their donor has removed their anonymity.

**10.5.** We have been working with clinics over several years to promote the benefits of good and clear information, for example in raising the quality of donors' pen portraits. Further, it is vital that all information relating to donor treatment is accurate with no room for error. Our focus on data cleansing in preparation for data migration of the Register to the new system has placed donor treatment at front and centre. We will wish to explore with clinics whether, collectively, more needs to be done to improve the quality of information relating to donor treatment. Our starting point for this conversation is as follows:

**10.6.** Our role and responsibilities are to:

- provide an easily accessible mechanism via which donor-conceived individuals, donors and parents can apply for information;
- maintain the confidentiality of applicant and register information;
- return supporting documentation to applicants (e.g. identity documents) promptly;
- respond to their application requests promptly.

**10.7.** Clinics' responsibilities are to:

- submit require patient and donor related register information accurately and promptly in accordance with Directions;
- maintain patient and donor records in accordance with Directions;
- to respond promptly to HFEA requests for OTR application related clarifications and confirmations.

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## **11. Recommendation**

**11.1.** The Authority is asked to note:

- The areas of focus for consultation regarding the HFEA policy on information
- Identify areas where more or particular attention should be paid
- That following consultation a revised Information Policy together with General Directions and revisions to the Code of Practice will be presented to the Authority for approval.

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## Annex A Policy on collection, confirmation and publication of Register Data (Current policy)

### HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY POLICY ON COLLECTION, CONFIRMATION AND PUBLICATION OF REGISTER DATA

**Policy Version:** 3.0

**Date:** 12 September 2012

**Review Date:** September 2015

**Policy Ownership:** Head of Business Intelligence

#### 1.0 POLICY STATEMENT/INTENTIONS

1.1 This document sets out the Authority's policy on:

- 1.1.1 the methods and timescales for collection of data which the Authority is required to maintain in a Register in accordance with Section 31 of the Human Fertilisation and Embryology Act 1990 (as amended) ('Register Data');
- 1.1.2 the process by which licensed clinics are required to confirm the accuracy and authenticity of the Register Data that they provide to the Authority; and
- 1.1.3 the arrangements for publication of extracts of Register Data on the 'Choose a Fertility Clinic' pages of the Authority's website.

1.2 This policy replaces all previous policies relating to these matters.

1.3 This policy is to be read in conjunction with Direction 0005 on Collecting and Recording Information for the Human Fertilisation and Embryology Authority, the Authority's Code of Practice, and the Authority's Compliance and Enforcement Policy.

#### 2.0 COMMENCEMENT

2.1 This policy first came into effect on 1 October 2009 with this version in effect from 1 October 2012.

#### 3.0 INTRODUCTION

3.1 Under the Human Fertilisation and Embryology Act 1990 (as amended), the Authority has a statutory duty to:

- 3.1.1 provide, to such extent as it considers appropriate, advice and information for persons to whom licences apply or who are receiving treatment or to those who may wish to do so;
- 3.1.2 promote compliance with the Act and the Authority's Code of Practice; and
- 3.1.3 maintain a register of information relating to:
  - 3.1.3.1 the provision for any identifiable individual of treatment services other than basic partner treatment services;

- 3.1.3.2 the procurement or distribution of any sperm, other than sperm which is partner-donated sperm and has not been stored, in the course of providing non-medical fertility services for any identifiable individual;
  - 3.1.3.3 the keeping of the gametes of any identifiable individual or of an embryo taken from any identifiable woman;
  - 3.1.3.4 the use of the gametes of any identifiable individual other than their use for the purpose of basic partner treatment services;
  - 3.1.3.5 the use of an embryo taken from any identifiable woman; or
  - 3.1.3.6 information which shows that an individual was or may have been born as a result of treatment services (other than basic partner treatment services) or the procurement or distribution of sperm (other than partner-donated sperm which has not been stored) in the course of providing non-medical fertility services.
- 3.2 As the UK Competent Authority, the HFEA is required under the EU Tissues and Cell Directive (Directive 2004/23/EC) to compile summary statistics of Intra Uterine Insemination ('IUI') and Gamete Intra-Fallopian Transfer ('GIFT') treatments using partner sperm. This information is published on a calendar year basis.
- 3.3 The Authority publishes extracts of Register Data in the form of 'Choose a Fertility Clinic' pages on its website (<http://www.hfea.gov.uk/guide/>), which is updated twice a year, in April and October.
- 3.4 The published data covers a three-year period.
- 3.5 These data extracts generate considerable interest from the sector, and are the subject of media and public scrutiny. The Authority therefore considers it important to state clearly the procedures and timelines that it expects to be followed in respect of the collection, confirmation and publication of Register Data.

### 3.6 COLLECTION OF REGISTER DATA

- 3.6.1 The Authority requires all licensed clinics undertaking IVF, Donor Insemination, Egg Retrieval for Storage, or Donation to create, store and submit records relating to Register Data to the Authority through the HFEA's Electronic Data Interchange ('EDI') system or through the clinic's own system providing it integrates with the HFEA's EDI system.
- 3.6.2 The Authority requires all licensed clinics undertaking IUI or GIFT with partner sperm to submit an annual return to the Authority no later than 28 February in each calendar year. The annual return must be in the form set out in Direction 0005 on Collecting and Recording Information for the Human Fertilisation and Embryology Authority.
- 3.6.3 The Authority requires all licensed clinics to submit Register Data on the following forms:

Type of Form	Purpose of Form
Patient registration	To provide details of the

	patient receiving fertility treatment.
Partner registration	To provide details of the partner of the patient receiving fertility treatment.
Donor information	<p>To provide identifiable details of a donor and the reasons why they are donating.</p> <p>Licensed centres must use Donor Information for D v.2009 to record information relating to donors and ensure that sections 1-20 are completed for each donor.</p> <p>Patients providing gametes for a surrogacy arrangement must be registered as donors, therefore Donor Information forms must be completed for them.</p>
Donor re-registration (also known as a B form)	This form enables a previously anonymous donor to register as identifiable on the HFEA register.
Intention to treat	To inform the HFEA when a cycle in which eggs are to be collected has started.
IVF treatment & embryo creation and use	To inform the HFEA about the circumstances surrounding egg collection, embryo creation and /or transfer.
Donor insemination treatment	To inform the HFEA when a patient has been inseminated with donor sperm.
Early pregnancy outcome	To inform the HFEA of the early outcome of a treatment.
Pregnancy outcome	To inform the HFEA of the outcome of any early outcome recording 'fetal pulsation seen'.
Donor Sperm procurement	To inform the HFEA about the quantity of sperm donated by each donor.
Embryo & gamete movement – in	To inform the HFEA about the number of embryos, eggs and ampoules, straws or vials of sperm transferred from another UK centre or imported from outside the UK.
Embryo & gamete	To inform the HFEA about the

movement – out	number of embryos, eggs and ampoules, straws or vials of sperm removed from storage at the centre; the reason for the removal; the centre code or the country of destination to which transferred or exported.
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4.2.4 The Authority requires all licensed clinics to submit Register Data on the appropriate forms within the following timescales:

<b>Category of Information</b>	<b>Timescale for Records to be submitted to the Authority no later than:</b>
Patient registration details	5 working days after the patient has confirmed intention to undergo treatment
Partner registration details	5 working days after the patient has confirmed intention to undergo treatment
Intention to treat	3 <b>calendar</b> days after last menstrual period or stimulatory drugs being administered to/taken by a patient with the intention to perform IVF treatment.
Donor information	5 working days after confirmation of sperm being released for use by the clinic, the harvesting of oocytes or in the case of imports, receipt of the imported eggs, sperm or embryos
IVF treatment & embryo creation and use	5 working days after the treatment cycle completion date
Donor insemination treatment	5 working days after the last insemination of the cycle
Early pregnancy outcome	8 weeks after the treatment cycle completion date
Pregnancy outcome	8 weeks after the predicted outcome date

Donor Sperm procurement	This form can be submitted at the end of a donation cycle for an individual donor or weekly/monthly for a number of donors
Embryo & gamete movement – in	5 working days after embryos or gametes are received at the centre
Embryo & gamete	5 working days of embryos or

movement – out	gametes being removed from storage.
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- 4.2.5 The Authority requires the staff of licensed clinics to complete the appropriate forms according to the guidance issued by the Authority. This guidance is available on the Authority's website at <http://www.hfea.gov.uk/fertility-clinic-forms.html>
- 4.2.6 Where licensed clinics wish to amend the data that they have previously supplied to the Authority, they will be required to submit a correcting form. This will be the same version as the original form supplied to the Authority, but clearly marked as a correcting form, and referencing the number of the original form that is to be corrected.
- 4.2.7 Where a licensed clinic has submitted duplicate forms, a deletion request should be made to the Authority via the EDI system or integrated systems, clearly referencing the form to be deleted and stating the reasons for the request.
- 4.2.8 The forms received by the Authority from licensed clinics through the EDI system will be held in database tables on the Authority's computer servers. The date of receipt of the form will be recorded as the 'Envelope Receipt date'. Each form will be given a unique reference number.
- 4.2.9 Upon receipt of the forms by the HFEA, the Authority will process them against a series of validation rules, to assess whether the forms are filled in correctly and whether all required information on the forms is supplied. The forms are also cross-referenced to ensure all other expected forms have also been submitted to the Authority (e.g. when an early outcome form is received the system checks that the relevant treatment and patient registration forms are on the system).
- 4.2.10 The Authority's validation process does not assess the veracity of the information supplied by licensed clinics, and does not check the data supplied by licensed clinics against the medical records held by them.
- 4.2.11 The data received by the Authority from these forms submitted by licensed clinics will be used to produce a number of reports, including:
- 4.2.11.1 the 'Validation Error Report', which identifies any inconsistencies or omissions on forms submitted. The Validation Error Report is updated daily and highlights what information or amendments are required.
  - 4.2.11.2 other reports which identify any information gaps or queries that may affect a clinic's statistics for the 'Choose a Fertility Clinic' entry ('verification reports').

### **4.3 CONFIRMATION OF REGISTER DATA FOR THE 'CHOOSE A FERTILITY CLINIC' SECTION OF THE AUTHORITY'S WEBSITE**

- 4.3.1 8 weeks prior to the sign-off deadline, the Authority's Register Information Team will contact the Person Responsible of each licensed clinic, setting out the deadlines for submission of data to the Authority, sign-off, and publication of Register Data on the Authority's website.

- 4.3.4 The letter will also inform Persons Responsible when the verification reports for that clinic's data will be available, and will inform the Person Responsible of the requirements set out in paragraphs 4.3.7, 4.3.8 and 4.6.4.
- 4.3.5 At least 8 weeks prior to the sign-off deadline, the Authority will make available to clinics a set of verification reports. The purpose of these reports is to identify any missing or erroneous forms or highlight any information the Authority considers necessary to complete the confirmation process.
- 4.3.6 8 weeks prior to the sign-off deadline, the Authority will also supply the licensed clinics with spreadsheets of raw data. The raw data details every treatment form for a specified 12-month period and identifies which of those cycles have been included in the 'Choose a Fertility Clinic' entry.
- 4.3.7 If a licensed clinic cannot access the verification reports on the EDI system, it is the Person Responsible's responsibility to contact the Information team and inform them of this fact as soon as possible. Upon notification, the Information Team will find an alternative method to supply the reports.
- 4.3.8 2 weeks prior to the sign-off deadline, a Person Responsible should ensure that:
- 4.3.8.1 all verification reports relating to his clinic have been cleared or confirmed;
  - 4.3.8.2 the raw data is reviewed against their clinical records to identify any discrepancies not identified by the verification reports (e.g. verification reports have been cleared but the licensed clinic still does not agree with the 'Choose a Fertility Clinic' draft entry);
  - 4.3.8.3 any outstanding forms have been submitted to the Authority; and
  - 4.3.8.4 the Register Information Team is informed no later than 1 week prior to sign-off if there are any concerns about the data, (the HFEA cannot guarantee to resolve any queries raised later than this before publication).
- 4.3.9 Any data or forms provided to the Authority after the deadline for submission of data notified to the licensed clinics will not be reflected in the 'Choose a Fertility Clinic' entry.
- 4.3.10 Where there remain unresolved discrepancies between data held by the Authority and that held by the licensed clinics or where there are outstanding items missing or unconfirmed on verification reports after the deadline for submission of data, that clinic's 'Choose a Fertility Clinic' entry will be published as unconfirmed. Unconfirmed data is accompanied by the following caveat:
- "This centre was unable to complete the data verification process to the required deadline and the Person Responsible has not confirmed the accuracy of the data published."
- 4.3.11 When a Person Responsible is satisfied with accuracy of the data for their licensed clinic, they must sign-off this data. To do this, the Person Responsible must sign and date a hard copy of their summary data and return it to the HFEA no later than 5pm on the date notified to the clinics (the 'sign-off deadline'). The draft entry must be returned by post, fax or by email with a scanned pdf file.

4.3.12 Where the Register Information team has not received the signed hard copy (or there remain unresolved discrepancies) of the draft 'Choose a Fertility Clinic' entry from a Person Responsible by the sign-off deadline, the data for that licensed clinic data will be published as unconfirmed with the caveat outlined above.

4.3.13 After midnight on the date notified to the clinics as the deadline for submission of data, the draft entry for each licensed clinic will be frozen, and any subsequent submission of data via the EDI or integrated system by a licensed clinic will not be registered in the draft entry.

#### **4.4 PUBLICATION OF EXTRACTS FROM REGISTER DATA ON 'CHOOSE A FERTILITY CLINIC' SECTION OF THE AUTHORITY'S WEBSITE**

4.4.1 The data that is published on the 'Choose a Fertility Clinic' section of the Authority's website will be accompanied by the following caveat:

“The information that we publish on our website is a snap shot of data provided to us by licensed centres at a particular time. This information may be subject to change as individual centres notify us of amendments. Before publication, we perform a preliminary validation process on the data, and ask centres to confirm its accuracy, for which they remain responsible”.

4.4.2 Alternative caveats may be necessary under the conditions identified in sections 4.1.1.7 outlining why complete data is not available for the whole verification period.

4.4.3 The following data will not be published in the 'Choose a Fertility Clinic' part of the Authority's website:

4.4.3.1 treatment cycles in which both fresh and frozen embryos were transferred in the same cycle;

4.4.3.2 any mixed IVF and GIFT cycle.

4.4.4 The information listed at 4.4.3 will not be published because there would be ambiguity as to which treatment type the outcome should be attributed to.

4.4.5 Confirmed and unconfirmed data will be clearly distinguished on the 'Choose a Fertility Clinic' part of the Authority's website.

#### **4.5 DIRECTIONS**

4.5.1 This policy should be read in conjunction with Direction 0005 on Collecting and Recording Information for the Human Fertilisation and Embryology Authority.

#### **4.6 FAILURE TO COMPLETE THE CONFIRMATION PROCESS AND TO CLEAR ERROR REPORTS**

4.6.1 The Authority will only publish and update data on the 'Choose a Fertility Clinic' part of its website at six monthly intervals.

4.6.2 The Authority will require Persons Responsible who have not confirmed the data for their centre by the original sign off date, to confirm such data by the next sign-off

date. Failure to do so may be brought to the attention of the Authority's Executive Licensing Panel or Licence Committee.

- 4.6.3 The Authority considers that data which has been signed-off by a Person Responsible is suitable for publication as 'confirmed data'. Upon publication, such data may be used and relied on by potential patients to make decisions about their treatment. Therefore, the Authority stresses that Persons Responsible should not sign off the data for their licensed clinic unless and until they are satisfied as to the accuracy of the data that they have provided.
- 4.6.4 In particular, the Authority requires Persons Responsible to ensure that, before they sign-off their data, they are satisfied that:
- 4.6.4.1 the number of treatment cycles completed within the reporting period is 100% accurate;
  - 4.6.4.2 all early outcome forms and all outcome forms have been submitted to the Authority, and have been filled in accurately; and
  - 4.6.4.3 all registration forms relating to patients undergoing treatment have been submitted to the Authority and have been filled in accurately.
- 4.6.5 Where the Authority becomes aware that a licensed clinic has made amendments to its data after that data has already been signed-off by the Person Responsible for the clinic, and those amendments relate to issues that the Person Responsible should reasonably have been aware of, or addressed, before signing-off the data, the matter may be brought to the attention of the Authority's Executive Licensing Panel or Licence Committee.
- 4.6.6 Where the confirmation process in respect of any data has not been completed by the deadline, the data will be published as 'unconfirmed data'.
- 4.6.7 The Authority requires Persons Responsible to ensure that the error reports made available by the Authority are reviewed by their licensed clinics on a weekly basis. This is in order to prevent a build up of unresolved data issues, which may affect the quality of the data held by the Authority in its statutory Register.

## 5.0 REVIEW

- 5.1 This policy will be reviewed every 3 years.
- 5.2 The date of the next review is scheduled for September 2015.

## Control sheet

### Document control

Doc Name:	Policy on Collection, Confirmation and Publication of Register Data
Trim ref/Doc No:	2012/013458
Latest Version No:	3.0
Release date:	12 September 2012
Approved by:	Authority
Next review due:	September 2015
Total pages:*	12

### Version/revision control

Version	Changes	Drafted/Updated by:	Release date
1.0	First draft	David Gomez	17/09/08
2.0	Revised to accommodate launch of updated Choose a Fertility Clinic, publication of 3 years' data, and implementation of new directions	Richard Martin	09/09/09
3.0	Review and update of version 2.0. Minor corrections of terminology, punctuation and dates, particularly: 6 monthly publication cycle and updated caveats, clarification of ELP as appropriate decision making body	Charlotte Augst	12?09/12

\* Excluding control sheet

# Governance and transparency

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

## Details:

Meeting	Authority
Agenda item	9
Paper number	HFEA (15/03/2017) 829
Meeting date	15 March 2017
Author	Siobhain Kelly, Head of Corporate Governance (interim)

## Output:

For information or decision?	For decision
Recommendation	The Authority is asked to: <ul style="list-style-type: none"> <li>• note the committees' annual reviews</li> </ul>
Resource implications	Minimal
Implementation date	1 April 2017
Communication(s)	N/A
Organisational risk	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High
Annexes	Standing Orders

## 1. Introduction

- 1.1. For the HFEA to be an effective and trusted regulator, we must have high quality decision making processes which are clear to clinics, patients and the wider public. To achieve that, we have a number of committees, with clear instructions from the Authority about how they should make decisions. The rules governing decision making is set out in our Standing Orders and explained on our website.
- 1.2. The Authority is committed to an annual review of our governance structures, consisting of:
  - a review of each committee's effectiveness; and
  - a review of our Standing Orders.

## 2. Annual review of committee effectiveness

- 2.1. All committees are required annually to assess their own effectiveness. Generally, the feedback is positive. Committees have been through a period of consolidation, following changes in committee membership.
- 2.2. The committees which make licensing and authorisation decisions are attended well. The biggest risk to quoracy has been IT issues in Spring Gardens, but these connectivity issues have peaked with meetings rooms now being booked offsite for more reliability. We have taken expert advice on these issues and expect to resume meetings in Spring Gardens shortly.
- 2.3. The table below summarises the feedback from each committee.
- 2.4. The areas for improvement identified will be considered over the coming year.

Committee	Positives	Areas for improvement
<b>Licence Committee</b>	<p>The committee business is managed well by the Executive with ample committee time scheduled to discuss business properly.</p> <p>The scientific expertise within the committee has enabled the committee to function without the attendance of external advisers.</p> <p>The committee has retained oversight of tougher licensing decisions.</p> <p>Member attendance is good and quoracy is not an issue at the moment.</p> <p>The Chair intends to continue being present as this works best when other members are attending via V/C or</p>	<p>Technical problems have still been an issue which has meant that sometimes conversations have to be repeated to ensure all members are involved in the discussion.</p> <p>Papers are still being tabled, thus meaning members have less time to absorb the content. The committee agree that this should be avoided where possible.</p>

teleconference.

<b>Statutory Approvals Committee</b>	<p>Following feedback from SAC the Executive met with the Genetic Alliance (GA) to discuss expectations from their opinion papers. Since the meeting the GA papers have been outstanding in conveying the patient perspective. The committee now find the GA opinion papers a key part of an application for PGD.</p> <p>The Chair of the committee has continued to effectively chair the meeting and gives members of the committee ample time to express their opinions and raise questions.</p> <p>The committee agreed that any expressions of disagreement faced by members was fully explored to ensure collective ownership of decisions.</p>	<p>Work needs to be completed in respect of applications for special directions for import or export. The committee felt that consistency regarding the information provided by centres/Executive for special directions could be improved.</p> <p>The committee felt that work needed to be completed in respect of conditions with familial inheritance and X-linked conditions and how clinics are licensed to test for these conditions.</p> <p>Keeping the committee up to speed with new technologies and techniques and feedback from the sector via the inspection team. The committee has been informed that a PGD workshop is planned.</p> <p>SAC agreed that ongoing IT issues have disrupted some meetings and the committee were looking forward to these issues being resolved.</p> <p>The committee agreed that there should be a quarterly standing item to discuss the general governance of the committee to give members an opportunity to raise any issues faced.</p>
<b>Executive Licensing Panel</b>	<p>The volume of work and high frequency of meetings are manageable and continue to be responsive to demand from the Compliance department.</p> <p>The Licensing Officer role has started to process the first change of Licence Holder and change of centre's name or address. This has proved to be a much quicker process for the Executive and a faster decision for centres.</p>	<p>There have been some discussions between Licensing and the Inspectorate to improve the flow of paperwork, but this generally works well.</p> <p>The ELP felt that more information on the inspection process would be beneficial, such as timing of inspections and inspection themes. An annual meeting with compliance could achieve this.</p> <p>It would also be good if more could be done to schedule meetings after the main deadlines for recommendations, especially where the deadline is very soon after the committee (assuming there is time for this before the licence lapses).</p>
<b>Audit and Governance Committee</b>	<p>The committee continues to benefit from having external members and their experience and perspective has proven to be invaluable.</p> <p>The relationships between the chair, committee and internal and external audit are well developed and meetings are attended by all the appropriate</p>	<p>Both External member's appointment terms expire in late summer and this needs to be planned for carefully.</p> <p>AGC felt that when papers are given to them as an update, it is not always clear what the committee is being asked to do.</p> <p>AGC wondered what risks would be getting their attention if IfQ was not in</p>

	<p>organisations. Pre-meetings with all parties occur.</p> <p>Annual appraisals of external members have taken place and inspection observations have been completed.</p> <p>Chair attends DH audit chairs meetings and training when it is provided.</p> <p>The committee felt that they were supported well by both the Finance team and the Committee Secretary.</p> <p>AGC annual report to the Authority introduced in July 2016.</p>	<p>play. This might mean looking at longer term risks like OTR or legal challenges.</p> <p>Some meetings have been problematic due to IT issues, when members have attempted to attend remotely.</p>
<b>Scientific and Clinical Advances Advisory Committee</b>	<p>SCAAC agreed the meetings are chaired effectively and spirited and involving discussions take place.</p> <p>The papers received by this committee are of high quality, with comprehensive background information provided.</p> <p>Committee members were asked to provide information for a high profile television programme. Members forwarded the requests to the Executive and the issue was dealt with centrally which worked well.</p>	<p>The committee felt frequency of meetings should increase or the extension of one meeting beyond the usual length to cover relevant issues.</p> <p>SCAAC find the annual horizon scanning meeting at ESHRE useful and informative, however not all SCAAC members are able to attend.</p> <p>Declarations of Interest were not stated at the beginning of meetings (this has been addressed following this review).</p> <p>Minutes should be circulated in a timely manner even though they are signed off at the next meeting.</p>
<b>Remuneration, Appointments and Oversight committees</b>	<i>Formal reviews not undertaken due to infrequency of meetings</i>	
<b>Appeals</b>	The committee has not heard any appeals this year.	

### 3. Review of Standing Orders

- 3.1. The Authority is asked to note that there has been no need to amend Standing Orders this year so the version released in April 2016 still stands.
- 3.2. The current version is attached at Annex A for information.
- 3.3. The Standing Orders version control has been updated to reflect the fact that the Authority agrees that there is no need to change this year.

### 4. Recommendation

- 4.1. The Authority is asked to:
  - note the committees' annual reviews; and

- high note the proposed Standing Orders remain unchanged.

# Standing orders

**Effective 1 April 2017**

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## Version control

Reviewed and approved by Authority on [9 December 2009](#).

Amendments approved by Authority on [20 January 2010](#) and [12 May 2010](#).

Typographical corrections made on 4 August 2010

Reviewed and amendments approved by Authority via written resolution (issued 12 November 2010) and decision noted at Authority meeting on [8 December 2010](#).

Reviewed and amended in light of new equalities legislation and approved by Authority on [23 March 2011](#).

Reviewed, amended and approved by Authority on [7 December 2011](#).

Amendments approved by Authority on [12 September 2012](#).

Amendments approved by Authority on [23 January 2013](#).

Reviewed, amended and approved by Authority on [20 March 2013](#).

Amendments approved by Authority on [13 November 2013](#).

Reviewed, amended and approved by Authority on [5 March 2014](#).

Reviewed, amended and approved by Authority on [11 March 2015](#).

Reviewed, amended and approved by Authority on [17 September 2015](#).

Reviewed, amended and approved by Authority on [9 March 2016](#).

[Reviewed with no amendments by Authority on 15 March 2017](#)

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# Foreword<sup>1</sup>

1. The Human Fertilisation and Embryology Authority (HFEA) is an executive non-departmental public body sponsored by the Department of Health. The HFEA is a body corporate, established by Section 5 of the Human Fertilisation and Embryology Act 1990 (as amended) (the Act). In accordance with Schedule 1 to that Act, the Chair and members of the Authority are appointed by the Secretary of State for Health.
2. The HFEA is the UK's independent regulator of treatment using eggs and sperm, and of treatment and research involving human embryos. The HFEA sets standards for, and issues licences to, centres. It provides authoritative information for the public, in particular for people seeking treatment, donor-conceived people and donors. The HFEA determines the policy framework for fertility issues, which are sometimes ethically and clinically complex.
3. The HFEA is committed to adopting best practice in corporate governance. These Standing orders form part of the corporate governance framework with which the HFEA must comply, and which includes:
  - the Act
  - regulations issued by the Secretary of State for Health or the HFEA
  - the framework agreement between the HFEA and the Department of Health, or any other memorandum of understanding (MoU) or other agreement
  - standing financial instructions adopted by the HFEA, and
  - financial procedures for procurement and payment of goods and services, budget management and travel and subsistence.
4. As a public body, the HFEA is also required to comply with applicable legislation including that relating to human rights, equalities, freedom of information, environment information and data protection; and with relevant government policies on information assurance and data security. In addition, the HFEA is expected to comply with the statutory code of practice for regulators ('The regulators' code').
5. In accordance with the Act (under Section 8) the HFEA shall:
  - i. keep under review information about embryos and any subsequent development of embryos and about the provision of treatment services and activities governed by this act, and advise the Secretary of State, if he/she asks it to do so, about these matters
  - ii. publicise the services provided to the public by the HFEA or provided in pursuance of licences
  - iii. provide, to such extent as it considers appropriate, advice and information for persons to whom licences apply or who are receiving treatment services or providing gametes or embryos for use for the purpose of activities governed by the Act, or may wish to do so
  - iv. maintain a statement of the general principles which it considers should be followed in the carrying-on of activities governed by the Act, and in the carrying-out of its functions in relation to such activities

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<sup>1</sup> This foreword is not part of the standing orders.

- v. promote, in relation to activities governed by this act, compliance with requirements imposed by or under this act, and the Code of Practice under Section 25 of the Act, and
  - vi. perform such other functions as may be specified in regulations.
- 6. In accordance with the Act (under Section 8ZA) the HFEA must carry out its functions effectively, efficiently and economically and, so far as relevant, have regard to the principles of best regulatory practice.
- 7. These standing orders take account of the relevant Cabinet Office guidance for public bodies which is intended to secure the public service values of impartiality, integrity, objectivity, openness and accountability, and to ensure that value for money is optimised.
- 8. These standing orders primarily govern the procedures for meetings of the Authority and the committees established by the Authority.
- 9. In the conduct of operational activities, Authority members and employees are also expected to comply with the HFEA's published principles and policies approved by the Authority and employees of the HFEA are, in addition, expected to comply with the requirements set out in the employee handbook.

# Standing orders

Effective 1 April 2016

## **1. Use of standing orders**

### **1.1. Power to make standing orders**

1.1.1. These standing orders are made in accordance with the powers of the HFEA:

- a) under paragraph 9 of Schedule 1 to the Act, to regulate its own proceedings and to make such arrangements as it considers appropriate for the discharge of its functions, and
- b) under section 9A of the Act, to establish committees and to delegate functions to committees, Authority members and employees.

1.1.2. These standing orders shall govern the proceedings of the Authority and its committees and working groups.

### **1.2. Commencement**

1.2.1. These standing orders were adopted by the Authority at its public meeting on 9 December 2009, and first came into force on 1 January 2010.

### **1.3. Variation and amendment of standing orders**

1.3.1. These standing orders can be amended by the Authority, provided that:

- a notice of motion has been given, and
- no fewer than half of the Authority members vote in favour of amendment, and
- at least two-thirds of the Authority members are present, and
- the variation proposed does not contravene any statutory provision, or a direction made by the Secretary of State.

### **1.4. Standing orders to be given to Authority members, committee members and officers**

1.4.1. It shall be the duty of the Chief Executive to ensure that:

- a) existing Authority members, committee members and officers and all new appointees are provided with a copy of these standing orders and informed of their obligation to comply with these standing orders; and
- b) a copy of these standing orders is published on the Authority's website.

### **1.5. Non-compliance with standing orders**

1.5.1. All Authority members, committee members, officers and employees shall have a duty to disclose any non-compliance with these standing orders to the Chair of the HFEA or Chief Executive.

1.5.2. If for any reason these standing orders are not complied with, details of the non-compliance and any justification for non-compliance shall be reported to the next formal meeting of the Authority for action or ratification.

## **1.6. Review of standing orders**

- 1.6.1. These standing orders shall be reviewed at least annually by the Authority. The scope or extent of such a review can be agreed in advance by the Chair, with input from the executive and committee chairs, where relevant.

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## 2. Interpretation

### 2.1. Role of Chair of the Authority

- 2.1.1. The Chair of the HFEA shall be the final authority on the interpretation of these standing orders.

### 2.2. Definition of terms

- 2.2.1. The following terms are used in these standing orders:

‘The Act’ means the Human and Fertilisation and Embryology Act 1990 (as amended).

‘Adviser’ means persons appointed to provide advice to the Authority, its committees or working groups.

‘Advisory group’ means a group of persons appointed to provide advice to the Authority, its committees or working groups.

‘Chair of the HFEA’ means the person appointed by the Secretary of State for Health to chair the HFEA and shall be deemed to include the Deputy Chair of the Authority, if the Chair is absent from the meeting or is otherwise unavailable.

‘Chief Executive’ means the person appointed by the HFEA to act as Chief Officer and Accounting Officer of the Authority.

‘Committee’ means a committee established by the HFEA (under s.9A(2) of the Act).

‘Committee members’ means persons formally appointed by the Chair of the HFEA to sit on or to chair specific committees.

‘Corporate Management Group’ (CMG) means the executive management group established by the Chief Executive for effective management of the HFEA.

‘Deputy Chair of the HFEA’ means the HFEA member appointed by the Secretary of State to take on the Chair’s duties if the Chair of the HFEA is absent for any reason.

‘Lay member’ means a member of the Authority, who is not, nor has been:

- a medical practitioner registered under the Medical Act 1983,
- concerned with keeping or using gametes or embryos outside the body, or
- directly concerned with commissioning or funding any research involving such keeping or use, or actively participated in any decision to do so.

‘Officer’ means a member of the CMG.

‘Secretary of State’ means the Secretary of State for Health.

‘Working group’ means a non-standing committee of the HFEA, established and maintained for a specific purpose.

‘Working group members’ means persons formally appointed by the Chair of the HFEA to sit on or to chair specific working groups.

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## **3. The Authority**

### **3.1. Responsibilities of Authority members**

- 3.1.1. Authority members shall, at all times, act in accordance with the provisions of the Act and with the provisions of the Code of conduct for Authority members annexed to these Standing orders.
- 3.1.2. Authority members shall not give the Chief Executive instructions which conflict with his/her duties as the Authority's accounting officer.
- 3.1.3. No Authority member shall solicit for any person any appointment as a member or employee of the Authority, or recommend any person for such appointment.
- 3.1.4. Authority members shall, as soon as possible, disclose to the Chief Executive any relationship between them and a candidate of whose candidature they become aware. It shall be the duty of the Chief Executive to report to the Authority any such disclosure made.
- 3.1.5. Authority members shall, in the conduct of Authority business, have regard to the functions and duties of the Authority set out in sections 8 and 8ZA of the Act.
- 3.1.6. Authority members shall, in the conduct of Authority business, comply with all relevant legislation applying to public bodies and with government policies on information assurance and data security. In addition, Authority members shall have proper regard to the principles set out in the statutory code of practice for regulators ('The regulators' code').
- 3.1.7. Authority members shall ensure that the financial transactions of the Authority are carried out in accordance with the standing financial instructions and other financial procedures adopted by the Authority.
- 3.1.8. The Authority shall appoint an Authority member to act as equality champion, who will promote compliance with equalities legislation and from time-to-time report to the Authority on it.

### **3.2. Responsibilities of Authority members, committee members and employees**

- 3.2.1. In the conduct of operational activities, Authority members and employees shall comply with applicable policies approved by the HFEA.
- 3.2.2. Authority members, committee members and employees shall ensure compliance with the financial procedures for procurement and payment of goods and services, budget management and travel and subsistence adopted by the Authority.

### **3.3. Particular responsibilities of Chair of the Authority**

- 3.3.1. The Chair of the HFEA shall in addition to the responsibilities shared by all Authority members have particular responsibility for:
  - a) approving the agenda for meetings of the Authority
  - b) chairing meetings of the Authority

- c) signing minutes of Authority meetings
- d) briefing Authority members
- e) ensuring that these Standing orders are complied with
- f) the appraisal of Authority members
- g) the appraisal of the Chief Executive
- h) the appointment of members to committees or working groups
- i) taking decisions on litigation
- j) ensuring a log of whistle blowing incidents is maintained
- k) liaison with the Secretary of State for Health and other relevant Ministers on behalf of the Authority
- l) representing the HFEA to the public, and
- m) issuing 'Chair's letters' to licensed centres setting out changes of policy, the issuing of new directions under the Act, or any other important messages.

3.3.2. The Chair of the HFEA may consult with two or more Authority members as appropriate before discharging the particular responsibilities set out above or before undertaking any action on behalf of the Authority.

### **3.4. Particular responsibilities of Deputy Chair of the Authority**

3.4.1. Where the Chair of the HFEA has died or has ceased to hold office, or where he/she has been unable to perform his/her duties as Chair owing to illness, absence from the UK or any other cause, the Deputy Chair shall act as chair until a new Chair is appointed or the existing Chair resumes his/her duties, as the case may be; and reference to the Chair in these standing orders shall, so long as there is no Chair able to perform his/her duties, be taken to include references to the Deputy Chair.

### **3.5. Particular responsibilities of the Chief Executive**

3.5.1. The Chief Executive is the HFEA's designated accounting officer and, as such, is accountable to Parliament and the Secretary of State for:

- a) safeguarding the public funds for which he/she has been charged
- b) handling those public funds, ensuring propriety and regularity when doing so
- c) day-to-day operations and management of the HFEA.

3.5.2. The Chief Executive shall establish the Corporate Management Group to ensure:

- a) effective management of the HFEA's business and operational activities
- b) achievement of the HFEA's strategic and statutory objectives
- c) continuous improvement within the HFEA, and
- d) monitoring of compliance with applicable legislation, and oversight of executive working groups on particular subjects.

3.5.3. The Chief Executive shall determine the membership and terms of reference of the Corporate Management Group.

### **3.6. Registers of interests and hospitality**

- 3.6.1. The HFEA shall maintain and publish a register of interests and a register of hospitality, formally to record declarations of Authority members and employees.

### **3.7. Declarations of interest and potential conflicts**

- 3.7.1. At every meeting of the Authority or of a committee, members shall be required to declare any interests they may have.
- 3.7.2. Authority members and committee members shall identify any potential conflicts as soon as possible after receipt of papers in advance of any meeting of the Authority or of a committee.
- 3.7.3. Where a potential for a conflict of interests is identified, Authority members and committee members shall consult and follow the 'Guidance for Authority and committee members on handling conflicts of interest'.

### **3.8. Access to external legal advice by Authority members**

- 3.8.1. All external legal advice must usually be commissioned through the Authority's legal advisers and no advice can be commissioned without the approval of the Chair of the HFEA or the Chief Executive.

### **3.9. Register of policies**

- 3.9.1. The Authority shall maintain a register of all policies approved by it and relating to the effective running of the Authority, and shall review all such policies at regular intervals.

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## 4. Meetings

### 4.1. Ordinary meetings

- 4.1.1. Members of the Authority shall usually meet as a full Authority no fewer than six times in each calendar year, and such meetings shall be held at such intervals and venues as the Chair may determine.
- 4.1.2. All ordinary meetings of the Authority will be open to members of the public to attend.
- 4.1.3. All ordinary meetings may begin with a private session of the Authority (which may, at the Chair's discretion, be attended by officers, advisers, auditors or Department of Health representatives), at which may normally be discussed:
- a) the Authority's risk register
  - b) any legal update
  - c) any commercially sensitive matters, and
  - d) any other business that the Chair judges is reasonable to be conducted in private.

### 4.2. Extraordinary meetings

- 4.2.1. In addition to the fixed ordinary meetings, extraordinary meetings of the Authority may be called:
- a) at any time by the Chair, and
  - b) subject to paragraph 4.2.2, at the request of any Authority member.
- 4.2.2. An extraordinary meeting requested by an Authority member shall only be held if:
- a) the request is made in writing to the Chair of the Authority, specifying the item(s) to be considered at the meeting
  - b) the written request is signed by at least one-third of the Authority members, and
  - c) the written request sets out the need for an extraordinary meeting and the reason why the matters to be considered should not be considered at the next ordinary meeting of the Authority.
- 4.2.3. It will be for the Chair to decide whether the extraordinary meeting is held in public or in private.

### 4.3. Written resolutions

- 4.3.1. A written resolution shall be as valid and effectual as if it had been passed at a full meeting of the Authority provided that:
- a) the resolution is circulated by email to all Authority members
  - b) Authority members shall have at least three days to respond to the resolution
  - c) no fewer than one-third of the Authority members respond, and
  - d) the majority of those responding are in favour of, and approve, the resolution.

## 4.4. Notice of meetings and written resolutions

- 4.4.1. Other than in exceptional circumstances, the Chair of the HFEA shall notify Authority members of the dates of the ordinary meetings of the Authority in any calendar year at least one month before the beginning of that year.
- 4.4.2. Failure to serve notice on any Authority member shall not affect the validity of an ordinary meeting.
- 4.4.3. The Chair of the HFEA shall notify Authority members of the date of an extraordinary meeting or written resolution to be considered by the Authority and shall provide Authority members with such notice as is reasonable in the circumstances.

## 4.5. Agendas

- 4.5.1. The Chair of the Authority, in consultation with the Chief Executive, shall determine the agenda for all meetings of the full Authority.
- 4.5.2. An Authority member desiring a matter to be included on an agenda shall make his/her request to the Chair at least 10 working days before the meeting, and should include appropriate supporting information. Requests made less than 10 days before a meeting may be included on the agenda at the discretion of the Chair.
- 4.5.3. Papers may be tabled at a meeting of the full Authority only with the permission of the Chair and no business other than that set out in the agenda shall be considered at a meeting of the Authority, except where the Chair considers that the nature or urgency of the matter is such that it would be desirable to consider the matter at that meeting.
- 4.5.4. Agenda items which are not considered at a meeting may be carried forward for consideration at an appropriate later ordinary meeting, or at an extraordinary meeting.

## 4.6. Distribution of papers

- 4.6.1. The Chief Executive shall endeavour to ensure that agendas and supporting papers (where possible) are sent to Authority members in good time before an Authority meeting, and shall usually send out such papers five working days before the meeting.
- 4.6.2. Agendas and papers may be distributed by such method as the Chief Executive considers appropriate, including by email.
- 4.6.3. Agendas and papers for a meeting, including those sent by email, shall be deemed to have been received on the day following the day they were sent.
- 4.6.4. Provided that the agenda and/or papers for a meeting have been sent to Authority members in accordance with this standing order, their non-receipt by any Authority member shall not invalidate the business transacted at that meeting.
- 4.6.5. Papers for consideration by the full Authority or by a committee shall be presented in the standard template approved by the Chief Executive.

- 4.6.6. The papers considered by Authority members at a meeting of the Authority and the minutes of the meetings of the Authority shall be published in accordance with the HFEA's policy on the publication of Authority and committee papers and shall be made available to the public in accordance with the HFEA's publication scheme and the Freedom of Information Act 2000.

## 4.7. Chair of meeting

- 4.7.1. At any meeting of the Authority, the Chair, if present, shall preside. If the Chair is absent from the meeting, the Deputy Chair shall preside. If the Chair and Deputy Chair are absent, such Authority member as the Authority members present shall choose, shall preside.
- 4.7.2. If the Chair of the HFEA is absent temporarily or is disqualified from participating on the grounds of a declared conflict of interest, the Deputy Chair, if present, shall preside. If the Chair and Deputy Chair are absent, or are disqualified from participating, such Authority member as the Authority members present shall choose, shall preside.
- 4.7.3. The decision of the Chair of the meeting on questions of order, procedure, relevancy, regularity and any other matters shall be final.

## 4.8. Quorum

- 4.8.1. No business shall be transacted at a meeting unless at least one third of the Authority members are in attendance at that meeting.
- 4.8.2. At the discretion of the Chair, Authority members may attend meetings of the Authority by telephone or video-conferencing.
- 4.8.3. In determining whether or not there is a quorum, the Chair shall take into account the provisions of section 4 (4) of Schedule 1 of the Act regarding the composition of the Authority. If the quorum comprises a majority of non-lay Authority members, the Chair of the HFEA may decide that a particular vote or decision cannot be taken. The decision of the Chair on such matters is final.
- 4.8.4. Any Authority member (including the Chair of the Authority) who has been disqualified from participating in the discussion on any matter and/or from voting on any question by reason of the declaration of a conflict of interest shall no longer count towards the quorum. If a quorum is then not available for the discussion and/or the decision on any matter, that matter may not be discussed further or voted upon at that meeting. Such a position shall be recorded in the minutes of the meeting.

## 4.9. Voting

- 4.9.1. The Authority shall usually seek to achieve consensus on issues requiring a decision by the Authority members.
- 4.9.2. Where the Chair determines that a vote is necessary, the nature of that vote shall be at the discretion of the Chair, and may be by oral expression or show of hands or by paper ballot if a majority of the Authority members present so request.

- 4.9.3. Only those Authority members (including the Chair of the Authority) actually in attendance at the time that a vote is to be taken shall be entitled to vote. Voting by proxy is not permitted.
- 4.9.4. Where a vote is held, the issue shall be decided by a majority of the votes of the Authority members who are in attendance at the meeting (including the Chair of the Authority) and who have not been disqualified from participating in the decision by reason of any declared conflict of interest.
- 4.9.5. In the event of the number of votes for and against a motion being equal, the Chair of the meeting shall have a second or casting vote.

## 4.10. Minutes

- 4.10.1. The proceedings of every meeting of the Authority shall be formally recorded. The recording shall be made available on the Authority's website as soon as is reasonably practicable.
- 4.10.2. The Chief Executive shall ensure that an employee is present at every meeting of the Authority to act as secretary to that meeting and to produce the minutes of the meeting.
- 4.10.3. The names of the Chair and Authority members present at the meeting shall be recorded in the minutes.
- 4.10.4. The minutes shall not usually record:
  - a) the names of individual Authority members who made specific comments, contributions or suggestions at a meeting, or
  - b) the vote (or abstention) of individual Authority members.
- 4.10.5. If an Authority member so requests, his/her vote or the fact that he/she abstained from participating in a discussion or voting on any matter, shall be recorded in the minutes.
- 4.10.6. The draft minutes of the proceedings of a meeting of the Authority shall be drawn up and submitted for agreement by the Authority members at the next meeting, and the person chairing that meeting shall sign the minutes with any agreed amendments which may be necessary.

## 4.11. Attendance by officers and auditors

- 4.11.1. The following persons shall be entitled to attend all meetings of the Authority and to bring any matter to the attention of the Authority members:
  - a) Chief Executive
  - b) Corporate Management Group
  - c) internal auditors, and
  - d) external auditors.

## 4.12. Attendance of non-Authority members

- 4.12.1. Observers from the Department of Health and employees of the Authority may attend ordinary meetings of the Authority.
- 4.12.2. At any meeting of the Authority, the Chair may require persons who are not Authority members (including members of the public, officers, other observers, and employees) to withdraw for any part of a meeting, if the Chair considers it desirable for the Authority members to meet in private or in the absence of some of those present.
- 4.12.3. The Chair of the HFEA may require any person whose presence the Chair considers to be disruptive to the proceedings to withdraw from the meeting.
- 4.12.4. The Chair of the HFEA may invite such persons as he or she considers desirable to attend a meeting of the Authority and to advise the Authority members on any matter on the agenda for that meeting.

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## **5. Reservation of powers to the Authority**

### **5.1. List of reserved matters**

- 5.1.1. The following matters shall be reserved to the Authority and shall not be delegated:
- a) appointment of the Chief Executive, with the approval of the Secretary of State
  - b) disciplinary action against the Chief Executive
  - c) approval and amendments of standing orders
  - d) establishing of committees and working groups
  - e) agreement of the terms of reference and reporting arrangements of committees and working groups
  - f) receiving reports from committees, working groups and individual members
  - g) the appointment of HFEA representatives on external bodies
  - h) approving the strategic aims of the HFEA
  - i) approving the HFEA's corporate strategy or any equivalent documentation required by the Department of Health
  - j) approving the HFEA's annual business plan
  - k) approving the annual budget
  - l) approving the annual report and accounts
  - m) (in consultation with the Department of Health and the Treasury) approving the structure and level of fees levied on licence holders and applicants for licences
  - n) monitoring of the HFEA's performance against the annual plan and budget
  - o) determination of all policies relating to the performance of the HFEA's functions under Section 8 of the Act
  - p) approval of the annual update to the Code of Practice and general directions
  - q) ratification of any urgent decisions taken by the Chair in accordance with section 5.2 of these standing orders.

### **5.2. Emergency powers of Chair and Chief Executive**

- 5.2.1. The powers which the Authority has reserved to itself in paragraph 5.1 may, in an emergency, be exercised by the Chair of the HFEA and the Chief Executive.
- 5.2.2. An emergency is any situation in which decisions or actions are required and such decisions or actions cannot be postponed until the next ordinary meeting of the Authority.
- 5.2.3. The Chair of the HFEA shall, before exercising emergency powers under this section, make best endeavours to obtain the views of Authority members on the required decision or action.
- 5.2.4. The exercise of emergency powers by the Chair of the HFEA and the Chief Executive shall be reported to the next meeting of the Authority, and may be ratified by the Authority members.

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## **6. Arrangements for the exercise of functions by delegation**

### **6.1. Power to delegate**

6.1.1. The matters below are delegated in accordance with section 9A of the Act.

### **6.2. Litigation**

6.2.1. Decisions on litigation against or on behalf of the HFEA shall be delegated to the Chair of the HFEA.

6.2.2. Before making a decision on litigation, the Chair of the HFEA may consult with the Deputy Chair of the HFEA and the Chair of the Audit and Governance Committee, or where appropriate, with two other Authority members.

6.2.3. Subject to 6.2.4 below, the Chair of the HFEA shall ensure that Authority members are regularly updated on key decisions and stages reached, in respect of litigation affecting the HFEA.

6.2.4. Where the Chair of the HFEA considers that it would be inappropriate to update Authority members on litigation issues because there are associated matters that are yet to be determined by a committee of the HFEA, including licence applications, the Chair may defer updating Authority members until the associated matters are determined by the relevant committee.

### **6.3. Licensing functions**

6.3.1. The HFEA shall establish the role of Licensing Officer. The HFEA delegates to the Licensing Officer (who shall be an HFEA employee, member of the Executive Licensing Panel and be appointed by the Chief Executive):

a) the exercise of certain administrative licensing functions, as set out in annex B to these standing orders and amended from time to time by the Authority.

6.3.2. The HFEA shall establish and maintain an Executive Licensing Panel. The HFEA delegates to the Executive Licensing Panel:

a) the exercise of certain routine licensing functions (including those delegated to the Licensing Officer), as set out in annex B to these standing orders and amended from time to time by the HFEA, and

b) the power to issue directions under sections 24(5A) to (5E) and section 24(13) of the Act.

6.3.3. The Executive Licensing Panel shall be constituted and shall operate in accordance with the Executive Licensing Panel protocol set out in annex C to these standing orders.

6.3.4. In accordance with Section 9A(2) of the Act, the HFEA shall establish and maintain a Licence Committee which will include Authority members and such additional committee members as the HFEA considers necessary.

6.3.5. The HFEA delegates to the Licence Committee:

- a) the exercise of its complex or controversial licensing functions (but also including those delegated to the ELP and Licensing Officer), as set out in annex B to these Standing orders as amended from time to time by the HFEA, and
  - b) the power to issue directions under sections 24(5A) to (5E) and section 24(13) of the Act.
- 6.3.6. Save when considering representations under Section 19(4) of the Act, the Licence Committee shall be constituted and shall operate in accordance with the Licence Committee protocol set out in annex D to these standing orders.
- 6.3.7. When considering representations under Section 19(4) of the Act, the Licence Committee shall be constituted and shall operate in accordance with the Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal of Licences) Regulations 2009 (as amended).

## 6.4. Reconsideration of licensing decisions

- 6.4.1. In accordance with section 20A of the Act, the HFEA shall establish and maintain an Appeals Committee.
- 6.4.2. The HFEA delegates to the Appeals Committee the power to carry out its functions under section 20 of the Act.
- 6.4.3. The Appeals Committee shall be constituted and shall operate in accordance with the Human Fertilisation and Embryology (Appeals) Regulations 2009.

## 6.5. Disclosure of information for research purposes

- 6.5.1. The HFEA shall establish and maintain:

- a) a Register Research Panel
- b) a Register Research Review Panel, and
- c) an Oversight Committee

to exercise the Authority's functions under the Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010.

- 6.5.2. The Authority delegates to the Register Research Panel, the power to:
- a) authorise access to Register data for the purposes of medical or non-medical research, and
  - b) deny, suspend, revoke, vary or impose conditions upon authorisation to access Register data.
- 6.5.3. The Authority delegates to the Register Research Review Panel, the power to:
- a) uphold or overturn the decisions of the Register Research Panel
  - b) authorise access to Register data for the purposes of medical or non-medical research, and
  - c) deny, suspend, revoke, vary or impose conditions upon authorisation to access Register data.

- 6.5.4. The membership, functions, and arrangement for meetings of the Register Research Panel; Register Research Review Panel; and the Oversight Committee, shall be as set out in annex A to these Standing orders.

## **6.6. Delegation of amendments to the Code of Practice, General Directions and other guidance**

- 6.6.1. The HFEA may agree from time to time to the delegation of revisions to the Code of Practice and general directions.
- 6.6.2. The terms of reference of such delegations shall be approved by Authority members at meetings of the Authority, and the minutes of that meeting shall record the matters delegated by the HFEA.

## **6.7. Delegation to other committees, working groups and individual members**

- 6.7.1. The HFEA may agree from time to time to the delegation of functions and powers to other committees, sub-committees, working groups, or individual members.
- 6.7.2. The constitution and terms of reference of these committees, sub-committees or working groups, and their specific delegated powers and those of any individual member shall be approved by Authority members at meetings of the Authority, and the minutes of that meeting shall record the matters delegated by the Authority.

## **6.8. Delegation to officers**

- 6.8.1. Those functions of the Authority, which have not been reserved by the Authority or delegated to the Chair (in Section 5 of these standing orders); or delegated to a committee, working group, panel, or officer (in Section 6 of these standing orders), shall be exercised by the Chief Executive on behalf of the Authority.
- 6.8.2. The Chief Executive shall determine which functions he/she will perform personally and shall nominate officers or other employees, as appropriate, to undertake the remaining functions for which he/she will retain accountability to the Authority.
- 6.8.3. The Chief Executive shall report periodically to the Authority on the exercise of powers so delegated.

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## **7. Committees, working groups and advisory groups**

### **7.1. Power to establish committees and working groups**

- 7.1.1. In accordance with section 9A(2) of the Act, the Authority shall establish and maintain the committees set out in annex A to these standing orders.
- 7.1.2. In accordance with paragraph 9 of schedule 1, the Authority may from time to time, establish working groups of Authority members and other members as deemed necessary by the Authority.
- 7.1.3. A proposal to establish a working group shall identify the purpose of the group, the likely budget and employee resources needed; the outputs required of the group, and the timeframe for which the group shall exist.
- 7.1.4. The Chief Executive shall ensure that a person is appointed to act as secretary to each Committee or working group and to take the minutes of each meeting.

### **7.2. Membership of committees and working groups**

- 7.2.1. This paragraph does not apply to the Appeals Committee.
- 7.2.2. The Chair of the HFEA shall appoint the Chair of a Committee, committee members and the Chair and members of working groups established by the Authority.
- 7.2.3. The Chair of the HFEA shall only appoint persons who are not Authority members to a committee or working group where the Appointments Committee has agreed that such persons are suitable for appointment to a committee.
- 7.2.4. The remuneration for persons who are not Authority members but who have been appointed as a committee or working group member shall be as agreed from time to time with the Department of Health.
- 7.2.5. The terms of office for members of committees or working groups shall be decided by that committee or working group's Chair, but shall not normally be for more than three years.

### **7.3. Conduct of meetings of committees and working groups**

- 7.3.1. This paragraph does not apply to meetings of the Licence Committee, Executive Licensing Panel or Appeals Committee.
- 7.3.2. Subject to paragraph 7.3.3 and 7.3.4 below, and in accordance with paragraph 9 of schedule 1 to the Act, committees and working groups established by the Authority may regulate their own proceedings.
- 7.3.3. The Chair of the committee or working group shall at each meeting:
  - a) inquire whether any committee or working group member has any interests to declare, and if so, ensure that such interests are recorded
  - b) where potential conflicts are identified, ensure that the committee or working group refers to and follows the 'Guidance for Authority and committee members on handling conflicts of interest'

- c) where appropriate, sign the minutes of any previous meetings with any agreed amendments that may be necessary, and
- d) ensure that the proceedings of the committee or working group comply with the terms of reference and delegated powers set out in Annex A to these standing orders or established by the Authority.

7.3.4. With the permission of the Chair of the committee or working group, committee members may participate in a meeting by the use of telephone- or video-conferencing facilities, or other appropriate means.

## **7.4. Distribution of agenda and papers**

7.4.1. The committee secretary shall send the agenda and papers to all committee or working group members in good time before the meeting, and usually no less than five working days before the meeting.

7.4.2. Papers shall be distributed by such method as is determined by the committee Chair.

## **7.5. Minutes of meetings**

7.5.1. Paragraph 4.10 of these standing orders shall apply with appropriate modifications.

## **7.6. Publication of papers**

7.6.1. The minutes of the meetings of committees shall be published in accordance with the HFEA's policy on the publication of Authority and committee papers and shall be made available to the public in accordance with the HFEA's publication scheme and the Freedom of Information Act 2000.

## **7.7. Advisers and advisory groups**

7.7.1. The Authority delegates to the Chief Executive and his/her Senior Management Team the power to appoint advisers or advisory groups to support committees or working groups, and to determine remuneration necessary (if any) for those appointees.

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## **8. Sealing and execution of documents**

### **8.1. Application of seal**

8.1.1. The application of the Authority's seal shall be authenticated by the signature of the Chair or Deputy Chair of the Authority.

### **8.2. Signing of documents**

8.2.1. The following Authority members and officers shall be authorised to sign deeds or other documents on behalf of the Authority:

- a) Chair of the Authority
- b) Deputy Chair of the Authority
- c) Chief Executive, and
- d) Members of the Corporate Management Group.

### **8.3. Signing of contracts**

8.3.1. Officers and employees shall be authorised to sign contracts on behalf of the Authority in accordance with the authorised delegations for ordering goods and services set out in the financial procedures approved by the Authority.

# Standing orders: Annex A

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**Standing committees and additional committees established by the Authority and their terms of reference**

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## 1. Standing committees of the Authority

- 1.1.** The Authority shall maintain the following standing committees concerned with licensing:
- a) Licence Committee, and
  - b) Appeals Committee.
- 1.2.** The membership and procedures of the Licence Committee (other than when considering representations made under section 19(4) of the Human Fertilisation and Embryology Act 1990) are set out in the 'Protocol for the conduct of meetings of the Licence Committee' (Annex D to the Authority's standing orders).
- 1.3.** The membership and procedures of the Licence Committee when considering representations made under section 19(4) of the Human Fertilisation and Embryology Act 1990 are set out in the Human Fertilisation and Embryology (procedure for revocation, variation or refusal of licences) regulations 2009 (as amended).
- 1.4.** The membership and procedures of the Appeals Committee are set out in the Human Fertilisation and Embryology (appeals) regulations 2009.
- 1.5.** The Authority shall maintain the following additional committees:
- a) Audit and Governance Committee
  - b) Statutory Approvals Committee
  - c) Remuneration Committee
  - d) Appointments Committee
  - e) Scientific and Clinical Advances Advisory Committee, and
  - f) Oversight Committee.
- 1.6.** A report of the activities of the non-licensing standing committees shall be presented to every ordinary meeting of the Authority (if they have met since the last Authority meeting), and presentation of such reports shall be a standing item on the agenda for all ordinary Authority meetings.
- 1.7.** All the Authority's additional standing committees may:
- a) receive expert advice where the committee Chair considers that such advice would assist the committee in its deliberations, and
  - b) sit with a legal adviser in attendance and may allow the legal adviser to remain with the committee during any private deliberations.
- 1.8.** Where an issue is considered by a committee across several meetings, the validity of the proceedings of that committee shall not be affected by reason only that members of that committee,
- a) who were in attendance at a former meeting were not in attendance at a later meeting of the committee, or

- b) who were not in attendance at a former meeting of the committee are in attendance at a later meeting.

**1.9.** The validity of the proceedings of any of the committees shall not be affected by reason only of:

- a) a defect in the appointment of any committee member, or
- b) a vacancy in the membership of that committee.

## **2. The Audit and Governance Committee**

### **Purpose of the committee**

- 2.1.** The purpose of the Audit and Governance Committee is to oversee corporate governance, risk, audit arrangements and financial matters.

### **Delegated powers and functions of the Audit and Governance Committee**

- 2.2.** The Authority delegates to the Audit and Governance Committee, the following powers:

- a) approval of the internal audit programme, and
- b) approval of the statement on internal control or equivalent annual governance statement included in the annual accounts.

- 2.3.** The functions of the Audit and Governance Committee shall be to:

- a) oversee the general corporate governance of the Authority (including supervision and review of the operational effectiveness of the Authority's internal control and risk management procedures)
- b) ensure that the Authority complies with its statutory functions, and with the requirements of the regulators' code, requirements applicable to arm's length bodies, and the principles and best practice guidance issued by the Better Regulation Executive
- c) meet regularly with the Authority's internal and external auditors to ensure that the Authority is complying with statutory requirements and best practice relating to internal control systems risk management, audit, and financial reporting requirements
- d) review the annual financial statements before their submission to the Authority focusing particularly on changes in, and compliance with accounting policies and practices, and
- e) review and manage the effectiveness of the Authority's whistle-blowing policy.

- 2.4.** In particular, the Audit and Governance Committee shall:

- a) review the adequacy of all risk and control related disclosure statements, together with any accompanying statement from the internal auditors, prior to endorsement by the Authority
- b) review the adequacy of structures, processes and responsibilities for identifying and managing key risks facing the Authority
- c) review the adequacy of internal audit policies to ensure compliance with the controls assurance standards and other relevant guidance
- d) review the adequacy of policies and procedures for all work related to fraud and corruption as set out in the Secretary of State directions and as required by the National Health Service Counter Fraud Service
- e) make recommendations to the Authority about the appointment (including renewal) and, where necessary, dismissal of the internal audit service and the audit fee payable

- f) manage the relationship with the external auditor (the Comptroller and Auditor General), and ensure that any chargeable non-audit services provided do not compromise the auditors' independence or objectivity
- g) review the planning, conduct and conclusions of the external audit process (including review of all reports and annual audit letters, together with the associated management responses)
- h) receive reports from the tender panel established in accordance with the financial procedures approved by the Authority, and
- i) receive reports about all consultancy contracts made by the Authority.

**2.5.** In pursuance of these functions, the Authority authorises the Audit and Governance Committee to:

- a) require a review or investigation of any procedures and activities undertaken by the Authority that fall within its remit
- b) obtain from any employee, such information as it considers relevant to the carrying out of its functions (all employees are directed to co-operate with any request made by the Audit and Governance Committee)
- c) obtain such external legal or other professional advice as it considers necessary to enable it to fulfil its functions, and
- d) provide such advice or recommendations to the Chair, the Authority members and the Authority's Chief Executive, as it considers necessary or appropriate.

### **Membership of the Audit and Governance Committee**

**2.6.** The Audit and Governance Committee shall consist of up to five members including:

- a) a Committee Chair (who shall be an Authority member)
- b) a Deputy Committee Chair (who shall be an Authority member)
- c) two persons who shall not be Authority members and who have relevant legal, financial, public sector or other corporate governance expertise.

**2.7.** The Chair of the HFEA shall appoint the members of the Audit and Governance Committee.

**2.8.** Members of the Audit and Governance Committee shall usually be appointed for a term of three years.

### **Meetings of the Audit and Governance Committee**

**2.9.** The quorum for a meeting of the Audit and Governance Committee shall be three, which shall include the Committee Chair or Deputy Committee Chair.

**2.10.** The Audit and Governance Committee shall usually meet no fewer than four times a year.

### **Attendance at meetings of the Audit and Governance Committee**

**2.11.** In addition to members of Audit and Governance Committee, the following persons shall usually attend its meetings:

- a) the Chief Executive (or his delegated representative)
- b) the Director of Finance and Resources
- c) the Head of Corporate Governance
- d) the Committee Secretary
- e) a representative from the Department of Health
- f) a representative from the Authority's internal auditors, and
- g) a representative from the Authority's external auditors.

**2.12.** The Committee Chair may invite such other persons (including employees) as he/she considers appropriate, to attend the meetings of the committee and/or to provide advice to inform the deliberations of the committee.

**2.13.** The Committee Chair may determine when and whether it is necessary or desirable for any non-members of the Audit and Governance Committee to withdraw from the meeting to enable the committee to deliberate in private.

### **3. The Statutory Approvals Committee**

#### **Purpose of the committee**

- 3.1.** The purpose of the Statutory Approvals Committee is to keep under review and to authorise the use of embryo testing; to authorise the use of mitochondrial donation treatment; to issue special directions for the import/export of gametes; and to authorise the use of novel processes in licensed activities.

#### **Delegated powers and functions of the Statutory Approvals Committee**

- 3.2.** The Authority delegates to the Statutory Approvals Committee the following powers:
- a) the authorisation of the use of embryo testing for conditions not previously authorised by the Authority (under schedule 2, paragraph 1ZA(1)(a), (b) and (c) of the Act)
  - b) the authorisation of the use of embryo testing to establish whether the tissue of any resulting child would be compatible with that of a sibling that suffers from a serious medical condition (under schedule 2, paragraph 1ZA(1)(d))
  - c) the authorisation of the use of embryo testing to establish whether an embryo is one of those whose creation was brought about by using the gametes of a particular person (under schedule 2, paragraph 1ZA(1)(e))
  - d) the authorisation of the use of maternal spindle transfer (MST) and/or pronuclear transfer (PNT) for a named patient (under The Human Fertilisation and Embryology (mitochondrial donation) regulations 2015)
  - e) the issuing of special directions for the import/export of gametes or embryos (under section 24 of the Act), and
  - f) the authorisation of the use of novel processes in licensed activities.
- 3.3.** The functions of the Statutory Approvals Committee shall include:
- a) keeping under review the genetic conditions authorised by the Authority for embryo testing.

#### **Membership of the Statutory Approvals Committee**

- 3.4.** The Statutory Approvals Committee shall consist of no more than six members, which shall include:
- a) a Committee Chair (who shall be a lay Authority member)
  - b) a Deputy Committee Chair (who shall be a lay Authority member);
  - c) up to four other Authority members.
- 3.5.** The Chair of the HFEA shall appoint the members of the Statutory Approvals Committee.
- 3.6.** Members of the Statutory Approvals Committee shall usually be appointed for a term of three years.

## Meetings of the Statutory Approvals Committee

- 3.7.** The quorum for a meeting of the Statutory Approvals Committee shall be three including the Committee Chair or Deputy Committee Chair and two other members.
- 3.8.** The Statutory Approvals Committee shall usually meet 12 times per year. At the discretion of the Chair, the committee may meet additionally at short notice (and, if necessary, by telephone- or video-conference) if the Chair considers there is an item (or items) which cannot be delayed until the next meeting.
- 3.9.** No member of the Statutory Approvals Committee present at a meeting shall abstain from voting.
- 3.10.** Decisions of the Statutory Approvals Committee to authorise embryo testing or novel processes, or to issue special directions, require a simple majority (and in the event of a tie, the Committee Chair shall have a casting vote).

## Attendance at meetings of the Statutory Approvals Committee

- 3.11.** In addition to members of the Statutory Approvals Committee, the following persons shall usually attend its meetings:
- a) a legal adviser
  - b) a specialist adviser
  - c) the Head of Corporate Governance
  - d) the Committee Secretary.
- 3.12.** The Committee Chair may invite such other persons (including employees) as he/she considers appropriate, to attend the meetings of the Statutory Approvals Committee and/or to provide advice to inform the deliberations of the Statutory Approvals Committee.
- 3.13.** The Committee Chair may determine when and whether it is necessary or desirable for any non-members of the committee to withdraw from the meeting to enable the committee to deliberate in private.

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## **4. The Remuneration Committee**

### **Purpose of the committee**

- 4.1.** To consider matters relating to remuneration and human resources.

### **Delegated powers and functions of the Remuneration Committee**

- 4.2.** The Authority delegates to the Remuneration Committee the power to approve annual employee pay levels.

- 4.3.** The functions of the Remuneration Committee shall be to:
- a) develop the Authority's pay policy and strategy
  - b) monitor overall levels of remuneration
  - c) review, moderate and approve the remuneration of the Chief Executive and directors, and
  - d) consider human resource issues referred to it by the Chief Executive or Chair of the Authority.

### **Membership of the Remuneration Committee**

- 4.4.** The Remuneration Committee shall consist of three members, which shall include:
- a) a Committee Chair (who shall be the Chair of the Authority)
  - b) a Deputy Committee Chair (who shall be the Deputy Chair of the Authority), and
  - c) the Chair of the Audit and Governance Committee.

### **Meetings of the Remuneration Committee**

- 4.5.** The quorum for a meeting of the Remuneration Committee shall be two.

- 4.6.** The Remuneration Committee shall usually meet at least once a year.

### **Attendance at meetings of the Remuneration Committee**

- 4.7.** The Committee Chair may invite such other persons (including employees) as he/she considers appropriate, to attend the meetings of the Remuneration Committee and/or to provide expert advice to inform the deliberations of the committee.
- 4.8.** The Committee Chair may determine when and whether it is necessary or desirable for any non-members of the Remuneration Committee to withdraw from the meeting to enable the committee to deliberate in private.

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## **5. The Appointments Committee**

### **Purpose of the committee**

- 5.1.** To oversee the appointments of external members contributing to the work of the committees and working groups.

### **Functions of the Appointments Committee**

- 5.2.** The Authority delegates to the Appointments Committee, the following functions:
- a) Advising the Chair of the HFEA on the appointment of all non-Authority members to the committees and working groups
  - b) Monitoring the balance of expertise, experience and backgrounds of committee members in accordance with the purpose and requirements of each committee or working group, and
  - c) Oversight of the Authority's mechanisms for identifying and appointing non-Authority members to the committees and working groups.

### **Membership of the Appointments Committee**

- 5.3.** The Appointments Committee shall consist of three members, which shall include:
- a) a Committee Chair (who shall be the Chair of the Authority)
  - b) a Deputy Committee Chair (who shall be the Deputy Chair of the Authority), and
  - c) the Chair of the Audit and Governance Committee.

### **Meetings of the Appointments Committee**

- 5.4.** The quorum for a meeting of the Appointments Committee shall be two.

- 5.5.** The Appointments Committee shall usually meet at least once a year.

### **Attendance at meetings of the Appointments Committee**

- 5.6.** The Committee Chair may invite such other persons (including employees) as the he/she considers appropriate, to attend the meetings of the Appointments Committee and/or to provide expert advice to inform the deliberations of the committee.
- 5.7.** The Committee Chair may determine when and whether it is necessary or desirable for any non-members of the Appointments Committee to withdraw from the meeting to enable the committee to deliberate in private.

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## **6. The Scientific and Clinical Advances Advisory Committee**

### **Purpose of the committee**

- 6.1.** The purpose of the Scientific and Clinical Advances Advisory Committee is to advise the Authority on scientific and clinical developments (including research) in assisted conception, embryo research and related areas.

### **Functions of the Scientific and Clinical Advances Advisory Committee**

- 6.2.** The functions of the Scientific and Clinical Advances Advisory Committee shall be to:
- a) make recommendations to the Authority on the safety and efficacy of scientific and clinical developments (including research) in assisted conception, embryo research and related areas
  - b) make recommendations to the Authority on patient information relating to those scientific and clinical developments
  - c) advise the Authority on significant implications for licensing and regulation arising out of such developments, and
  - d) where required, work with the Authority members to consider the social, ethical and legal implications arising out of such developments.

### **Membership of the Scientific and Clinical Advances Advisory Committee**

- 6.3.** The Scientific and Clinical Advances Advisory Committee shall consist of five Authority members, which shall include:
- a) a Committee Chair (who shall be an Authority member)
  - b) a Deputy Committee Chair (who shall be an Authority member), and
  - c) three other Authority members.
- 6.4.** In addition, up to eight other persons, who shall not be Authority members, shall be appointed as expert advisers to the committee. Such persons shall not be entitled to vote.
- 6.5.** At least one of the Authority members of the Scientific and Clinical Advances Advisory Committee shall have clinical or scientific expertise.
- 6.6.** The Chair of the HFEA shall appoint the members of the Scientific and Clinical Advances Advisory Committee.
- 6.7.** Members of the Scientific and Clinical Advances Advisory Committee shall usually be appointed for a term of three years. Expert advisers may be appointed for a period of one, two or three years.

## **Meetings of the Scientific and Clinical Advances Advisory Committee**

- 6.8.** The quorum for a meeting of the Scientific and Clinical Advances Advisory Committee shall be three including the Committee Chair or Deputy Committee Chair of the committee.
- 6.9.** The Scientific and Clinical Advances Advisory Committee shall usually meet three times each year.

## **Attendance at meetings of the Scientific and Clinical Advances Advisory Committee**

- 6.10.** The Committee Chair may invite such other persons (including employees) as he/she considers appropriate, to attend the meetings of the Scientific and Clinical Advances Advisory Committee and/or to provide expert advice to inform the deliberations of the committee.
- 6.11.** The Committee Chair may determine when and whether it is necessary or desirable for any non-members of the Scientific and Clinical Advances Advisory Committee to withdraw from the meeting to enable the committee to deliberate in private.

## **7. Oversight Committee**

### **Purpose of the Oversight Committee**

- 7.1.** The purpose of the Oversight Committee is to fulfil the functions set out in the Human Fertilisation and Embryology (disclosure of information for research purposes) regulations 2010 ('the 2010 regulations').

### **Functions of the Oversight Committee**

- 7.2.** The functions of the Oversight Committee shall be to:
- a) monitor the grant of authorisations to access Authority Register data made under the Human Fertilisation and Embryology (disclosure of information for research purposes) regulations 2010
  - b) monitor the processing of patient-, partner- and child-identifying Register data by research establishments
  - c) consider annual reports submitted by research establishments
  - d) consider such other matters relating to the 2010 regulations as the committee determines
  - e) oversee the functions of the Register Research Panel and the Register Research Review Panel
  - f) make recommendations to the Register Research Panel and the Register Research Review Panel about improvements to processes and the operation of the panels
  - g) approve any memorandum of understanding (MoU) or any contractual arrangements between the Authority and other public bodies with an interest in the safeguarding of personal information in the United Kingdom where these relate to the disclosure of Authority Register data for research purposes, and
  - h) approve variations of and amendments to such MoUs, contracts and agreements.

### **Membership of the Oversight Committee**

- 7.3.** The Authority is the Oversight Committee and, when performing the statutory functions of the Oversight Committee as set out in regulation 21 of the Human Fertilisation and Embryology (disclosure of information for research purposes) regulations 2010, the relevant sections of the standing orders will apply.

### **Meetings of the Oversight Committee**

- 7.4.** The quorum for a meeting of the Oversight Committee shall be four.

- 7.5.** The Oversight Committee shall consider an overview report submitted by the Register Research Panel at least once a year.

### **Attendance at meetings of the Oversight Committee**

- 7.6.** The Chair of the HFEA may invite such other persons (including non-Authority members and representatives from the Department of Health) as he/she considers appropriate, to attend the

meetings of the Oversight Committee and/or to provide expert advice to inform the deliberations of the committee.

- 7.7.** The Chair of the HFEA may determine when and whether it is necessary or desirable for any non-members of the Oversight Committee to withdraw from the meeting to enable the committee to deliberate in private.

## **8. Executive Panels concerned with Disclosure of Information for Research Purposes**

### **Register Research Panel**

#### **Purpose of the Register Research Panel**

- 8.1.** The purpose of the Register Research Panel is to consider applications made under the Human Fertilisation and Embryology (disclosure of information for research purposes) regulations 2010 ('the 2010 regulations').

#### **Delegated powers and functions of the Register Research Panel**

- 8.2.** The Authority delegates to the Register Research Panel, the power to:
- a) authorise access to Register data for the purposes of medical or non-medical research, and
  - b) deny, suspend, revoke, vary or impose conditions upon authorisation to access Register data.
- 8.3.** The functions of the Register Research Panel shall be to:
- a) comply with the requirements of the 2010 regulations
  - b) review annual reports submitted by research establishments
  - c) publish lay summaries of research projects involving the use of Authority Register data
  - d) submit a report to the Authority's Oversight Committee about the work of the Register Research Panel not less than once a year
  - e) refer appeals against the decisions of the Register Research Panel to the Register Research Review Panel, and
  - f) liaise and collaborate with any appropriate bodies in the UK with an interest in the safeguarding of personal data and the oversight of research studies involving the linkage of complex datasets.

#### **Membership of the Register Research Panel**

- 8.4.** The Register Research Panel shall consist of:
- a) the Director of Compliance and Information, who will act as the Chair of the Register Research Panel
  - b) the Authority's Caldicott Guardian, and
  - c) the Head of Information Technology.

#### **Meetings of the Register Research Panel**

- 8.5.** The quorum for a meeting of the Register Research Panel shall be three.

**8.6.** Meetings of the Register Research Panel will be scheduled as required and in accordance with any memorandum of understanding between the Authority and bodies responsible for national information governance.

**8.7.** Meetings of the Register Research Panel will be private.

#### **Attendance at meetings of the Register Research Panel**

**8.8.** In addition to the Chair and members of the Register Research Panel, such other employees as the Chair considers necessary may attend the meetings of the Register Research Panel.

**8.9.** The Chair of the Register Research Panel may invite such other persons (including non-Authority members and representatives from the Department of Health) as the Chair considers appropriate, to attend the meetings of that panel and/or to provide expert advice to inform the deliberations of the panel.

#### **Register Research Review Panel**

##### **Purpose of the Register Research Review Panel**

**8.10.** To consider appeals against the decisions of the Register Research Panel in accordance with Regulation 12 of the 2010 Regulations.

##### **Delegated powers and function of the Register Research Review Panel**

**8.11.** The Authority delegates to the Register Research Review Panel, the power to:

- a) uphold or overturn the decisions of the Register Research Panel
- b) authorise access to Register data for the purposes of medical or non-medical research, and
- c) deny, suspend, revoke, vary or impose conditions upon authorisation to access Register data.

##### **Membership of the Register Research Review Panel**

**8.12.** The Register Research Review Panel shall consist of:

- a) the Chief Executive, who will act as the Chair of the Register Research Review Panel, and
- b) the Senior Information Risk Owner (SIRO) of the Authority.

##### **Meetings of the Register Research Review Panel**

**8.13.** Meetings of the Register Research Review Panel shall be scheduled as required following receipt of an appeal against the decisions of the Register Research Panel.

##### **Attendance at meetings of the Register Research Review Panel**

**8.14.** In addition to the Chair and members of the Register Research Review Panel, such other employees as the Chair considers necessary may attend the meetings of the Register Research Review Panel.

- 8.15.** The Chair of the Register Research Review Panel may invite such other persons (including non-Authority members and representatives from the Department of Health) as the Chair considers appropriate, to attend the meetings of that panel and/or to provide expert advice to inform the deliberations of the panel.

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## Standing orders: Annex B

### Instrument of delegation in respect of Authority licensing functions

#### 1. Licensing functions delegated to a Licensing Officer

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Consideration of the following variations of licences on application (under Section 18A(2) of the Act):

- change of licence holder, and
  - change of a centre's name or address.
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Consideration of applications for voluntary revocation of licences under Section 18(1) of the Act

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#### 2. Licensing functions delegated to the Executive Licensing Panel

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**All powers delegated to a Licensing Officer in table 1, above, plus:**

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Consideration of applications for initial licences for treatment, storage and provision of non-medical fertility services, and exercise of the Authority's power to grant such licences under section 16 of the Act.

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Consideration of applications for the renewal of licences for treatment, storage and provision of non-medical fertility services, and exercise of the Authority's power to grant such licences under section 16 of the Act.

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Consideration of renewal applications for research licences, which the Licence Committee has not reserved to itself for consideration or which do not raise complex or controversial issues, and exercise of the Authority's power to grant such licences under section 16 of the Act.

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Consideration of interim inspections reports (treatment and/or storage, and research).

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The following variation of licences either on application or otherwise:-

- change of Person Responsible (under section 18A(1) of the Act)
  - changes to licensed activities (under section 18A(2) of the Act), and
  - change of a centre's premises (under section 18A(2) of the Act).
- 

Authorisation to undertake HLA tissue typing for genetic conditions previously authorised by the Authority.

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Consideration of reports of random unannounced inspections.

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Consideration of reports of targeted inspections.

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Consideration of executive proposals to place non-standard conditions on licences and exercise of the Authority's power to issue notices under section 19 of the Act.

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Exercise of the Authority's power to issue directions under sections 24(5A) to (5E) and 24(13) of the Act.

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### 3. Licensing functions delegated to Licence Committee in relation to research licences

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**All powers related to research licences delegated to a Licensing Officer in table 1 and Executive Licensing Panel in table 2, above, plus:**

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Consideration of applications for initial research licences and exercise of the Authority's power to grant such licences under section 16 of the Act.

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Consideration of renewal applications for research licences and exercise of the Authority's power to grant such licences under section 16 of the Act.

---

Consideration of Grade A incidents and, where appropriate, Grade B incidents.

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Consideration of executive proposals to revoke/suspend licences and exercise of the Authority's powers to revoke/suspend licences in accordance with sections 18(1) and (2) and 19(c) of the Act.

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Consideration of representations under section 19(4) of the Act.

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Exercise of the Authority's powers to vary a licence in accordance with section 18A of the Act.

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Exercise of the Authority's power to issue notices under section 19 of the Act.

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### 4. Licensing decisions delegated to Licence Committee relating to treatment and/or storage licences

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**All powers delegated to a Licensing Officer in table 1 and Executive Licensing Panel in table 2, above, plus:**

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Consideration of applications for initial licences for treatment, storage and provision of non-medical fertility services, and exercise of the Authority's power to grant such licences under section 16 of the Act.

---

Consideration of Grade A incidents and, where appropriate, Grade B incidents.

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Consideration of executive proposals to revoke/suspend licences and exercise of the Authority's powers to revoke/suspend licences in accordance with sections 18(1) and (2) and 19(c) of the Act.

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Consideration of representations under section 19(4) of the Act.

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Exercise of the Authority's powers to vary a licence in accordance with section 18A of the Act.

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## Standing orders: Annex C

### Protocol for the conduct of meetings of the Authority's Executive Licensing Panel

This Protocol is made by the Authority in accordance with its powers under paragraph 9 of Schedule 1 to the Human Fertilisation and Embryology Act 1990 (as amended) ('the Act') to regulate its own proceedings; its duty as a public body to comply with the Human Rights Act 1998; its common law duties and powers to ensure fairness in its procedures; and its duties under paragraph 8.4 of the statutory code of practice for regulators to enforce in a transparent manner, and to be transparent in the way in which it applies and determines penalties.

This protocol aims to ensure fairness and consistency in the proceedings before the Authority's Executive Licence Panel ('the panel') and should be followed save where fairness requires otherwise.

The panel shall retain the power and duty to take such action, (provided always that any action is consistent with the requirements of the Act) as they consider appropriate and necessary to ensure fairness in a particular matter.

This protocol was approved by the Authority on 9 September 2009.

#### 1. Composition and function of the panel

1.1. The Authority shall maintain an Executive Licensing Panel.

1.2. The function of the panel is to:

perform the Authority's licensing functions under the Act in accordance with the delegated powers specified in the Authority's Standing orders, and

promote compliance with the requirements of the Act and the Code of Practice issued by the Authority.

1.3. In making its decisions, the panel shall have regard to relevant policies and guidance approved by the Authority.

1.4. The panel shall consider matters on the papers at a meeting in accordance with the provisions of this Protocol.

1.5. The panel shall consist of a Chair and Deputy Chair (or Deputy Chairs) and a pool of employees, appointed by the Chief Executive from amongst the employees of the Authority. In the absence of the Chair of the Panel, a Deputy Chair or other person nominated by the Chair of the Panel may act as Chair of the Panel.

1.6. The panel shall sit with three members at each meeting.

1.7. No member of the panel present at a meeting shall abstain from voting.

1.8. Decisions of a panel shall be taken by simple majority and the Chair of the Panel shall not have a casting vote.

1.9. Members of the panel shall attend regular training and update sessions on human rights and regulatory law, and matters relating to the provision of fertility treatment.

## 2. Advisers to committees

- 2.1. Where the Chair of the Panel considers it appropriate, the panel may seek written advice from a legal, clinical or specialist adviser before making its decision.
- 2.2. The Chair of the Panel shall ensure that the applicant, the proposed or actual person responsible, licence holder or person whose licence is under consideration is afforded a reasonable opportunity to comment on any written advice received by the panel before the panel makes its decision.
- 2.3. Where the Chair of the Panel considers it appropriate, the panel may sit with a legal adviser in attendance. Any advice provided in the course of a meeting shall be recorded in the minutes.
- 2.4. Where the panel does not accept the advice tendered by an adviser, the Chair of the panel should ensure that:
  - a) a written record is kept of the advice tendered, and the reasons why the panel refused to accept that advice, and
  - b) the written record is sent to the person concerned, together with the decision of the panel, and the reasons for its decision.

## 3. Secretary to the panel

- 3.1. A secretary shall be present at every meeting of the panel.
- 3.2. The function of the secretary shall be to make all administrative arrangements necessary for the proceedings of the panel to be effective, and to keep a record of:
  - a) the panel's decision and of the reasons for such decision
  - b) any advice tendered by a legal, clinical or specialist adviser, and
  - c) any declarations of interest (or potential conflicts of interest) made by a member of the panel during the proceedings.
- 3.3. The secretary shall not participate in the decision making of the panel (and is not entitled to vote).

## 4. Determination of agenda items

- 4.1. In determining the agenda for the panel, the relevant officers shall have regard to the instrument of delegation set out in Annex B to the Authority's standing orders.
- 4.2. Where the relevant officers are unsure whether a matter should be placed on the agenda of the panel or on the agenda of the Licence Committee, the presumption should be that the matter should be placed on the agenda of the panel. Where necessary, the Chair of the panel should be consulted.

## 5. Conduct of meeting

- 5.1. The panel shall consider matters on the papers.
- 5.2. Subject to paragraph 5.3, only the Chair and members of the panel, the secretary, and the Head of Corporate Governance may be present at a meeting of the panel.

- 5.3. Employees of the Authority who have been appointed to the panel, or an external lawyer or auditor charged by the Authority with audit and evaluation of the effectiveness of the panel may attend a meeting of the panel as observers, or as part of their induction training. However, such observers shall not take any part in the discussion or deliberation of the panel, and are not entitled to vote.

## 6. Documents before the panel

- 6.1. At each meeting, the panel shall have access to:
- a) this protocol
  - b) relevant edition(s) of the HFEA Code of Practice
  - c) the Human Fertilisation and Embryology Act 1990 (as amended)
  - d) the Human Fertilisation and Embryology (research purposes) regulations 2001 (where relevant)
  - e) General directions 0008 (where relevant), and any other relevant directions issued by the Authority
  - f) any relevant decision trees and explanatory notes approved by the Authority
  - g) 'Guidance for Authority and committee members on handling conflicts of interest'
  - h) 'Guidance on licensing' (where relevant)
  - i) the licence application (where relevant) and any relevant documentation in support of the application from the applicant and/or proposed person responsible for the centre to be licensed
  - j) the recommendation of the Authority's inspector dealing with the matter and any relevant supporting documentation (usually including three years' worth of a centre's licensing history, as appropriate, and in the case of applications for a research licence, any relevant academic literature and advice from the Authority's Scientific and Clinical Advances Advisory Committee)
  - k) the compliance and enforcement policy.
- 6.2. The panel shall not usually receive the recommendation of the Authority's inspector dealing with the matter or any relevant supporting documentation from that inspector, unless the applicant or person concerned (as appropriate) has been provided with a reasonable opportunity to comment on this material beforehand.

## 7. Panel papers

- 7.1. The secretary shall usually send the papers for a meeting of the panel to the Chair and members of the panel scheduled to attend the meeting, seven days in advance of the meeting.
- 7.2. Upon receipt of the papers, members of the panel must identify any potential conflicts of interest as soon as possible.
- 7.3. Where an actual or potential conflict is identified, members must inform the Chair of the panel and the secretary as soon as possible, and the procedure set out in the 'Guidance for Authority and committee members on handling conflicts of interest' shall be followed in deciding whether or not a conflict exists.

- 7.4. No member of the panel shall consider a matter if that member has an actual or potential conflict of interest in relation to that matter.
- 7.5. Members of the panel shall read the papers thoroughly in advance of the meeting and shall refrain from discussing matters to be considered by the panel with anyone except the other members of the panel, at the panel meeting.
- 7.6. Members of the panel shall only discuss panel business and the papers to be considered by the panel when the panel is in session.

## **8. Procedure to be followed at the meeting**

- 8.1. Before any papers are considered by the panel, the Chair of the panel should:
- a) check that the panel is quorate, and
  - b) ask for declarations of interest from each member.
- 8.2. Any interests declared should be noted and recorded by the secretary.
- 8.3. Where a potential or actual conflict is identified, the panel should follow the procedure set out in the 'Guidance for Authority and committee members on handling conflicts of interest'.
- 8.4. Each item on the agenda should be considered separately.
- 8.5. Where the panel is considering an application to grant or renew a licence, the Chair should direct the members of the panel to consider the requirements of section 16 of the Act.
- 8.6. In making its decision, the panel may be aided by the relevant decision tree. Each stage of the decision tree should be considered separately, and in order.
- 8.7. Before the panel makes its decision, the Chair may adjourn to:
- a) seek the advice of a legal, clinical or specialist adviser, and
  - b) require further information from the applicant or person responsible for the centre to be licensed (as appropriate), or from the Authority's inspector dealing with the matter.
- 8.8. In accordance with section 16(4) of the Act, where the panel considers that the information provided with an application is insufficient to enable it to determine that application, it need not consider the application until the applicant has provided it with such further information as the panel may require.

## **9. Decision to be taken by the panel**

### **Applications to grant a licence (for the purposes of the panel, this covers renewal applications only)**

- 9.1. On each application before it, the panel must decide:
- a) whether the requirements of section 16 of the Act have been satisfied, and if so, whether to make a proposed decision to grant (renew) the licence

- b) if the proposed decision is for the licence is to be granted (renewed), whether it is on the same or different terms, including whether any additional conditions should be attached to the licence in addition to the standard licence conditions, and
  - c) if the proposed decision is for the licence is to be granted (renewed), for what period that new licence is to be granted.
- 9.2. In determining the period of any licence to be granted (renewed), the panel should consider the indicative applications guidance.

### **Particular requirements for applications authorising embryo testing**

- 9.3. Before the panel can grant an application authorising the testing of embryos, it must consider the requirements of paragraph 1ZA of schedule 2 to the Act.
- 9.4. Where the application seeks authorisation for the testing of an embryo in circumstances in which there is a particular risk that an embryo may have a gene, chromosome or mitochondrion abnormality, the panel must consider the requirement of paragraph 1ZA(2) of schedule 2 to the Act. In particular, the panel must be satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition.

## **10. Procedure for adding non-standard conditions and for refusal, variation or revocation of licence**

- 10.1. If the panel is minded to refuse an application to grant, revoke or vary a licence, or minded to grant a licence subject to non-standard conditions, it must follow the procedure in section 19(1) of the Act.
- 10.2. If the panel is minded to revoke a licence on application, it must follow the procedure in section 19A(2) of the Act.
- 10.3. If the panel is minded to vary or revoke a licence otherwise than on application, it must follow the procedure in section 19(2) of the Act.
- 10.4. If the panel is minded to vary a licence otherwise than in accordance with the application, it must follow the procedure in section 19(3) of the Act.
- 10.5. In all cases where the panel has refused, varied or revoked a licence otherwise than on application, it must issue a notice under section 19A (4) and (5) of the Act.
- 10.6. After issuing any notice under section 19A (4) and (5) of the Act, the panel must refer the matter to the Licence Committee for consideration and have no further dealings with the matter.

## **11. Reasons for the panel's decision**

- 11.1. The panel shall give reasons for each decision that it makes. These reasons must be recorded in the minutes.
- 11.2. The reasons shall set out:
- a) any relevant findings of fact made by the panel

- b) any matters taken into account by the panel (including any advice received from a legal, clinical, scientific or specialist adviser), and
  - c) why the panel reached its decision.
- 11.3. Additionally, in the case of applications to authorise embryo testing for gene, chromosome or mitochondrion abnormalities, the reasons must set why the panel is satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition, and why the disability/illness/condition is considered to be serious.
- 11.4. The reasons should tell the person concerned in broad terms why the decision was reached, and may in some circumstances require an explanation of why a particular argument was rejected.
- 11.5. Where additional conditions have been proposed the reasons should indicate why the panel considers this course of action to be a proportionate response to any concerns identified from the papers before it.
- 11.6. The reasons should refer to the indicative applications guidance and indicative sanctions guidance where relevant.

## 12. Postponements and adjournments of meetings

- 12.1. The Chair may, of his or her own motion, or upon the application of a party to the proceedings, postpone any meeting of which notice has been given before such meeting begins.
- 12.2. The Chair may, of his or her own motion, adjourn the proceedings at any stage.
- 12.3. In considering whether or not to grant a request for postponement, or to adjourn, the Chair of the Panel should, amongst other matters, have regard to:
- a) the public interest in the expeditious disposal of the proceedings
  - b) fairness to the parties, and
  - c) the conduct of the person seeking the postponement or adjournment.
- 12.4. Where the proceedings have been postponed or adjourned, the secretary should, as soon as practicable, notify the parties of the date and time of the postponed or resumed meeting.

## 13. Burden and standard of proof

- 13.1. The Authority's inspector dealing with the matter should bear the burden of establishing that a licence should be revoked, varied (otherwise than on an application) or that a licence should be suspended.
- 13.2. The person to whom the notice under section 19(1) is given should bear the burden of establishing that a licence should not be refused or additional conditions should not be imposed.
- 13.3. Where facts are in dispute, the panel should consider whether they have been established in accordance with the civil standard of proof.
- 13.4. Where the panel considers that a finding on disputed facts can only be made after oral evidence is heard, it shall refuse the application and issue a notice of proposal under section 19; invite the person to whom the notice is addressed to make oral representations to the Licence Committee

and refer the matter for a hearing to be held in accordance with the Human Fertilisation and Embryology Act (procedure for revocation, variation or refusal of a licence) regulations 2009 (as amended).

## **14. Evidence at meetings**

- 14.1. The panel may receive any written or real evidence whether or not such evidence would be admissible in a civil court of law in England and Wales, provided that it is satisfied that such evidence is relevant to the issues on which it has to make a decision, and that it is fair to admit such evidence.
- 14.2. The panel shall have regard to the Code of Practice in the circumstances set out in section 25(6) of the Act.

## **15. Directions**

- 15.1. The Authority has delegated to the panel the power to issue directions under sections 24(5A) to (5E) and 24(13) of the Act.
- 15.2. When:
  - a) postponing or adjourning the consideration of a matter
  - b) making a proposed decision to refuse, vary, suspend or revoke a licence, or
  - c) considering evidence of an adverse incident or non-compliance with the Act, Code of Practice, licence conditions or directions issued by the Authority,the panel should consider whether or not to issue directions under section 24 of the Act.

## **16. Evaluation and report to the Authority**

- 16.1. The Chair of the panel shall hold regular periodic meetings for the purpose of reviewing decisions made by the panel to ensure consistency in the panel's decision making processes.
- 16.2. The Chair of the panel shall present a report to the Chair of the Licence Committee at six monthly intervals detailing the activities of the panel and identifying trends and feedback for the sector.
- 16.3. The Chair of the Executive Licensing Panel shall prepare an annual written report to the Authority detailing the activities of the panel (see also the equivalent paragraph for Licence Committee).

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## Standing orders: Annex D

### Protocol for the conduct of meetings of the Licence Committee

This Protocol is made by the Authority in accordance with its powers under paragraph 9 of Schedule 1 to the Human Fertilisation and Embryology Act 1990 (as amended) ('the Act') to regulate its own proceedings; its duty as a public body to comply with the Human Rights Act 1998; its common law duties and powers to ensure fairness in its procedures; and its duties under paragraph 8.4 of the statutory code of practice for regulators to enforce in a transparent manner, and to be transparent in the way in which it applies and determines penalties.

This protocol aims to ensure fairness and consistency in the proceedings before the Authority's Licence Committee and should be followed save where fairness requires otherwise.

The Licence Committee shall retain the power and duty to take such action, (provided always that any action is consistent with the requirements of the Act) as they consider appropriate and necessary to ensure fairness in a particular matter.

This protocol was approved by the Authority on 9 September 2009 and adopted by the chairs of the Authority's Licence and Research Licence Committees on the same date.

## 1. Composition and function of the Committee

- 1.1. The Authority shall maintain a Licence Committee.
- 1.2. The function of the Licence Committee is to:
  - a) perform the Authority's licensing functions under the Act in accordance with the delegated powers specified in the Authority's standing orders, and
  - b) promote compliance with the requirements of the Act and the Code of Practice issued by the Authority.
- 1.3. In making its decisions, the Licence Committee shall have regard to policies approved by the Authority, and where relevant, to the indicative applications guidance and indicative sanctions guidance.
- 1.4. Save where a Licence Committee is considering representations in accordance with section 19 of the Act, it shall consider matters on the papers at a meeting in accordance with the provisions of this protocol.
- 1.5. Where a Licence Committee is considering representations made under section 19(4) of the Act, it shall follow the procedure set out in the Human Fertilisation and Embryology (procedure for revocation, variation or refusal of licences) regulations 2009 (as amended).
- 1.6. The Licence Committee shall consist of no more than six members including a Chair and Deputy Chair, appointed by the Chair of the Authority. In the absence of the Committee Chair, the Deputy Chair or other person nominated by the Chair of the HFEA may act as Committee Chair.
- 1.7. The quorum for a meeting of the Licence Committee shall be three.
- 1.8. No member of a Licence Committee present at a meeting shall abstain from voting.
- 1.9. Decisions of a Licence Committee shall be taken by simple majority (and the Chair of a Licence Committee shall not have a casting vote).

- 1.10. Where there is a tied vote:
- a) in the case of an application for a licence, that application shall not be granted
  - b) in the case of a proposal to impose non-standard conditions on a licence, or to vary, suspend or revoke a licence, that proposal shall not succeed, and
  - c) in any other case, the motion under consideration by the Licence Committee shall not be passed.
- 1.11. Members of the Licence Committee shall attend regular training and update sessions on human rights and regulatory law, and matters relating to the provision of fertility treatment.

## **2. Advisers to the Committee**

- 2.1. A legal adviser shall be present at every meeting of the Licence Committee.
- 2.2. Where the Chair of the Licence Committee considers it appropriate, a clinical, scientific or specialist adviser may be present at a meeting or hearing of that Committee.
- 2.3. The function of an adviser to a Committee shall be to:
- a) advise that committee on any areas within the adviser's expertise, and
  - b) intervene to advise that committee on an issue where it appears that without an intervention there is the possibility of an error being made.
- 2.4. With the consent of the Chair of the Licence Committee, an adviser who is present at a meeting of that committee may be present during the private deliberations of the committee, but the adviser shall not participate in the decision making of that committee (and is not entitled to vote).
- 2.5. The Chair of the Licence Committee shall ensure that a written record is kept of any advice tendered to the committee by an adviser.
- 2.6. The Chair of the Licence Committee shall also ensure that a written record is kept of any interventions made by an adviser during the private deliberations of that committee.
- 2.7. The Chair of the Licence Committee shall ensure that a copy of any advice tendered by an adviser to that committee is sent to the parties to the proceedings.
- 2.8. Where any advice tendered by an adviser to the Licence Committee is not accepted by that committee:
- a) the committee Chair shall ensure that a written record is kept of the advice tendered, and the reasons why the committee refused to accept that advice; and
  - b) a copy of the record of the advice tendered and the reasons why the committee refused to accept that advice should be sent to the parties to the proceedings.

## **3. Executive support to the committee**

- 3.1. A secretary shall be present at every meeting of the committee.
- 3.2. The function of the secretary shall be to make all administrative arrangements necessary for the proceedings of the Licence Committee to be effective, and to keep a record of:

- a) the committee's decision and the reasons for such decision
- b) any advice tendered by a legal, clinical, scientific or specialist adviser (and any interventions made by them when they are present during the private deliberations of the committee), and
- c) any declarations of interest (or potential conflicts of interest) made by a member of the committee during the proceedings.

3.3. The secretary shall not participate in the decision making of the committee (and is not entitled to vote).

3.4. The Head of Corporate Governance shall usually be present at every meeting of the committee. At the conclusion of every meeting of the Licence Committee, the Head of Corporate Governance shall collate feedback from the Chair and members of the committee on matters that the Chair considers should be brought to the attention of the Authority's Director of Compliance and Information.

## 4. Determination of agenda items

4.1. In determining the agenda for a committee, the relevant officers shall have regard to the instrument of delegation set out in Annex B to the Authority's Standing orders.

4.2. Where the relevant officers are unsure whether a matter should be placed on the agenda of a committee or on the agenda of the Executive Licensing Panel, the presumption should be that the matter should be placed on the agenda of the panel. Where necessary, the committee Chair should be consulted.

## 5. Conduct of meeting

5.1. The Licence Committee shall consider matters on the papers.

5.2. Subject to paragraph 5.3 only the Chair and members of the committee, the Head of Corporate Governance and the secretary, and advisers to that committee may be present at the meeting of the committee.

5.3. Members of the Licence Committee, or employees who have been appointed to the Executive Licensing Panel, may attend a meeting of the committee as observers, or as part of their induction training. However, such observers shall not take any part in the discussion or deliberation of the committee, and are not entitled to vote.

## 6. Documents before the committee

6.1. At each meeting, the Licence Committee shall have access to:

- a) this protocol
- b) relevant edition(s) of the HFEA Code of Practice
- c) the Human Fertilisation and Embryology Act 1990 (as amended)
- d) the Human Fertilisation and Embryology (Research Purposes) Regulations 2001 (where relevant)
- e) direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- f) any relevant decision trees and explanatory notes approved by the Authority

- g) guidance for Authority and committee members on handling conflicts of interest
- h) 'guidance on licensing' (where relevant)
- i) the licence application (where relevant) and any relevant documentation in support of the application from the applicant and/or proposed person responsible for the centre to be licensed
- j) the recommendation of the Authority's inspector dealing with the matter and any relevant supporting documentation (usually including three years' worth of a centre's licensing history as appropriate, and in the case of applications for a research licence, any relevant academic literature and advice from the Authority's Scientific and Clinical Advances Advisory Committee)
- k) the compliance and enforcement policy.

6.2. The Licence Committee shall not usually receive the recommendation of the Authority's inspector dealing with the matter or any relevant supporting documentation from that inspector, unless the applicant or person concerned (as appropriate) has been provided with a reasonable opportunity to comment on this material beforehand.

## 7. Committee papers

- 7.1. The secretary shall usually send the papers for a meeting of the Licence Committee to the Chair and members of that committee seven days in advance of the meeting.
- 7.2. Upon receipt of the papers, members of the committee must identify any potential conflicts of interest as soon as possible.
- 7.3. Where an actual or potential conflict is identified, members must inform the committee Chair and the secretary as soon as possible, and the procedure set out in the 'Guidance for Authority and committee members on handling conflicts of interest' shall be followed in deciding whether or not a conflict exists.
- 7.4. No member of the Licence Committee shall consider a matter if that member has an actual or potential conflict of interest in relation to that matter.
- 7.5. Members of the committee shall read the papers thoroughly in advance of the meeting and shall refrain from discussing matters to be considered by the committee with anyone except the other members of the committee, at the committee meeting.
- 7.6. Members of the committee shall only discuss committee business and the papers to be considered by the committee when the committee is in session.

## 8. Procedure to be followed at the meeting

- 8.1. Before any papers are considered by the Licence Committee, the Committee Chair should:
  - a) check that the committee is quorate, and
  - b) ask for declarations of interest from each member.
- 8.2. Any interests declared should be noted and recorded by the secretary.
- 8.3. Where a potential or actual conflict is identified, the Committee Chair should follow the procedure set out in the 'Guidance for Authority and committee members on handling conflicts of interest'.

- 8.4. Each item on the agenda should be considered separately.
- 8.5. Where the committee is considering an application to grant or renew a licence, the Chair should direct the members of the committee to consider the requirements of section 16 of the Act.
- 8.6. In making its decision, the committee may be aided by the relevant decision tree. Each stage of the decision tree should be considered separately, and in order.
- 8.7. Before the committee makes its decision, the Chair may adjourn to:
- a) seek the advice of a legal, clinical or specialist adviser, and
  - b) require further information from the applicant or person responsible for the centre to be licensed (as appropriate), or from the Authority's Inspector dealing with the matter.
- 8.8. In accordance with section 16(4) of the Act, where the committee considers that the information provided with an application is insufficient to enable it to determine that application, it need not consider the application until the applicant has provided it with such further information as the committee may require.

## **9. Decision to be taken by the committee**

### **Applications to grant a licence (including renewals)**

- 9.1. On each application before it, the committee must decide:
- a) whether the requirements of section 16 of the Act have been satisfied, and if so, whether to make a proposed decision to grant (renew) the licence
  - b) if the proposed decision is for the licence to be granted (renewed), whether it is on the same or different terms, including whether any additional conditions should be attached to the licence in addition to the standard licence conditions, and
  - c) if the proposed decision is for the licence to be granted (renewed), for what period that new licence is to be granted.
- 9.2. In determining the period of any licence to be granted (renewed), the committee should consider the indicative applications guidance.

### **Particular requirements for applications authorising embryo testing**

- 9.3. Before the Licence Committee can grant (or renew) an application authorising the testing of embryos, it must consider the requirements of paragraph 1ZA of schedule 2 to the Act.
- 9.4. Where the application seeks authorisation for the testing of an embryo in circumstances in which there is a particular risk that an embryo may have a gene, chromosome or mitochondrion abnormality, the Licence Committee must consider the requirement of paragraph 1ZA(2) of schedule 2 to the Act. In particular, the Licence Committee must be satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition.

### **Particular requirements for applications for research licences**

- 9.5. Before the committee can grant (renew) an application for a research licence, it must consider the requirements of paragraphs 3(5) and 3A (1) of schedule 2 to the Act.

- 9.6. In particular, the committee must be satisfied that any proposed use of embryos or human admixed embryos is (and in the case of applications for renewal) or remains necessary for the purposes of the research.
- 9.7. In addition, the committee must consider whether the activities to be authorised by the licence are or remain necessary or desirable:
- a) for the listed purposes set out in paragraph 3A (2) or in regulations
  - b) for the purpose of providing knowledge that may be capable of being applied for the purpose of
  - c) increasing knowledge about serious disease or other serious medical conditions, or
  - d) developing treatments for serious disease or other serious medical conditions.

## **10. Procedure for adding non-standard conditions and for refusal, variation or revocation of licence**

- 10.1. If the committee is minded to refuse an application to grant, revoke or vary a licence, or minded to grant a licence subject to non-standard conditions, it must follow the procedure in section 19(1) of the Act.
- 10.2. If the committee is minded to vary or revoke a licence, it must follow the procedure in section 19(2) of the Act.
- 10.3. If the committee is minded to vary a licence otherwise than in accordance with the application, it must follow the procedure in section 19(3) of the Act.
- 10.4. In all cases, the committee must issue a notice. In addition to issuing the notice, the committee must give the person to whom the notice is addressed, an opportunity to make representations before making its decision. Representations may be oral and written.
- 10.5. Representations shall not be considered by the committee that issues the notice. Where a notice has been issued by the Licence Committee, any representations shall be considered by a Licence Committee normally comprised of members who are not Authority members. Where a notice has been issued by the Executive Licensing Panel, representations may be considered by the Licence Committee.
- 10.6. Where the person to whom the notice has been given indicates that he wishes to make representations, the committee hearing those representations shall consider the matter in accordance with the provisions of the Human Fertilisation and Embryology Authority (procedure for revocation, variation or refusal of a licence) regulations 2009 (as amended).
- 10.7. Where after the expiry of the period of 28 days from the date on which the notice was served, the person to whom the notice was given has not responded, or has confirmed that he does not wish to make representations, the committee shall resume its consideration of the matter and shall proceed to make its decision.

## **11. Reasons for the committee's decision**

- 11.1. The committee shall give reasons for each decision that it makes. These reasons must be recorded in the minutes.

- 11.2. The reasons shall set out:
- a) any relevant findings of fact made by the committee
  - b) any matters taken into account by the committee (including any advice received from a legal, clinical, scientific or specialist adviser), and
  - c) why the committee reached its decision.
- 11.3. Additionally, in the case of applications to authorise embryo testing for gene, chromosome or mitochondrion abnormalities, the reasons must set why the committee is satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition, and why the disability/illness/condition is considered to be serious.
- 11.4. Additionally, in the case of applications to grant (renew) licences for research, the reasons must set out why the committee is satisfied that any proposed use of embryos or human admixed embryos is or remains necessary for the purposes of the research, and why the committee considers that the activities to be authorised by the licence are or remain necessary or desirable:
- a) for the listed purposes set out in paragraph 3A (2) or in regulations; or
  - b) for the purpose of providing knowledge that may be capable of being applied for the purpose of:
    - i. increasing knowledge about serious disease or other serious medical conditions, or
    - ii. developing treatments for serious disease or other serious medical conditions.
- 11.5. The reasons should tell the person concerned in broad terms why the decision was reached, and may in some circumstances require an explanation of why a particular argument was rejected.
- 11.6. Where additional conditions have been proposed the reasons should indicate why the committee considers this course of action to be a proportionate response to any concerns identified from the papers before it.
- 11.7. The reasons should refer to the indicative applications guidance and indicative sanctions guidance where relevant.

## **12. Postponements and adjournments of meetings**

- 12.1. The Chair may, of his or her own motion, or upon the application of a party to the proceedings, postpone any meeting of which notice has been given before such meeting begins.
- 12.2. The Chair may, of his or her own motion, adjourn the proceedings at any stage.
- 12.3. In considering whether or not to grant a request for postponement, or to adjourn, the Committee Chair should, amongst other matters, have regard to:
- a) the public interest in the expeditious disposal of the proceedings
  - b) fairness to the parties, and
  - c) the conduct of the person seeking the postponement or adjournment.
- 12.4. Where the proceedings have been postponed or adjourned, the secretary should, as soon as practicable, notify the parties of the date and time of the postponed or resumed meeting.

### 13. Burden and standard of proof

- 13.1. The Authority's inspector dealing with the matter should bear the burden of establishing that a licence should be revoked, varied (otherwise than on application) or that a licence should be suspended.
- 13.2. The person to whom the notice under section 19(1) is given should bear the burden of establishing that a licence should not be refused or additional conditions should not be imposed.
- 13.3. Where facts are in dispute, the Licence Committee should consider whether they have been established in accordance with the civil standard of proof.
- 13.4. Where the committee considers that a finding on disputed facts can only be made after oral evidence is heard, it shall refuse the application and issue a notice of proposal under Section 19; invite the person to whom the notice is addressed to make oral representations and hold a hearing in accordance with the Human Fertilisation and Embryology Act (procedure for revocation, variation or refusal of a licence) regulations 2009 (as amended).

### 14. Evidence at meetings

- 14.1. The committee may receive any written or real evidence whether or not such evidence would be admissible in a civil court of law in England and Wales, provided that it is satisfied that such evidence is relevant to the issues on which it has to make a decision, and that it is fair to admit such evidence.
- 14.2. The committee shall have regard to the Code of Practice issued by the Authority in the circumstances set out in section 25(6) of the Act.

### 15. Directions

- 15.1. The Authority has delegated to the Licence Committee the power to issue directions under sections 24(5A) to (5E) and 24(13) of the Act.
- 15.2. When:
  - a) postponing or adjourning the consideration of a matter
  - b) making a proposed decision to refuse, vary, suspend or revoke a licence, or
  - c) considering evidence of an adverse incident or non-compliance with the Act, Code of Practice, licence conditions or directions issued by the Authority,the Chair should consider whether or not to issue directions under section 24 of the Act.

### 16. Evaluation and report to the Authority

- 16.1. The Chair and Deputy Chair of the Licence Committee shall hold regular periodic meetings for the purpose of reviewing decisions taken by the Committee to ensure consistency in the decision-making processes of the Committee, and to hear updates from the Chair of the Executive Licensing panel on the activities of the panel. The Chair may also reflect on any general licensing trends or issues arising from such review and propose such action to the Executive or Authority as they consider appropriate.

- 16.2. The Chair of the Licence Committee shall prepare an annual written report to the Authority detailing the activities of his/her Committee (see also the equivalent paragraph for the Executive Licensing Panel).

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**Standing orders: Annex E**

**Code of Conduct for Authority members and the seven principles underpinning public life**

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## 1. Code of Conduct for Authority members

All Authority members **undertake** to:-

- have regard to the functions and duties of the Authority set out in sections 8 and 8ZA of the Human Fertilisation and Embryology Act 1990 (as amended) ('the Act') and which are annexed to this code, when undertaking the business of the Authority or a committee
- comply with the standing orders and relevant protocols and policies approved by the Authority when undertaking the business of the Authority or a committee
- follow and support by example the principles published by the committee on standards in public life (the Nolan principles) which are annexed to this code
- follow and support by example best practice on equality and diversity issues and promote compliance by others
- in the conduct of Authority business, treat people equally and fairly and not discriminate unlawfully against anyone on the basis of any protected characteristics including their race or racial group, sex (including gender reassignment), sexual orientation, religion or belief marriage or civil partnership, pregnancy and maternity, age or disability
- in carrying out their public functions, have due regard to the need to eliminate any conduct prohibited under equality legislation including the Equality Act 2010, and to promote equality of opportunity and foster good relations between people with protected characteristics and others
- comply with the statement of general principles published by the Authority in accordance with Section 8(ca) (ii) of the Human Fertilisation and Embryology Act 1990 (as amended) which are annexed to this code
- ensure that actions taken in a personal capacity do not bring the Authority into disrepute
- in their interactions with each other and with employees, model the 'ways of working' agreed by the Authority
  - taking responsibility
  - challenging well
  - taking interest in others' ideas
  - demonstrating enthusiasm.
- be alert to the possibility of any conflicts of interest, and to declare any potential conflicts as soon as practicable
- in the event of a potential conflict of interest, consult and follow the Authority's 'Guidance for Authority and committee members on handling conflicts of interest'
- ensure that entries relating to them in the register of interests maintained by the Authority are accurate, complete and up-to-date
- declare any hospitality received which may be relevant to their work as an Authority member in the register of interests maintained by the Authority for that purpose
- only discuss Authority and committee papers at formal meetings of the Authority or

committee to which the papers relate

- keep the deliberations of the Authority or committee meetings which are not open to the public confidential, and not to disclose such deliberations to any external party (save in accordance with the Authority's publication policy or where required to by a court, or by law)
- ensure that any telephone or videoconferencing facilities used to attend Authority or committee meetings are appropriate and ensure confidentiality
- use any information acquired solely by virtue of their membership of the Authority or a committee only for the purpose of Authority or committee proceedings, and not to use such information for personal gain
- comply with the provisions of section 33A of the Human Fertilisation and Embryology Act 1990 (as amended) and to uphold strictly the confidentiality of any patient identifying information that may be revealed to them as members of the Authority or of a committee
- make no public comment on behalf of the Authority without first obtaining approval from the Chair of the Authority
- when providing media interviews or commenting in public, make it clear that they are speaking in a private capacity or as an Authority member
- make every effort to attend all meetings, hearings and training sessions at which their presence is required
- once diaries have been checked and meetings scheduled, only cancel their attendance under exceptional and wholly unavoidable circumstances
- take all reasonable steps to give advance warning of absence to the Chair of the HFEA or committee of which they are a member in the event that they are unable to attend a scheduled meeting or hearing
- prepare for any meeting or hearing by reading any papers sent to them beforehand, and
- undertake periodic training provided or organised by the Authority.

## 2. The seven principles underpinning public life

The principles of public life apply to anyone who works as a public office-holder. This includes all those who are elected or appointed to public office, nationally and locally, and all people appointed to work in the civil service, local government, the police, courts and probation services, NDPBs, and in the health, education, social and care services. All public office-holders are both servants of the public and stewards of public resources. The principles also have application to all those in other sectors delivering public services.

### Selflessness

Holders of public office should act solely in terms of the public interest.

### Integrity

Holders of public office must avoid placing themselves under any obligation to people or organisations that might try inappropriately to influence them in their work. They should not act or take decisions in order to gain financial or other material benefits for themselves, their family, or their friends. They must declare and resolve any interests and relationships.

### Objectivity

Holders of public office must act and take decisions impartially, fairly and on merit, using the best evidence and without discrimination or bias.

### Accountability

Holders of public office are accountable to the public for their decisions and actions and must submit themselves to the scrutiny necessary to ensure this.

### Openness

Holders of public office should act and take decisions in an open and transparent manner. Information should not be withheld from the public unless there are clear and lawful reasons for so doing.

### Honesty

Holders of public office should be truthful.

### Leadership

Holders of public office should exhibit these principles in their own behaviour. They should actively promote and robustly support the principles and be willing to challenge poor behaviour wherever it occurs.

# A strategic approach to facilitating research and responsible innovation

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

## Details:

Meeting                      Authority

Agenda item                10

Paper number              HFEA (15/03/2017) 830

Meeting date                15 March 2017

Author                        Joanne Anton, Head of Regulatory Policy

## Output:

For information or decision?              For decision

Recommendation              Members are asked to:

- discuss the Authority's strategic role to help facilitate high quality research and responsible innovation;
- note the suggested next steps throughout the paper; and
- have a wider discussion about our role on emerging issues (set out in section five of the paper).

Resource implications

Implementation date        2017–2020 Strategy

Communication(s)

Organisational risk         Low                       Medium                       High

Annexes

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## 1. Background

- 1.1.** In assisted reproduction, as in medicine generally, there is a clear link between improvements in clinical practice and high quality research. As the specialist regulator of IVF and embryo research, we therefore want to facilitate high quality research and responsible innovation in the UK. We also want to use our position as a well-respected public body to facilitate or contribute to debates on emerging issues, such as new scientific developments.
- 1.2.** The intention of this paper is twofold. The first is to summarise the issues in embryo and data research and to update you on the steps we might take to encourage responsible innovation. The second intention is to provide an opportunity for a first-time conversation about the Authority's strategic role in relation to emerging issues and new scientific developments.

### Facilitating research

- 1.3.** The ambition to help facilitate research is central to our strategy for 2017-2020, endorsed by Authority. The strategy places a renewed emphasis on improving the evidence base for both embryo and data research. We want help facilitate a more research focused sector so that patients can to provide their data for research and to donate their unused embryos for research, if they so wish. By acting now, we will ultimately benefit patients who, as a result of more high quality research and better research outcomes, will have access to more effective treatments and better quality information.

### Why is this ambition central to our strategy?

- 1.4.** We think we are uniquely placed to have a real impact in this area. We regulate two areas of research, embryo and data research, so can affect change, and we are well placed to influence clinical research. We have well established links with professional bodies who publish guidelines and best practice. We already have a mechanism for keeping up to date with scientific developments and keeping our patient information up to date through our Scientific and Clinical Advances Advisory Committee (SCAAC). We want to do more to respond to emerging issues and new scientific developments and associated reporting, correcting myths and misunderstandings. We are also able to communicate directly with patients through our website and engagement work. On top of this we have a proven track record of making an impact and of affecting change – both to culture and clinical practice, as demonstrated by the success of our multiple births policy. The opportunities for us to make a positive impact on facilitating research and responsible innovation are therefore significant.

### Our strategic positions

- 1.5.** The context for these discussions is the following overarching strategic positions:

- We should be facilitating high quality embryo research and responsible innovation - by encouraging a more research focused sector we would improve the quality and take-up of research in the UK.
- An inquisitive and research focused culture will lead to higher quality research and better outcomes for patients - if clinics are more research focused they would be more likely to promote the benefits of research to patients and patients would be better informed and arguably more likely to participate in research. In turn, this could lead to a greater sample size and therefore higher quality research outcomes.
- A robust approach to good clinical research will mean the use of more clinical trials to establish the efficacy of new techniques before offering them in patient treatment - this links to the Authority's decision to endorse work to tackle the overuse of treatment add-ons where there is not a solid evidence base to demonstrate efficacy.
- As a highly regarded regulator we facilitate discussion and debate, and share our expertise on the domestic and world stage to support responsible innovation – although there is an open question as to how far we can and should go in this direction and this is explored in section 5 below. This is not the time to reach a final position on this issue but the Authority is asked to consider how to balance its role as a regulator and decision maker with its ambition to do more to provide information on emerging issues.

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## 2. Facilitating high quality embryo research

**2.1.** Research on human embryos has been a central component of the UK regulated landscape since the passing of the Human Fertilisation and Embryology Act in 1990. Scientists have benefited from a stable, yet flexible, framework in which UK bio-science and clinical expertise has been allowed to flourish. Two recent world first examples are:

- Parliament's decision to make lawful for the first time in a regulated environment treatment which could avoid the inheritance of serious mitochondrial diseases, and
- Authority's decision to license the Francis Crick Institute in London to undertake research involving the new gene editing technique CRISPR-Cas9 in human embryos for the first time in a regulated environment.

**2.2.** These ground-breaking developments have been able to happen because of the public's support and trust in the HFEA and our regulatory framework.

### Current landscape of embryo research in the UK

**2.3.** Although the UK has an international reputation for innovative research and clinical treatment, the total amount of embryo research activity in the UK is relatively small. We currently license 21 research projects and receive around

two research applications per year. The level of embryo research activity in the UK during 2015 is set out in the table below:

Embryo research activity in 2015			
No. of fresh embryos donated by patients and received by researchers	No. of fresh embryos used in research projects	No. of frozen embryos donated and received by researchers	No. of frozen embryos used in research projects
604 fresh embryos	588 fresh embryos	1154 frozen embryos	990 frozen embryos

### Facilitating embryo research

- 2.4.** To explore how we can best help facilitate research on human embryos we are carrying out a wide-ranging project on embryo research. A key part of this work is how we give patients greater opportunity to donate embryos to research if they so wish, and how clinics can have improved access to donated embryos for research projects. Early feedback from the sector presents a complex picture with different issues affecting different types of clinics.
- 2.5.** From the research phase of this project, we have found, perhaps unsurprisingly, that clinics who carry out research or have well-established links to research projects generally find it easier to access donated embryos. They have established procedures for providing information to patients about the merits of research and for supplying donated embryos to research.
- 2.6.** However only a small number of clinics are in this position. The majority do not carry out research, neither do they have established links to research projects. As a result, these clinics have less incentive to provide patients with information about research or to form collaborations with research teams to supply them with embryos for their research. This means that it can be harder for patients at these clinics to find out information about research or to donate their embryos because there is not the necessary information provided, or the practical administrative processes in place to do so.
- 2.7.** Another key area of this work is to review the patient consent process for embryo research and how this affects the availability of embryos. We currently require clinics to obtain patient consent to donate embryos for a specific research project. Initial feedback suggests that requiring specific consent for a research project (rather than, for example, obtaining generic consent) presents a significant barrier to researchers. This may be creating:
- an obstacle to honouring patients' wishes to donate their embryos to research; and
  - contributing to fewer embryos being available for research than might otherwise be the case.

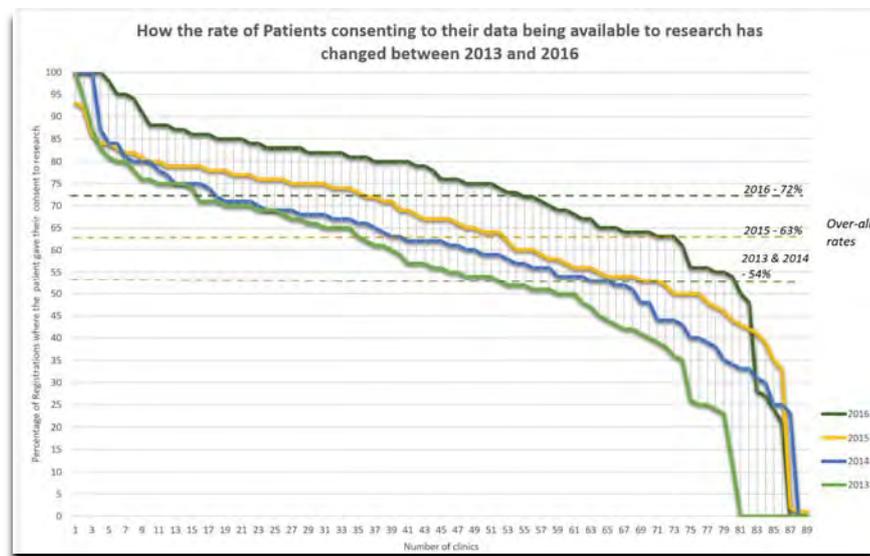
### Next steps

- 2.8.** Over the coming months we will be continuing to explore potential barriers to embryo research. We will develop ways of overcoming the barriers to clinics (especially large clinics) collaborating with research teams.
- 2.9.** We will also be seeking further views from patients to explore whether specific consent remains appropriate, and look at the merits (or otherwise) of adopting different models for generic consent. To this end, we will shortly be issuing clinic and patient surveys and contributing to the Health Research Authority's patient consultation exercise on generic consent. We will return to Authority in June to incorporate changes into the Code of Practice for October 2017.

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## 3. Improving consent rates for data research

- 3.1.** We also regulate data research – a key area that can drive up the quality of information patients receive about fertility treatment. We are in the unique position of holding HFEA register data, dating back to 1991, about donors, patients and children born as a result of those treatments. This can be used by itself or linked to other data sets and several important studies have been published in recent years using HFEA data. Those working in the IVF sector, professional researchers, or research organisations, can access this data – via either the anonymised register or patient identifying data, where consent is provided. It is important that the Register can be used to best effect to promote understanding and facilitate good research.
- 3.2.** To maximise the amount of data available to researchers, clinics should be providing good quality information to patients about the value of data research before they are asked whether they consent to the disclosure of their identifying information. However, we know from a review in 2014 that:
  - only around half of patients give their consent to disclosing their information to researchers
  - the rate of consent varies substantially across clinics
  - the most significant factors in obtaining consent are how patients are given information, and whether the staff giving that information perceived consent to disclosure to be important and desirable.
- 3.3.** Following the review, we amended the consent to disclosure form to make it easier for clinics and patients to understand the different consents to disclosure and provided more information on the form about the types of research their data could be used in, and the value of research, if they gave their consent.
- 3.4.** The following graph shows the rate of patients consenting to their data being available to research (either contact, non-contact or both) on the vertical axis, and the number of clinics achieving those rates on the horizontal axis. The horizontal dotted lines show how this has changed between 2013 and 2016.



**3.5.** The graph shows that in 2016 the overall rate of consent was around 72% - an increase from 63% in 2015 and 54% in 2013 and 2014. However, despite this welcome improvement, there is still a marked variation in the rate of consent between clinics - in 2016 only half of clinics (some 45 clinics) achieved a consent rate of 75% or higher; in the remainder consent rates that were lower than the average, some as low as 0-30%. This suggests that there is still a variance in how information is provided to patients and the potential impact of the attitudes of clinic staff on consent rates.

### Next steps

**3.6.** Over the coming months we will work to increase patient awareness of data research (along with awareness of embryo research). We will be holding a clinic-led research workshop at the annual conference, where we will discuss with the sector the best way of providing information to patients and look at the potential reasons for the fluctuation of consent rates across the sector. Other actions we will take, include:

- Developing a patient leaflet on data research to provide patients with more information about the types and benefits of research.
- Exploring the advantages and disadvantages of setting a minimum target for consent to disclosure rates (in a similar way as we introduced a minimum target for reducing multiple births) to help the Inspectorate measure the effectiveness of the clinic.
- Making data research a key part of our Information Policy which will be developed by the new Intelligence team. This will set out how we plan to work differently to carry out and facilitate data research to improve the quality of fertility services.

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## 4. Promoting responsible innovation for new treatments

**4.1.** The final area of research that our 2017-2020 strategy focuses on is how we promote responsible innovation – particularly encouraging clinical research on new fertility techniques. Some of these techniques, such as preimplantation genetic screening, fall within our regulatory remit and others, such as reproductive immunology, do not. In January, the Authority noted its concerns about the apparent proliferation of fertility treatment add ons that have not been rigorously tested in a clinical trial setting before being offered to patients. This section of the paper summarises those discussions.

**4.2.** Treatment add ons are not a straight forward issue. We do not want to create a situation in which innovation in fertility treatment is stifled and there may well be a place for treatment add ons in the clinic. However, we want patients to have access to good quality, reasonably-priced treatments which maximise their chance of a pregnancy and birth. The Authority agreed that there is an important role for us to play in achieving that goal.

### Next steps

- 4.3.** We are taking the following steps to encourage more robust clinical research:
- Our Scientific Clinical Advances Advisory Group have produced clear, honest information for patients about add ons; how safe they are, whether they work to increase pregnancy and birth rates, and how much they are likely to cost.
  - We will encourage more clinics to participate in clinical trials by publishing on the new HFEA website information about which clinics are carrying out clinical trials and providing information to patients on how to get involved.
  - We will use our new Intelligence Team to carry out a thorough analysis of our data and encourage clinics to carry out studies and publish their findings – all carried out through collaboration with scientific and clinical professional bodies, patient organisations and perhaps scientific publications.
  - We will develop a consensus about responsible innovation in fertility treatment that we could agree with stakeholders and encourage clinics to sign up to. Our success with changing professional and patient attitudes towards single embryo transfer suggests ways that we could make progress, utilising the same style of collaborative working, coupled with an effective public education campaign.
- 4.4.** We will bring a plan for the above work to the Authority later this year for further discussion.

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## 5. Our role on emerging research

- 5.1.** Scientific developments in this field move at a fast pace. Often this can lead to ethical, legal and societal debates on the implications of these developments long before they become a clinical reality or are lawful. SCAAC frequently considers scientific developments which may impact upon clinical practice in the long and short term.
- 5.2.** As noted above, as part of the 2017-2020 strategy we want to do more to respond to new scientific developments and associated reporting, correcting myths and misunderstandings, where necessary. We have done something similar on specific issues in the past, but our new strategic ambition may be interpreted by some as a sea change in the willingness of the Authority to do more to facilitate or contribute to debates on potentially contentious areas of science.
- 5.3.** This new stance raises an important question about when and how we could do more to facilitate or contribute to ethical or legal debates on new research. To date, we have tended to remain relatively quiet on issues which call for a change in legislation, or which have no short-term prospect on affecting fertility patients, preferring instead to provide advice to Government when requested. This is the approach we have so far adopted on issues such as:
- Extending the 14-day rule on embryo research
  - In vitro derived gametes
  - The use of mitochondrial donation for infertility reasons
  - Future use of gene editing in human embryos for disease avoidance
- 5.4.** As the regulator, we are constrained in how and when we can comment on certain areas of emerging research. First, unlike advisory bodies or think tanks, we perform an important statutory licensing function which means that we must be able to make impartial and credible decisions. Some may argue that taking a public position on an issue might make it harder to take such licensing decisions securely. Secondly, as a public body we should not publicly lobby the Government to change the legislation.
- 5.5.** Our approach to date has often had clear benefits for us. Our role in the debates to permit mitochondrial donation to avoid serious mitochondrial disease allowed us to provide important impartial advice to the Government. We were well positioned to carry out public dialogue work on the ethics of mitochondrial donation and to commission reviews of scientific evidence into the safety and efficacy of the techniques. To have voiced an opinion during the debates – either in support or against changing the legislation - may have compromised our credibility to carry out this important work.
- 5.6.** Although this approach has clear benefits in an issue like mitochondrial donation, it may be possible to take a different approach on issues which do not result in our having to take statutory decisions. People often look to us, as a well-respected public body, to provide advice and expertise on areas of

emerging science. As a statutory regulator with both domestic and global reach, do we have a moral responsibility to facilitate debate and/or provide a comment on the wider consequences of emerging science? Do we have a responsibility to our patients to provide earlier advice on ethically or legally contentious issues? What could we lose or gain in being more vocal? By remaining silent on emerging issues do we risk missing out on the opportunity to input into important debates earlier? By not doing so, are we more likely to be on the back foot when it comes to providing patient information and advice about the potential implications of new scientific developments?

**5.7.** The Authority is therefore asked to consider how we can best balance our aim to do more to facilitate research and support responsible innovation whilst being mindful of the constraints we face as a statutory regulator. The Authority may want to consider which, if any, of the one or more approaches below we could take, depending on the emerging issue:

- Use our experience in carrying out public engagement work to do more to facilitate ethical and legal debates on areas of emerging science – either with or without providing an opinion or recommendation
- Use our expertise more to provide information in the public domain on areas of emerging science (ie, responding to press enquiries, attending domestic and international conferences, speaking at debates) - either with or without an opinion or recommendation
- Provide a balanced overview of the ethical and legal considerations of emerging issues for patients on our website - with or without an opinion or recommendation.

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## **6. Summary**

**6.1.** Members are invited to

- note the steps we plan to take to improve the quality of treatment, by encouraging world class research and clinical trials across all types of research we regulate. What is clear is the important role we can play in encouraging a culture shift in clinics to be more research focused. This is in the interests of all clinics as it is in the inherent interest of their patients. We will achieve this by working collegiately with clinics and professionals and by using every channel we have to make an impact.
- start exploring our role on emerging issues and how we balance our regulatory responsibilities with our ambition to use our highly regarded position to do more to combat myth-busting and provide patient information about emerging research.

**6.2.** The Authority's discussion today will help frame our work and priorities over the next three years as part of our renewed focus on engendering high quality research and responsible innovation as set out in our new Strategy for 2017-

2020. It will also provide valuable direction to the new Intelligence team and the formation of an Information Strategy to improve quality across the sector.

# Choose a Fertility Clinic - patient rating trial and evaluation

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

## Details:

Meeting	Authority
Agenda item	11
Paper number	HFEA (15/03/2017) 831
Meeting date	15 March 2017
Author	Helen Crutcher, Policy Manager

## Output:

For information or decision?	For decision
Recommendation	That Authority discusses and agrees a trial of the patient rating system on the website
Resource implications	Beyond staff time, marketing costs of less than £5,000
Implementation date	Spring 2017, alongside launch of live website
Communication(s)	Ongoing stakeholder work with the sector and patient groups Marketing of ratings service to patients directly and with partner organisations
Organisational risk	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High

Annexes

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## 1. Background

- 1.1. Patient feedback has been an important part of our inspections for many years. However, this feedback is only available to the public in summarised form in the inspection report for each clinic. In the new Choose a Fertility Clinic (CaFC) tool, we will introduce publicly visible feedback from patients, with a star rating system which will appear on each clinic's CaFC profile.
- 1.2. Direct feedback from patients is not new in the health system and patients want it to help inform their choices. In the NHS the Friends and Family Test and patient surveys are well established and this is an area of public and regulatory policy which is only set to grow in importance. Patient feedback is particularly important in the fertility sector, particularly when a majority of patients have to pay for their treatment. That is why we first decided to include patient feedback in CaFC in our 2014-2017 strategy. The IfQ Advisory Group has subsequently made recommendations about how that should be done - recommendations which the Authority agreed in January 2015. Since then, we have been developing the new website and CaFC tool and have returned to the Authority twice, in 2015, for decisions around the methodology to be used.
- 1.3. Our patient feedback service will have two components: a rating system, with results visible on CaFC and free text comments to be seen by inspectors and incorporated into inspection reports (as they do now).
- 1.4. We committed to you in January 2015 to launch the system as a trial at the outset and to review it. Leaving this commitment to one side, we want to do feedback well and ensure it is transparent, auditable and fair and provides data that is helpful to us, clinics and patients. A trial will let us review and improve the system and address any flaws that might come to light.
- 1.5. The paper outlines proposals and we would welcome members' views and feedback on these.

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## 2. What we've done so far

### What you've agreed to already

- 2.1. As a reminder, the decisions agreed by Authority in 2015 included that:
  - we will not include a system to authenticate patients, as user feedback and the stakeholder group told us this would discourage patients from taking part
  - one questionnaire will be used for both patient ratings on CaFC and to gather patient feedback for inspection reports
  - any 'free text' comments submitted will not be published on the website but it will be available to clinics through their inspectors
  - feedback should be from recent patients and donors (within a year) and that it should only count towards the ratings on CaFC for 12 months

- we will promote the tool to patients to maximise uptake.

### The rating system on the beta site

- 2.2.** In 2016, we implemented these decisions and developed the rating system for the beta website. Throughout the process, we had feedback from the IfQ stakeholder group and the project team. We also tested the questions with users to see what they thought. The resulting rating questionnaire has been active since the start of beta. The questions are:
- How likely are you to recommend this clinic to friends and family if they needed similar care or treatment? (Five-point range from extremely unlikely - extremely likely)
  - To what extent did you feel you were treated with privacy and dignity? (Five-point range from never – always) plus a free text box to feed back to inspectors
  - To what extent did you feel you understood everything that was happening throughout your treatment? (Five-point range from never – always)
  - Was the level of empathy and understanding shown towards you by the clinic team? (Five-point range from unacceptable – excellent)
  - Did you pay what you expected? (Five-point range from it was much cheaper – it was way above the estimate) plus a free text box to feed back to inspectors
- 2.3.** The answers given are used to generate five star ratings for the first four questions. The average of the four ratings is used to create an overall star rating for the clinic, known as the ‘patient rating’. We also show the total number of ratings. A tally of answers to the cost question is shown and these do not feed into the star rating. Figure 1 shows how the ratings will look on a clinic page.
- 2.4.** Some patients and clinics have been so eager to use the new feature that we already have some ratings on the beta site. To ensure that the trial is fair, we need to launch it from scratch with all clinics on a level playing field. However, to make sure the valuable feedback we already have is not lost when the website launches, we will commit to reporting the feedback we have already received to clinics through their inspectors.

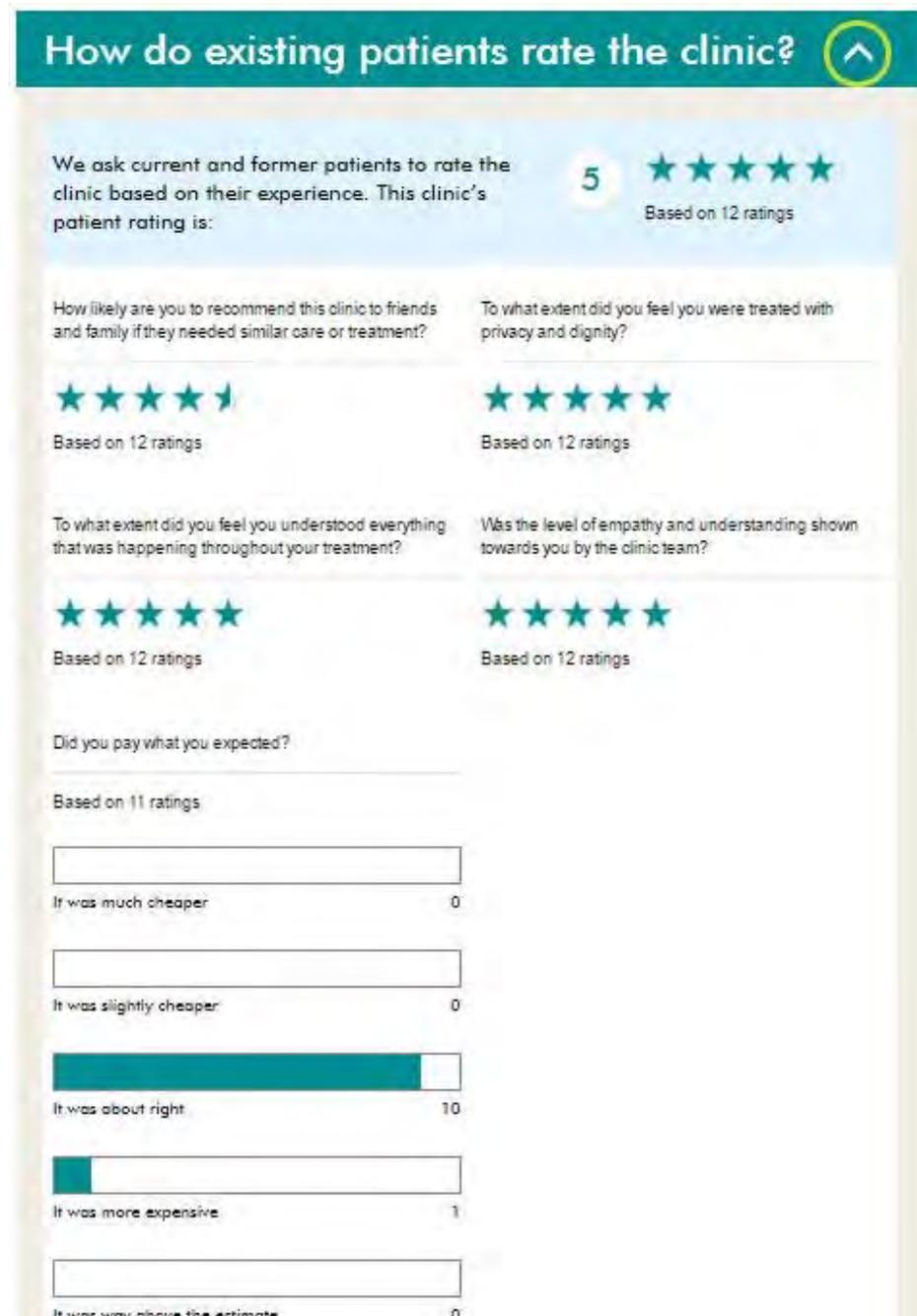


Figure 1

### What we already know we need and are now putting in place

**2.5.** We have reviewed the rating system on beta. It was clear that before going live we needed to add some features to the rating tool to make it more robust. We are adding:

- More guidance on the use of the tool, to remind users that they should be recent users of the clinic (within the last 12 months), must provide true information and should not use the ratings and free text feedback for complaints.
- A usage policy that links to our main website policy and includes:

- information on how we use the ratings and feedback and how they generate the overall rating
- the laws around gaming and providing false information
- the limitations of how the tool should be used and HFEA liability.
- Options to provide free text that will be available to inspectors for *every* question rather than only allowing this for two questions. More feedback would be beneficial to inspectors and could be helpful for clinics too.

**2.6.** The above steps will help to ensure that the tool is used by the correct people in the right way and will make it more robust. These are also steps which have proved effective and are in line with other similar tools elsewhere in the health system.

#### Further possible steps to ensure authenticity of users

**2.7.** We have sought patient feedback at various stages of development, to see if any changes were needed. One recurring theme relates to how we can ensure that people giving ratings are real (and recent) patients and donors. Patient opinion is divided on this issue. Early user testers said that they did not want to have to prove that they were a patient or donor as it would put them off using the tool. Some thought that this would mean only people who had real concerns about the clinic would use the tool, meaning that it wasn't representative.

**2.8.** However, later user testing gave an opposite view. User testers indicated that they would not trust the ratings if they weren't reassured that real patients had given them.

**2.9.** There is a tricky balance here, between ensuring authenticity of ratings and maximising the amount of information available to patients. Before writing this paper, we did a brief survey of a few more patients to ask what could we do that would give them confidence that real patients and donors were giving feedback. We provided examples of additional checks that we could add:

- providing an email address (which would be authenticated) and name,
- providing a unique code that was available from the clinic to prove you were treated there; or
- something else (if they had other ideas).

**2.10.** The responses were evenly divided between not wanting us to do more and adding one of the other checks. Although this was a very quick snapshot of user testers' views and was not fully representative, it mirrors the split in views at previous user testing stages.

**2.11.** Because views are divided, we do not intend to add email verification or code checks before the website goes live. However, at the end of the trial we should be able to re-evaluate the need for these and reconsider this position. If we wanted to add one of these features some further IT development would be needed.

- 2.12.** Some websites include a tool called a ‘CAPTCHA’ at the end of forms in which you have to write the word you can see, to make sure that only real people can complete them (and not automated robots). We have the capability to add this to the ratings, although these do frustrate some users and can make websites less accessible. We plan to consider adding this at the end of the trial if a need is indicated.

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### 3. Proposals for how we plan to trial the feature

#### What kind of test is it anyway?

- 3.1.** The beta period has already shown that the input side of this tool works well; we have been able to receive feedback and it displays on CaFC. It also feeds through to the Clinic Portal, where each clinic can see ratings for their own service. What is now needed is a test of the usefulness of the tool and the data submitted, to make sure that it is used as intended and provides valuable information for all users; patients and donors, inspectors and clinics themselves.
- 3.2.** We committed to Authority, and the sector, that we would see that the system works before we finalised it. This could be achieved in a variety of ways. We could run a test with a small number of representative clinics, but this would be problematic as the rating will be publically available on CaFC and might therefore be unfair to some clinics. Such inconsistency could also confuse patients. And if we did not publish the information it would not be a real test of the new system.
- 3.3.** Therefore, what we propose is a time-limited trial of the rating system running for all clinics. The aim is to understand what works well so that the final ratings system is as good as it can be. This proposal has several benefits:
- We should get more feedback and spot any issues earlier with all clinics involved
  - Until we get some feedback we don’t know whether misuse is a valid concern
  - We will have a stronger evidence base to support whether changes are needed
- 3.4.** The proposed duration of the trial is six months as this would be long enough to provide enough data to analyse, while reducing risk by still allowing changes in the near future if the trial indicates a need. As an indication of volumes, while we were receiving questionnaires to inform inspections we received about 300 responses over six months. We should receive more than this during the trial since it will be better publicised and more prominent on the website.

#### Elements of the trial

- 3.5.** There will be a number of elements to this trial and the activities will help us address a number of high level questions:

- Are the outputs from the rating system valuable to patients, inspectors and clinics?
- Will patients and donors use the tool to give their feedback and will potential patients use it to help make decisions about their treatment?
- Are HFEA procedures to manage the end to end feedback and ratings process effective?

**3.6.** Each element should provide valuable data to allow us to assess the effectiveness of the rating tool at the end of the trial. The activities are listed below in relation to the different groups who will work with the tool: patients, clinics and the HFEA.

### Patients

- 3.7.** Patients are at the heart of this new feature and we want to hear what they think at either end of the process; both giving and using the ratings. We will:
- run a survey alongside the tool throughout the trial period so that users who have rated clinics can tell us what they think, including whether they trust the information and were able to provide all the feedback they wanted to. **This will allow us to identify if any changes might be needed to the tool itself, ie, the questions, appetite for additional authentication**
  - do some outreach with patients who are looking for a clinic, to find out if patients are using the tool when choosing which clinic is best for them and whether it is making a difference. **This will help us evaluate our ongoing marketing plan as well as the perceived value of the information**
  - use our existing stakeholder groups and links with patient organisations to see what they think about the effectiveness of the tool. **This will help us to evaluate whether the tool is doing that it was designed to do.**

### Clinics

- 3.8.** We need to make sure that the outputs are helpful for all users and we know that for patients (and clinics themselves) to get the whole benefit from the tool we need clinics to work with us. We will:
- engage a cross-section of representatives from clinics to see what clinic staff think of the rating system and their patients using the tool. We will see whether attitudes change over time once clinics are used to the ratings. We can also ask how HFEA marketing of the tool works for different clinics and hear the clinic perspective on our inspectors using this patient feedback. **This will help us to evaluate the uptake of the system and find ways to build clinic support for the tool.**

### HFEA

- 3.9.** To make this tool effective and helpful for all users it will need to be properly supported. We will:
- have a marketing strategy and processes in place. We'll review the number of ratings received and analyse how effective our actions are in encouraging feedback and ratings and whether the strategy addresses the

needs of different clinics. **This will help us identify whether changes may make this more effective and fair**

- review ratings and feedback received to analyse whether there is any evidence of misuse. **This will indicate whether adding any further authentication or including 'CAPTCHA' may be justified**
- run internal workshops to review and develop processes with the teams who own them ie, communications for marketing, inspection team to feed comments back to clinics. **This will help us evaluate plans for business as usual and consider improvements to make them more effective**
- plan a second strand to the marketing to reach potential patients and raise awareness of the tool. We will only be able to develop the process for this once some ratings are in CaFC. This can be informed by potential patient outreach mentioned above. **This will allow us to evaluate ways to effectively improve awareness.**

**3.10.** At the end of the trial we propose that the executive should:

- Evaluate the findings, reviewing what is successful and whether changes may be required in other areas
- Present findings to the authority
- Recommend next steps

**3.11.** The Authority is asked to discuss and agree to the planned trial of patient ratings on the website.

# Strategic risk register

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

## Details:

Meeting	Authority
Agenda item	12
Paper number	HFEA (15/03/17) 832
Meeting date	15 March 2017
Author	Paula Robinson, Head of Business Planning

## Output:

For information or decision?	For information
Recommendation	The Authority is asked to note and comment on the latest edition of the strategic risk register.
Resource implications	In budget
Implementation date	Ongoing
Communication(s)	The risk register is reviewed quarterly by the Corporate Management Group (CMG), and presented at every Audit and Governance Committee (AGC) meeting. AGC last reviewed the risk register at its meeting on 7 December, and will review it again at its meeting on 21 March.
Organisational risk	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High
Annexes	Annex A: Strategic risk register

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## 1. Latest reviews

- 1.1. CMG reviewed the risk register at its meeting on 8 February. CMG reviewed all risks, controls and scores, and agreed to add a new risk relating to the forthcoming organisational changes that are being planned. CMG also reviewed the two risks relating to donor conception and agreed to merge these into one single risk centred on running a good Opening the Register service. CMG's comments are summarised on the second page of the risk register, at Annex A.
- 1.2. Four of the twelve risks are currently above tolerance.
- 1.3. The risk register was last discussed at AGC on 7 December. No changes were proposed to the risk scores at that time. Any comments from the March Authority meeting will be fed into the Committee's next review on 21 March.

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## 2. Recommendation

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

# HFEA strategic risk register 2016/17

## Risk summary: high to low residual risks

Risk area	Risk title	Strategic linkage <sup>1</sup>	Residual risk	Current status	Trend*
Information for Quality	IfQ1: Improved information access	Increasing and informing choice: information	<b>12 – High</b>	Above tolerance	↔↔↔↓↑
Information for Quality	IfQ3: Delivery of promised efficiencies	Efficiency, economy and value	<b>12 – High</b>	Above tolerance	↔↔↔↑↔
Data	D2: Incorrect data released	Efficiency, economy and value	<b>12 – High</b>	Above tolerance	↔↔↔↑↔
Capability	C1: Knowledge and capability	Efficiency, economy and value	<b>12 – High</b>	Above tolerance	↔↔↔↑↔
Legal challenge	LC1: Resource diversion	Efficiency, economy and value	<b>12 – High</b>	At tolerance	↔↔↔↔↔
Data	D1: Data loss or breach	Efficiency, economy and value	<b>10 – Medium</b>	At tolerance	↔↔↔↔↔
Organisational change	OC1: Change-related instability	Efficiency, economy and value	<b>9 – Medium</b>	At tolerance	• new
Financial viability	FV1: Financial resources	Efficiency, economy and value	<b>9 – Medium</b>	At tolerance	↔↔↔↔↔
Regulatory model	RM2: Loss of regulatory authority	Setting standards: quality and safety	<b>8 – Medium</b>	At tolerance	↔↔↔↔↔
Information for Quality	IfQ2: Register data	Increasing and informing choice: Register data	<b>8 – Medium</b>	At tolerance	↔↔↔↔↔
Regulatory model	RM1: Quality and safety of care	Setting standards: quality and safety	<b>4 – Low</b>	Below tolerance	↔↔↔↔↓
Opening the Register	OTR1: OTR service quality	Setting standards: donor conception	<b>4 – Low</b>	At tolerance	• new

\* This column tracks the four most recent reviews by AGC, CMG, or the Authority (eg, ↑↔↔↓↔↔).

Recent review points are: CMG 7 September/AGC 21 September ⇒ Authority 16 November ⇒ CMG 23 November/AGC 7 December ⇒ CMG 8 February

<sup>1</sup> Strategic objectives 2014-2017 (these will be updated in April when the new strategy has been launched):

Setting standards: improving the quality and safety of care through our regulatory activities. (Setting standards – quality and safety)

Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families. (Setting standards – donor conception)

Increasing and informing choice: using the data in the register of treatments to improve outcomes and research. (Increasing and informing choice – Register data)

Increasing and informing choice: ensuring that patients have access to high quality meaningful information. (Increasing and informing choice – information)

Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government. (Efficiency, economy and value)

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## AGC – December 2016 meeting

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The committee focused mainly on the three risks above tolerance at the time, which included Information for Quality (IfQ3) – delivery of promised efficiencies, Data (D2) – incorrect data release and Capability (C1) – knowledge and capability.

The committee questioned whether the Business Continuity Plan had been tested and was informed that there was an incident involving loss of power at the new HFEA premises in the summer of 2016 and the plan had been put into action. There were some lessons learned but generally things worked well.

The committee was concerned about the fluctuation of Parliamentary Questions that need to be answered within a tight timeframe and questioned how the organisation manages this area of work. The committee was informed that some questions could be tricky to answer. There is a small team of people in the organisation handling the questions, however the work is often extended to other staff with specialist knowledge to contribute to the answers. Answering parliamentary questions always takes priority in the organisation.

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## CMG – February 2017 meeting

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CMG discussed in particular how best to reflect the risks associated with organisational change in the risk register. It was agreed that this should be presented as a separate, new, risk, in addition to the existing ‘business as usual’ risk relating to knowledge and capability.

We agreed that the financial viability risk should be updated, since year end and a new strategic period are approaching.

We also considered the two donor conception risks, and agreed that these should now be merged into one single risk centred on running a good Opening the Register service.

CMG updated all the remaining risks and controls and adjusted some of the residual risk scores to reflect the current situation.

We also noted that the risk register would need a comprehensive review as soon as the new strategy for 2017-2020 had been finalised, to ensure that it reflected the risks to delivering the strategy. It was agreed that the Chief Executive and the Head of Business Planning would work together to produce a draft, for comment at the next CMG risk meeting, in early May.

The Department of Health ALB risk network would be running a workshop on 28 February on risk interdependencies within the health system, between ALBs or with the Department itself. The HFEA would participate in this workshop, and the new version of the risk register would need to incorporate a section under each risk, identifying any interdependencies with other ALBs or the Department, within each risk. It had also been agreed that each ALB should prepare a report for its Audit Committee on risk interdependencies – this will be prepared for the next available AGC meeting after the notes of the workshop have been released (probably the June meeting, which would fit well with the Committee’s first review of the new version of the risk register to reflect the new strategy). Further reporting on health system risk interdependencies to DH or to auditors may be requested in the future, so it would be beneficial to have interdependencies identified separately and clearly in our risk register, along with any resulting controls or actions.

## Criteria for inclusion of risks:

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

## Rank

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

## Risk trend

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

## Risk scoring system

See last page.

## Assessing inherent risk

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

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

## System-wide risk interdependencies

From April 2017 onwards, we will also explicitly consider whether any HFEA strategic risks or controls have a potential impact for, or interdependency with, the Department or any other ALBs. A distinct section to record any such interdependencies beneath each risk will be added to the risk register when it is reviewed to reflect the new strategy for 2017-2020, so as to be sure we identify and manage risk interdependencies in collaboration with relevant other bodies, and so that we can report easily and transparently on such interdependencies to DH or auditors as required.

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
<b>Regulatory model</b>  RM 1: Quality and safety of care	There is a risk of adverse effects on the quality and safety of care if the HFEA were to fail to deliver its duties under the HFE Act (1990) as amended.	Setting standards: improving the quality and safety of care through our regulatory activities.	Inherent risk level:		⇔ ⇔ ⇔ ↓	Peter Thompson	
			Likelihood	Impact			Inherent risk
			3	5			15 High
			Residual risk level:				
			Likelihood	Impact			Residual risk
1	4	4 Low					
Tolerance threshold:		8 Medium					
<b>Causes / sources</b>		<b>Mitigations</b>	<b>Timescale and ownership of mitigations</b>	<b>Commentary</b>			
Inspection/reporting failure.		Inspections are scheduled for the whole year, using licence information held on Epicentre, and items are also scheduled to committees well in advance.  Audit of Epicentre conducted to reveal data errors in 2014/15. Error correction completed in 2016.  Inspector training, competency-based recruitment, induction process, SOPs, QMS, and quality assurance all robust.	In place – Sharon Fensome-Rimmer  In place – Siobhain Kelly  In place – Sharon Fensome-Rimmer	Below tolerance.  Some elements of this risk, associated with staff turnover and legal parenthood issues, have now reduced in likelihood, and so the residual risk level has reduced.			
Regulatory monitoring processes may be disrupted as a result of the temporary inability of Electronic Patient Record System (EPRS) providers to submit data to the new register structure until their software has been updated. This could impact performance information used in inspection notebooks and RBAT alerts.		Earlier agreements to extend IfQ delivery help to address this risk by extending the release date for the EDI replacement (IfQ release 2).  Mitigation plans for this risk have been agreed as part of planning.	Mitigation in place - Nick Jones	On legal parenthood, a strong set of actions is in place and continues to be implemented. The inspection team continue to work with colleagues in licensed centres, with a focus on ensuring all affected patients are informed and appropriately supported.			
Monitoring failure.		Outstanding recommendations from inspection reports are tracked and followed up by the team.	In place – Sharon Fensome-Rimmer				
Unresponsiveness to or mishandling of non-compliances or grade A incidents.		Up to date compliance and enforcement policy.  Staffing model provides resilience in the inspection team for such events – dealing with high-impact cases, additional incident inspections, etc.	In place – Nick Jones  In place – Sharon Fensome-Rimmer				
Insufficient inspectors, administrative or licensing staff		Inspection team running at full complement.  Business support is operating below complement, and this will be addressed over the next few months, as part of organisational change implementation and the completion of IfQ.	In place – Nick Jones  To be addressed after IfQ, in the course of organisational restructuring – Sharon Fensome-Rimmer				

	Licensing team up to complement following earlier recruitment.	In place – Siobhain Kelly
Recruitment difficulties and/or high turnover/churn in various areas; resource gaps and resource diversion into recruitment and induction, with impacts felt across all teams.	So far recruitment rounds have yielded sufficient candidates, although this has required going beyond the initial ALB pool to external recruitment in some cases.	Managed as needed – Sharon Fensome-Rimmer
	Additional temporary resources available during periods of vacancy and transition.	In place – Rachel Hopkins
	Group induction sessions put in place where possible.	In place – Sharon Fensome-Rimmer
Resource strain itself can lead to increased turnover, exacerbating the resource strain.	Operational performance, risk and resourcing oversight through CMG, with deprioritisation or rescheduling of work an option.	In place – Paula Robinson
Unexpected fluctuations in workload (arising from eg, very high level of PGD applications received, including complex applications involving multiple types of a condition; high levels of non-compliances either generally or in relation to a particular issue; introduction of mitochondrial treatment decision-making).	Staffing model amended in May 2015, to release an extra inspector post out of the previous establishment. This increased general resilience, enabling more flex when there is an especially high inspection/report writing/application processing workload.	In place – Sharon Fensome-Rimmer
	Greater sector insight into our PGD application handling processes and decision-making steps achieved in the past few years; coupled with our increased processing rate since efficiency improvements were made in 2013 (acknowledged by the sector).	In place – Sharon Fensome-Rimmer
Some unanticipated event occurs that has a big diversionary impact on key resources, eg, legal parenthood consent issues, or several major Grade A incidents occur at once.	Resilient staffing model in place.	In place – Sharon Fensome-Rimmer
	Up to date compliance and enforcement policy and related procedures.	In place – Nick Jones / Sharon Fensome-Rimmer
	A detailed action plan in response to the legal parenthood judgment is in place.	In progress – Nick Jones/Sharon Fensome-Rimmer

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
<b>Regulatory model</b>  RM 2: Loss of regulatory authority	There is a risk that the HFEA could lose authority as a regulator, jeopardising its regulatory effectiveness, owing to a loss of public / sector confidence.	Setting standards: improving the quality and safety of care through our regulatory activities.	Inherent risk level:			↔ ↔ ↔ ↔	Peter Thompson
			Likelihood	Impact	Inherent risk		
			3	5	15 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
2	4	8 Medium					
Tolerance threshold:			8 Medium				
<b>Causes / sources</b>		<b>Mitigations</b>	<b>Timescale and ownership of mitigations</b>		<b>Commentary</b>		
Failures or weaknesses in decision making processes.		Keeping up to date the standard operating procedures (SOPs) for licensing, representations and appeals.	In place – Siobhain Kelly		At tolerance.  Although two additional risk sources exist at present (website outages until the new beta website is live and the plan of work to address legal parenthood consent issues), these are being well managed and/or tolerated, and the overall risk score has not increased.		
		Learning from past representations and Appeal Committee hearings incorporated into processes.	In place – Siobhain Kelly				
		Appeals Committee membership maintained. Ongoing process in place for regular appointments whenever vacancies occur or terms of office end.	In place – Siobhain Kelly				
		Staffing structure for sufficient committee support.	In place – Siobhain Kelly				
		Decision trees; legal advisers familiar.	In place – Siobhain Kelly				
		Proactive management of quoracy for meetings.	In place – Siobhain Kelly				
		New (ie, first application) T&S licences delegated to ELP. Licensing Officer role in place to take certain administrative decisions from ELP.	In place – Siobhain Kelly				
Failing to demonstrate competence as a regulator		Up to date compliance and enforcement policy and related procedures.	In place – Nick Jones / Sharon Fensome-Rimmer				
		Inspector training, competency-based recruitment, induction process, SOPs, quality management system (QMS) and quality assurance all robust.	In place – Sharon Fensome-Rimmer				
Effect of publicised grade A incidents.		Staffing model provide resilience in inspection team for such events – dealing with high-impact cases, additional incident inspections, etc.	In place – Sharon Fensome-Rimmer				
		SOPs and protocols with Communications team.	In place – Sharon Fensome-Rimmer				
		Fairness and transparency in licensing committee information.	In place – Sharon Fensome-Rimmer				

	Dedicated section on website, so that the public can openly see our activities in the broader context.	In place – Sharon Fensome-Rimmer
Administrative or information security failure, eg, document management, risk and incident management, data security.	Staff have annual information security training (and on induction).	In place – Dave Moysen
	A comprehensive review of our records management practices and document management system (TRIM) will be conducted in 2017, following planned organisational changes and the conclusion of IfQ.	To follow – Peter Thompson
	Guidance/induction in handling FOI requests, available to all staff.	In place – Siobhain Kelly
	The IfQ website management project has reviewed the retention schedule.	Completed – August 2015 – Juliet Tizzard
Until the IfQ website project has been completed, there is a continued risk of HFEA website outages, as well as difficulties in uploading updates to web pages.	Alternative mechanisms are in place for clinics to get information about materials such as the Code of Practice (eg, direct communications with inspectors, Clinic Focus).	In place – Sharon Fensome-Rimmer
	The IfQ work on the new website will completely mitigate this risk (the new content management system will remove the current instability we are experiencing from using RedDot). This risk has informed our decisions about which content to move first to the beta version of the new site.	In progress – go live expected in March 2017 – Juliet Tizzard
Negative media or criticism from the sector in connection with legally disputed issues or major adverse events at clinics.	HFEA approach is only to go into cases on the basis of clarifying legal principles or upholding the standards of care by challenging poor practice. This is more likely to be perceived as proportionate, rational and necessary (and impersonal), and is in keeping with our strategic vision.	In place - Peter Thompson
HFEA process failings that create or contribute to legal challenges, or which weaken cases that are otherwise sound, or which generate additional regulatory sanctions activity (eg, legal parenthood consent).	Licensing SOPs, committee decision trees in place. Mitochondria donation application tools completed.	In place – Siobhain Kelly
	Up to date compliance and enforcement policy and related procedures.	In place – Nick Jones / Sharon Fensome-Rimmer
	Seeking the most robust possible assurance from the sector with respect to legal parenthood consent issues, and detailed plan in operation to address identified cases and anomalies.	In progress – Nick Jones
	QMS and quality assurance in place in inspection team.	In place – Sharon Fensome-Rimmer

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
IfQ  IfQ 1: Improved information access	If the information for Quality (IfQ) programme does not enable us to provide better information and data, and improved engagement channels, patients will not be able to access the improved information they need to assist them in making important choices.	Increasing and informing choice: ensuring that patients have access to high quality meaningful information.	Inherent risk level:			↔ ↔ ↓ ↑	Juliet Tizzard
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
3	4	12 High					
Tolerance threshold:			8 Medium				
Causes / sources		Mitigations	Timescale and ownership of mitigations		Commentary		
Inability to extract reliable data from the Register.		Detailed planning and programme management in place to ensure this will be possible after migration. Migration strategy developed, and significant work being done to identify and cleanse all of the data that requires correction before migration. Decisions have been made about the degree of reliability required in each data field. For those fields where 100% reliability is needed, inaccurate or missing data is being addressed as part of project delivery.	All aspects – detailed project planning in place – Nick Jones		Above tolerance.  It has been necessary to remain in beta for the website for far longer than originally planned, owing partly to a judicial review whose outcome is still awaited, and partly to protracted contractor resource negotiations and end-stage planning (now concluded, with final work in progress). Our final 'go live' GDS assessment for the website took place on 8 March.		
Reduced ability to provide for patient choice based on CaFC information as a result of EPRS inability to submit/correct data in the new register structure if they do not update their systems in time to comply. This could impact the publication of CaFC data.		Proposals on an updated IfQ delivery plan were agreed at August IfQ Programme Board, these should help address this risk. A mitigation and communication plan for this risk is in place, including ongoing dialogue with EPRS centres and providers.	In place - Nick Jones		In the same time period, we are completing a detailed data verification process to update Choose a Fertility Clinic in readiness for Register migration and the new system, and this is proving challenging for the sector. Controls are in place, and it remains important for us		
Stakeholders dislike or fail to accept the new model for CaFC. Stakeholders not on board with the changes.		In-depth stakeholder engagement and extensive user research completed to inform the programme's intended outcomes, products and benefits. This included, consultation, expert groups and Advisory Board and this continues to be an intrinsic part of programme approach.	In place and ongoing – Juliet Tizzard /Nick Jones				

<p>Preparatory work to verify data in advance of the Register migration is effortful for clinics, with some struggling, and a risk that they could become disenchanted with IfQ or fail to see the future benefits.</p>	<p>Frequent sector communications about the current CaFC verification process, the reasons for it, and the ultimate pay-offs. Regular internal performance reports to track progress and problems. Focused support for the clinics who are struggling the most.</p>	<p>In place throughout the verification exercise – Nick Jones</p>	<p>to reiterate that the ultimate benefits of IfQ for the sector will make the extra effort invested now worthwhile.</p>
<p>Cost of delivering better information becomes too prohibitive, either because the work needed is larger than anticipated, or as a result of the approval periods associated with required DH/GDS gateway reviews (although these have improved markedly).</p>	<p>Costs were taken into account as an important factor in consideration of contract tenders and negotiations. Following earlier long timelines and unsuccessful attempts to discuss with GDS, our experience at the Beta gateway has been much improved and feedback was almost immediate. Watching brief being kept.</p>	<p>In place – Nick Jones  In place – Nick Jones</p>	
<p>Redeveloped website does not meet the needs and expectations of our various user types.</p>	<p>Programme approach and some dedicated resources in place to manage the complexities of specifying web needs, clarifying design requirements and costs, managing changeable Government delegation and permissions structures, etc. User research done, to properly understand needs and reasons. Tendering and selection process included clear articulation of needs and expectations. GDS Beta assessment was passed on all 18 points.</p>	<p>In place – user research delivered end Oct 2016 – Juliet Tizzard</p>	
<p>Government and DH permissions structures are complex, lengthy, multi-stranded, and sometimes change mid-process.</p>	<p>Initial external business cases agreed and user research completed. Final business case for whole IfQ programme was submitted and eventually accepted. All GDS approvals sought so far have been granted, albeit with some delays to the earlier ones. Additional sprints of work were incorporated in beta, in an attempt to allow sufficient time (and resources) for the remaining GDS gateway review processes and subsequent formal approval mechanisms. The beta timeline was extended by 3 months to compensate for previous and anticipated future delays.</p>	<p>In place – Juliet Tizzard  In place – Nick Jones (decision received April 2015)  In place – Nick Jones</p>	

Resource conflicts between delivery of website and business as usual (BAU).	Backfilling where possible/affordable to free up the necessary staff time, eg, Websites and Publishing Project Manager post backfilled to free up core staff for IfQ work.	In place – Juliet Tizzard
Delivery quality is very supplier dependent. Contractor management has at times been very resource-intensive for staff. Work delivered by one or more suppliers could be poor quality and/or overrun, causing knock-on problems.	Programme management resources and quality assurance mechanisms in place for IfQ to manage (among other things) contractor delivery. Agile project approach includes a 'one team' ethos and requires close joint working and communication among all involved contractors. Sound project management practices in place to monitor delivery. Previous lessons learned and knowledge exist in the organisation from managing previous projects. Ability to consider deprioritising other work, through CMG, if necessary. Regular contract meetings in place.	In place – Juliet Tizzard
New CMS (content management software) is ineffective or unreliable.	CMS options were scrutinised carefully as part of project. Appropriate new CMS chosen, and all involved teams happy with the selection.	In progress – implemented in beta phase, July 2016 – Juliet Tizzard
Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedded into new ways of working. Knowledge handover with the contractors will take place.	In place – Nick Jones

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
IfQ  IfQ 2: Register data	HFEA Register data becomes lost, corrupted, or is otherwise adversely affected during IfQ programme delivery.	Increasing and informing choice: using the data in the Register of Treatments to improve outcomes and research.	Inherent risk level:		↔ ↔ ↔ ↔	Nick Jones	
			Likelihood	Impact			Inherent risk
			2	5			10 Medium
			Residual risk level:				
			Likelihood	Impact			Residual risk
			2	4			8 Medium
Causes / sources			Timescale and ownership of mitigations		Commentary		
Risks associated with data migration to new structure, together with records accuracy and data integrity issues.		IfQ programme groundwork focused on current state of Register. Extensive planning in place, including detailed research and migration strategy.	In place – Nick Jones/Dave Moysen		At tolerance.  This risk is being intensively managed – a major focus of IfQ planning work, particularly around data migration.		
The firm (Avoca) which was scheduled to provide assurance on data migration has gone out of business.		The HFEA has considered other sources of assurance and sourced a supplier. Work is in progress.	In place – Nick Jones				
Historic data cleansing is needed prior to migration.		A detailed migration strategy is in place, and data cleansing is in progress.	In place – Nick Jones/Dave Moysen				
Increased reporting needs mean we later discover a barrier to achieving this, or that an unanticipated level of accuracy is required, with data or fields which we do not currently focus on or deem critical for accuracy.		IfQ planning work incorporated consideration of fields and reporting needs were agreed. Decisions about the required data quality for each field were 'future proofed' as much as possible through engagement with stakeholders to anticipate future needs and build these into the design.	In place – Nick Jones				
Reliability of existing infrastructure systems – (eg, Register, EDI, network, backups).		Maintenance of desktop, network, backups, etc. core part of IT business as usual delivery.	In place – Dave Moysen				
System interdependencies change / are not recognised		Strong interdependency mapping done between IfQ and business as usual.	Done – Nick Jones				
Benefits not maximised and internalised into ways of working.		During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedding into new ways of working. Knowledge handover with the contractors will take place.	In place – Nick Jones				

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
IfQ  IfQ 3: Delivery of promised efficiencies	There is a risk that the HFEA's promises of efficiency improvements in Register data collection and submission are not ultimately delivered.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:		↔ ↔ ↑ ↔	Nick Jones	
			Likelihood	Impact			Inherent risk
			4	4			16 High
			Residual risk level:				
			Likelihood	Impact			Residual risk
			3	4			12 High
Tolerance threshold:		9 Medium					
Causes / sources		Mitigations	Timescale and ownership of mitigations		Commentary		
Poor user acceptance of changes, or expectations not managed.		Stakeholder involvement strategy in place and user testing being incorporated into implementation phases of projects.	In place – Nick Jones/Juliet Tizzard		Above tolerance.		
Clinics not consulted/involved enough.		Working with stakeholders has been central to the development of IfQ, and will continue to be. Advisory Group and expert groups have ended, but a stakeholder group for the implementation phase is in place. Workshops were delivered with the sector regarding how information will be collected through the clinic portal. From beta live onwards we will receive feedback and iteratively develop the products.	In place – Nick Jones/Juliet Tizzard		In November 2016, in light of delays to release two of the portal (which includes the new electronic data interchange system for data submission by clinics), we increased the risk level. The delays stem from the intensive work in progress to complete release one of the website, which requires the attention of the same staff who are needed for release two of the portal.		
Scoping and specification are insufficient for realistic resourcing and on-time delivery of changes.		Scoping and specification were elaborated with stakeholder input, so as to inform the tender. Resourcing and timely delivery were a critical part of the decision in awarding the contract.	In place and contracts awarded (July 2015) – Nick Jones				
Efficiencies cannot, in the end, be delivered.		Detailed scoping phase included stakeholder input to identify clinic users' needs accurately. Specific focus in IfQ projects on efficiencies in data collected, submission and verification, etc.	In place – Nick Jones				
Cost of improvements becomes too prohibitive, or resources are insufficient to complete the Programme.		Contracts only awarded to bidders who made an affordable proposal. Detailed planning for release two (which includes the second iteration of the portal and the introduction of the new EDI interface) is in progress and the HFEA will continue to work within agreed costs.	In place (July 2015) – Nick Jones  In progress (September 2016 to present) – Nick Jones				

	<p>A contingency amount was built into the budget, although this has now been used.</p> <p>The support function has been re-shaped and streamlined to deal with the departure in November 2016 of the release two project manager.</p>	In place (from November 2016) – Nick Jones
Delivery is delayed, causing reputational damage to the HFEA.	Ongoing communication with clinics via Clinic Focus and direct correspondence, to keep them up to date and make them aware of delays.	In place – Nick Jones
Required GDS gateway approvals are delayed or approval is not given.	<p>All GDS approvals sought so far have been granted, albeit with some delays to earlier gateways.</p> <p>Our detailed planning includes addressing the requirements laid down by GDS as conditions of alpha and beta phase approval.</p> <p>Additional sprints of work were incorporated into beta, in an attempt to allow sufficient time (and resources) for the remaining GDS gateway review processes and subsequent formal approval mechanisms.</p> <p>The beta timeline was extended by 3 months to compensate for previous and anticipated future delays.</p>	In place – Nick Jones
Benefits not maximised and internalised into ways of working.	<p>During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedded into new ways of working.</p> <p>Knowledge handover with the contractors will take place.</p>	In place (from June 2015) – Nick Jones
Planned organisational changes to ensure the HFEA can make full use of the new functionality delivered through IfQ could create risks to the completion of IfQ (release 2).	<p>Staff consultation in progress.</p> <p>Additional resources within IfQ to ensure that delivery continues.</p> <p>In the event of turnover or other disruption to IfQ arising from organisational change, we will continue as now to seek temporary cover for vacancies.</p>	In place – Nick Jones

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
<b>Legal challenge</b>  LC 1: Resource diversion	There is a risk that the HFEA is legally challenged in such a way that resources are significantly diverted from strategic delivery.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇄ ⇄ ⇄ ⇄	Peter Thompson
			Likelihood	Impact	Inherent risk		
			5	4	30 Very high		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
4	3	12 High					
Tolerance threshold:			12 High				
Causes / sources		Mitigations	Timescale and ownership of mitigations		Commentary		
Complex and controversial area.		Panel of legal advisors from various firms at our disposal for advice, as well as in-house Head of Legal.	In place – Peter Thompson		At tolerance. <b>Current cases:</b> The judgment in 2015 and subsequent cases on consents for parenthood have administrative and policy consequences for the HFEA.  Further cases are going through court.  The HFEA is unlikely to participate in most of these legal proceedings directly, though the court has required us to provide information and clarification in relation to six legal parenthood cases. The hearing for these six cases is listed for May 2017.  A judicial review hearing of one discrete element of the IfQ CaFC project was held in December 2016 and January 2017.		
		Evidence-based policy decision-making and horizon scanning for new techniques.	In place – Joanne Anton				
		Robust and transparent processes in place for seeking expert opinion – eg, external expert advisers, transparent process for gathering evidence, meetings minuted, papers available online.	In place – Joanne Anton/Juliet Tizzard				
HFE Act and regulations lead to the possibility of there being differing legal opinions from different legal advisers, that then have to be decided by a court.		Panel in place, as above, to get the best possible advice. Case by case decisions regarding what to argue in court cases, so as to clarify the position.	In place – Peter Thompson				
Decisions and actions of the HFEA and its committees may be contested.  New guide to licensing and inspection rating (effective from go-live of new website) on CaFC may mean that more clinics make representations against licensing decisions.		Panel in place, as above.	In place – Peter Thompson				
		Maintaining, keeping up to date and publishing licensing SOPs, committee decision trees etc. consistent decision making at licence committees supported by effective tools for committees Standard licensing pack completely refreshed and distributed to members/advisers (April 2015).	In place – Siobhain Kelly				
		Well-evidenced recommendations in inspection reports.	In place – Sharon Fensome-Rimmer				
Subjectivity of judgments means the HFEA often cannot know in advance which way a ruling will go, and the extent to which costs and other resource demands may result from a case.		Scenario planning is undertaken at the initiation of any likely action.	In place – Peter Thompson		The outcome may impact on the presentation of our data in the new version of choose a fertility clinic.		

<p>HFEA could face unexpected high legal costs or damages which it could not fund.</p>	<p>If this risk was to become an issue then discussion with the Department of Health would need to take place regarding possible cover for any extraordinary costs, since it is not possible for the HFEA to insure itself against such an eventuality, and not reasonable for the HFEA's small budget to include a large legal contingency. This is therefore an accepted, rather than mitigated risk. It is also interdependent risk because DH would be involved in resolving it.</p>	<p>In place – Peter Thompson</p>
<p>Legal proceedings can be lengthy and resource draining.</p>	<p>Panel in place, as above, enabling us to outsource some elements of the work.</p>	<p>In place – Peter Thompson</p>
	<p>Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise work should this become necessary.</p>	<p>In place – Peter Thompson</p>
<p>Adverse judgments requiring us to alter or intensify our processes, sometimes more than once.</p>	<p>Licensing SOPs, committee decision trees in place.</p>	<p>In place – Siobhain Kelly</p>

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
<b>Data</b>  D 1: Data loss or breach	There is a risk that HFEA data is lost, becomes inaccessible, is inadvertently released or is inappropriately accessed.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Nick Jones
			Likelihood	Impact	Inherent risk		
			4	5	20 Very high		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
2	5	10 Medium					
Tolerance threshold:			10 Medium				
Causes / sources		Mitigations	Timescale and ownership of mitigations		Commentary		
Confidentiality breach of Register data.		Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality. Secure working arrangements for Register team, including when working at home.	In place – Dave Moysen		At tolerance.		
Loss of Register or other data.		As above.	In place – Dave Moysen				
		Robust information security arrangements, in line with the Information Governance Toolkit, including a security policy for staff, secure and confidential storage of and limited access to Register information, and stringent data encryption standards.	In place – Dave Moysen				
Cyber-attack and similar external risks.		Secure system in place as above, with regular penetration testing.	In place – Dave Moysen				
Infrastructure turns out to be insecure, or we lose connection and cannot access our data.		IT strategy agreed, including a thorough investigation of the Cloud option, security, and reliability.	In place – Dave Moysen				
		Deliberate internal damage to infrastructure, or data, is controlled through off-site back-ups and the fact that any malicious tampering would be a criminal act.	In place (March 2015) – Nick Jones				
Business continuity issue.		BCP in place and staff communication procedure tested. A new BCP is being produced by the Head of IT to reflect the changes to this following changes to infrastructure and the office move.	In place – Richard Sydee Update done Dave Moysen – September 2016				
Register data becomes corrupted or lost somehow.		Back-ups and warehouse in place to ensure data cannot be lost.	In place – Nick Jones/Dave Moysen				

Other HFEA data (system or paper) is lost or corrupted.	As above. Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality.	In place – Dave Moysen	
Poor records management	A comprehensive review of our records management practices and document management system (TRIM) will be conducted in 2017, following planned organisational changes and the conclusion of IfQ.	To follow – Peter Thompson	

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Data  D 2: Incorrect data released	There is a risk that incorrect data is released in response to a Parliamentary question (PQ), or a Freedom of Information (FOI) or data protection request.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			↔ ↔ ↑ ↔	Juliet Tizzard
			Likelihood	Impact	Inherent risk		
			5	4	20 Very high		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
3	4	12 High					
Tolerance threshold:			8 Medium				
Causes / sources		Mitigations	Timescale and ownership of mitigations		Commentary		
Poor record keeping		A comprehensive review of our records management practices and document management system (TRIM) will be conducted in 2017, following planned organisational changes and the conclusion of IfQ.	To follow – Peter Thompson		Above tolerance.  Although we have some good controls in place for dealing with PQs and other externally generated requests, it should be noted that we cannot control incoming volumes, complexity or deadlines.		
		Audit of Epicentre completed in 2014/15, errors corrected in 2016.	In place – Siobhain Kelly				
Excessive demand on systems and over-reliance on a few key expert individuals – request overload – leading to errors		PQs, FOIs and OTRs have dedicated expert staff/teams to deal with them. If more time is needed for a complex PQ, it is occasionally necessary to take the issue out of the very tightly timed PQ process and replace this with a more detailed and considered letter back to the enquirer so as to provide the necessary level of detail and accuracy in the answer. We also refer back to previous answers so as to give a check, and to ensure consistent presentation of similar data. FOI requests are refused when there are grounds for this.	In place – Juliet Tizzard / Nick Jones				
		PQ SOP revised and log created, to be maintained by Committee and Information Officer/Scientific Policy Manager.	In place - Siobhain Kelly				

<p>Staff turnover resulting in the loss of corporate knowledge regarding the history and handling of PQs, in particular, resulting in slower handling and therefore potential reputational effect with the Department of Health.</p>	<p>Staff have access to past records to inform new responses.  Recruitment completed in January 2017.  Additional legal advice will be sought when beneficial.  Good lines of communication with the Department so that any difficulties can be highlighted at the earliest possible point.</p>	<p>In place – Siobhain Kelly</p>
<p>Answers in Hansard may not always reflect advice from HFEA.</p>	<p>The PQ team attempts to catch any changes to drafted wording that may unwittingly have changed the meaning.  HFEA's suggested answer and DH's final submission both to be captured in new PQ log.</p>	<p>In place – Siobhain Kelly / Peter Thompson</p>
<p>Insufficient understanding of underlying system abilities and limitations, and/or of the topic or question, leading to data being misinterpreted or wrong data being elicited.</p>	<p>As above – expert staff with the appropriate knowledge and understanding in place.</p>	<p>In place – Juliet Tizzard / Nick Jones</p>

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
<b>Opening the Register</b>  OTR 1: OTR service quality	There is a risk that OTR service quality is adversely affected by data accuracy, inadequate support, or human error.	Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.	Inherent risk level:			<ul style="list-style-type: none"> <li>• New (combined from two previous risks)</li> </ul>	Nick Jones
			Likelihood	Impact	Inherent risk		
			3	5	15 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
1	4	4 Low					
Tolerance threshold:			4 Low				
Causes / sources		Mitigations	Timescale and ownership of mitigations			Commentary	
Data accuracy in Register submissions.		Continuous work with clinics on data quality, including current verification processes, steps in the OTR process, regular audit alongside inspections, and continued emphasis on the importance of life-long support for donors, donor-conceived people and parents.	In place – Nick Jones			At tolerance (which is low for this risk).  The pilot counselling service has been in place since 1 June 2015, with annual assessment reports to Authority.	
		Audit programme to check information provision and accuracy.	In place – Nick Jones				
		IfQ work has identified data accuracy requirements for different fields as part of migration planning, and will put in place more efficient processes.	In place – Nick Jones				
		If subsequent work or data submissions reveal an unpreventable earlier inaccuracy (or an error), we explain this transparently to the recipient of the information, so it is clear to them what the position is and why this differs from the earlier provided data.	In place – Nick Jones				
		Data verification work (February 2017) in preparation for Register migration will improve overall data accuracy, and the exercise includes tailored support for individual clinics that are struggling.	In place – Nick Jones				
Lack of counselling availability for applicants.		Counselling service established with external contractor in place.	In place (June 2015 onwards) – Nick Jones				

Insufficient Register team resource to deal properly with OTR enquiries and associated conversations.	Additional member of staff dedicated to handling such enquiries. IfQ delivery means there is still pressure on team capacity, and there has been a long term vacancy in the team, but this post has now been filled (start date 20 February 2017).	In place, with team capacity issue close to resolution (February 2017) – Nick Jones
Risk of inadequate handling of a request.	Trained staff, SOPs and quality assurance in place.	In place – Nick Jones
	SOPs reviewed by Register staff, CMG and PAC-UK, as part of the pilot set-up. Contract in place with PAC-UK for pilot delivery.	Done (May 2015) – ongoing management of the pilot by Rosetta Wotton.
Issuing of wrong person's data.	OTR process has an SOP that includes specific steps to check the information given and that it relates to the right person.	In place – Nick Jones
Process error or human error.	As above.	In place – Nick Jones

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
<b>Financial viability</b>  FV 1: Income and expenditure	There is a risk that the HFEA has insufficient financial resources to fund its regulatory activity and strategic aims.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇄ ⇄ ⇄ ⇄	Richard Sydee
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	3	9 Medium		
Tolerance threshold:			9 Medium				
Causes / sources		Mitigations	Timescale and ownership of mitigations		Commentary		
The complexity of accurately forecasting income, which is linked directly to treatment activity in licensed establishments, exposes HFEA to significant variability in annual income.		Activity levels are tracked and change is discussed at CMG, who would consider what work to deprioritise and reduce expenditure.	Monthly (on-going) – Richard Sydee		At tolerance.  At M10 (January) we have a surplus of £642k before IfQ.  The increase in fees approved by Treasury in 2015/16 continues to impact on the surplus being reported and we expect this to continue into the new business year.  We will continue to monitor activity levels monthly. The creation of the Intelligence team post IfQ implementation allows for more detailed analysis and potentially forecasting of activity levels.		
		Fees Group created enabling dialogue with sector about fee levels. Fee increase was agreed and approved by Treasury. This was implemented and the eSET discount ended (April 2016).	In place. Fees Group ongoing – Richard Sydee				
		Worked planned in 2017/18 to better understand the likely future trends in treatment cycle activity.	Being planned – Richard Sydee				
GIA funding could be reduced due to changes in Government/policy.		A good relationship with DH Sponsors, who are well informed about our work and our funding model.	Accountability Quarterly meetings (on-going) – Richard Sydee				
		Annual budget agreed with DH Finance team alongside draft business plan submission. GIA funding has been provisionally agreed through to 2020.	December annually – Richard Sydee				
		Detailed budgets for 2017/18 have been agreed with Directors. DH has previously agreed our resource envelope.	In place – Morounke Akingbola				
Annual budget setting process lacks information from directorates on variable/additional activity that will impact on planned spend.		Annual budgets are agreed in detail between Finance and Directorates with all planning assumptions noted. Quarterly meetings with directorates flags any shortfall or further funding requirements.	Quarterly meetings (on-going) – Morounke Akingbola				
Legal costs materially exceed annual budget as a result of unforeseen litigation.		Use of reserves, up to contingency level available. DH kept abreast of current situation and are a final source of additional funding if required.	Monthly – Morounke Akingbola				

Upwards scope creep during projects, or emerging during early development of projects.	Senior Finance staff present at Programme Board. Periodic review of actual and budgeted spend by IfQ project board and monthly budget meetings with finance.	Ongoing – Richard Sydee or Morounke Akingbola
	Cash flow forecast updated.	Monthly (on-going) – Morounke Akingbola

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Capability  C 1: Knowledge and capability	There is a risk that the HFEA experiences unforeseen knowledge and capability gaps, threatening delivery of the strategy.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:		↔ ↔ ↑ ↔	Peter Thompson	
			Likelihood	Impact			Inherent risk
			4	4			16 High
			Residual risk level:				
			Likelihood	Impact			Residual risk
4	3	12 High					
Causes / sources			Timescale and ownership of mitigations		Commentary		
Organisational change		See separate risk, below.					
High turnover, sick leave etc. leading to temporary knowledge loss and capability gaps.		People strategy will partially mitigate. Mixed approach of retention, staff development, and effective management of vacancies and recruitment processes.	Done – May 2015 – Rachel Hopkins		Above tolerance. This risk and the set of controls remains focused on business as usual capability, rather than capacity. There are obviously some linkages between capability and capacity, since managing turnover and churn also means managing fluctuations in capability and ensuring knowledge and skills are successfully nurtured and/or handed over. Organisational change is also a factor that can affect this general risk – this has been identified as a separate strategic risk (see below). Since the HFEA is a small organisation, with little intrinsic resilience, it seems prudent to retain a low tolerance level for this risk. Several staff (including end of contract IfQ staff) have left the organisation in the past six months. This means we are currently in a period of turnover		
		Staff have access to civil service learning (CSL); organisational standard is five working days per year of learning and development for each member of staff.	In place – Rachel Hopkins				
		Organisational knowledge captured via records management (TRIM), case manager software, project records, handovers and induction notes, and manager engagement.	In place – Rachel Hopkins				
		Vacancies are addressed speedily, and any needed changes to ways of working or backfill arrangements receive immediate attention.	In place – Peter Thompson				
		Staff are encouraged to identify personal development opportunities with their manager, through the PDP process, making good use of CSL.	In place – Peter Thompson				
The government may implement further cuts across all ALBs, resulting in further staffing reductions. This would lead to the HFEA having to reduce its workload in some way.		The HFEA was proactive in reducing its headcount and other costs to minimal levels over a number of years. We have also been reviewed extensively (including the McCracken review, and our recent Triennial Review). Turnover is variable, and so this risk will be retained on the risk register, and will continue to receive ongoing management attention.	In place – Peter Thompson				

Poor morale leading to decreased effectiveness and performance failures.	Engagement with the issue by managers. Ensuring managers have team meetings and one-to-one meetings to obtain feedback and identify actions to be taken.	In place – Peter Thompson	and internal churn, with some knowledge gaps, and IfQ work ongoing for both release one (although this is now close to completion) and release two.
	Staff survey and implementation of outcomes, followed up after December 2016 all staff conference. Task and Finish Groups working on recommendations for improvements.	Survey and staff conference done – Rachel Hopkins Follow-up plan and communications in place – Peter Thompson	
Particular changes or other pressures for individual teams could lead to specific areas of knowledge loss and low performance.	CMG and managers prioritise work appropriately when workload peaks arise.	In place – Peter Thompson	
	Policies and processes to treat staff fairly and consistently, particularly in scenarios where people are or could be ‘at risk’.	In place – Peter Thompson	
Additional avenues of work open up, or reactive diversions arise, and need to be accommodated alongside business as usual and (at present) the major IfQ programme.	Careful planning and prioritisation of both business plan work and business flow through our Committees. Regular oversight by CMG – standing item on planning and resources.	In place – Paula Robinson	
	Early emphasis given to team-level service delivery planning in preparation for the next business year, with active involvement of team members. CMG will continue to review planning and delivery.	In place – Paula Robinson	
	Planning prioritises IfQ delivery, and therefore strategy delivery, within our limited resources.	In place as part of business planning until IfQ ends (2015 to 2017) – Paula Robinson	
	IfQ has some of its own dedicated resources.	In place – Nick Jones	
	There is a degree of flexibility within our resources, and increasing resilience is a key consideration whenever a post becomes vacant.	In place – Peter Thompson	
Regarding the recent work on licensing mitochondrial replacement techniques, there is a possible future risk that we will need to increase both capability and capacity in this area, depending on uptake (this is not yet certain).	Future needs (capability and capacity) relating to mitochondrial replacement techniques and licensing applications are starting to be considered now, but will not be known for sure until later. No controls can yet be put in place, but the potential issue is on our radar, since it could impact on staff and committee capacity. For now it seems clear that only one clinic will be making applications and that there will not be large numbers of these. New licensing processes are in place, ready for first use (decision trees etc.).	Issue for further consideration when applications begin to be considered – Juliet Tizzard	

<p>Our IT communications systems are an inherent part of our general capability, and since our office move in 2016, we have experienced some technical infrastructure issues with Skype. This leads to poor service (missed calls, poor quality Skype meetings), reputational impacts, additional costs (meetings having to be held externally using non-Skype videoconferencing equipment), and potentially to complaints. Staff are incurring additional work and additional travel, to find and test their own work-arounds so as to avoid using Skype for decision-making meetings until the problems are fixed. This is compounded by a shortage of non-Skype-based videoconferencing solutions in conference venues.</p>	<p>IT team working to identify and resolve the issues, with staff encouraged to continue to send support tickets. External expert commissioned to assist. Staff running meetings continue to source external venues with appropriate facilities so as to avoid reliance on our own equipment until the problems have been solved. Use of mailboxes to provide an alternative channel when Skype calls are not received (however there are also some problems with these too).</p>	<p>In progress – Dave Moysen and Nick Jones</p>	
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Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
<b>Organisational change</b>  OC1: Change-related instability	There is a risk that the implementation of organisational changes is poor, resulting in instability, loss of capability and capacity, and delays in the delivery of the strategy.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			● New	Peter Thompson
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
3	3	9 Medium					
Tolerance threshold:			9 Medium				
<b>Causes / sources</b>		<b>Mitigations</b>	<b>Timescale and ownership of mitigations</b>		<b>Commentary</b>		
<p>Until the new model is formally decided, there will be a level of uncertainty among staff about their own or their colleagues' future roles.</p> <p>This initial phase and then the change period itself may lead to dips in morale, commitment, discretionary effort and goodwill.</p> <p>Anxieties about change during the whole process may sometimes lead to stress behaviours which decrease performance and damage delivery. It is possible that we could reach a tipping point where staff are less productive, or even counter-productive, or become unwell.</p> <p>There are likely to be differential impacts as different changes affect different groups of staff at different times.</p> <p>Risks are to the delivery of current work, including IfQ, and possibly technical or business continuity risks, arising from impacts on motivation, performance and effective capacity.</p>		Clear published process, with documentation	In place – Peter Thompson		At tolerance.		
		Consultation, discussion and communication, with opportunity to comment, and being responsive and empathetic about staff concerns.	Completed – Peter Thompson				
		Relatively short timeline for decision making, so that uncertainty does not linger.	In place – Peter Thompson				
		Staff kept informed of likely developments and next steps, and when applicable of personal role impacts and choices.	In place – Nick Jones				
		HR policies and processes are in place to enable us to manage any individual situations that arise.	In place – Rachel Hopkins				
		Employee assistance programme (EAP) support accessible by all. Effective line management training done for bands 4 and 3, with some band 2s also having this training now.	In place – Peter Thompson				

Organisational change combined with other pressures for particular teams could lead to specific areas of knowledge loss lasting some months (pending recruitment to fill any gaps). Such instances could affect our general capability and capacity for a period of time, and our ability to mitigate effectively against risks and issues.	Policies and processes (and the law) are in place to ensure we treat staff fairly and consistently, particularly if people are 'at risk'. We will seek to slot staff who are at risk into other roles (suitable alternative employment).	In place – Peter Thompson
	Well established recruitment processes, which can be followed quickly in the event of unplanned establishment leavers.	In place – Rachel Hopkins
	Good decision-making and risk management mechanisms in place. Knowledge retention via good records management practice, SOPs and documentation.	In place – Peter Thompson
The above risk factors could potentially challenge our ability to complete delivery of IfQ on time.	Ability to use more contract staff if need be.	In place – Peter Thompson
Once the new structure has been agreed, there will be significant additional work involved across several teams (eg recruitment, changed ways of working, communications) to set it in place and embed it so that the benefits are realised.	Business plan discussions acknowledging that the first part of the year will include completion of IfQ and change management, so should not be loaded up too much with new work (except in teams that are relatively uninvolved in delivering IfQ or organisational change).	In place – Paula Robinson
	CMG able to change priorities or timescales in the event that this becomes necessary, in order to ensure that change is managed well.	In place – Paula Robinson
	Organisational development activity will continue, including summer awayday, to support new ways of working development	In place for coming year – Rachel Hopkins
At the start of a new business year, there are particular pressures for some teams, and for all managers (service delivery planning, Annual Report and end of year accounts, PDPs, for example). This reality plus ongoing pressures from IfQ means that implementing change at this time could be particularly difficult.	Changes will be phased in at different times, depending on factors including IfQ work and formal HR processes. Changes will not all take effect in April.	In place – Peter Thompson
	CMG remains in place and will continue to consider resources, prioritisation questions, planning, risk and performance. We have also scheduled regular informal meetings to allow managers to discuss issues arising from change, so that these can be addressed and mutual support provided.	

Additional pressure on SMT, HR and Heads, arising from the need to manage different impacts, reactions and responses in a sensitive way, while also implementing formal processes and continuing to ensure that work is delivered throughout the change period.	Recognition that change management requires extra attention and work, which can have knock-on effects on other planned work and on capacity overall. Ability to reprioritise other work if necessary.	In place – Peter Thompson
	Time being set aside by managers to discuss the changes with staff as needed, with messaging about change repeated via different channels to ensure that communications are received and understood.	In place – Peter Thompson
	SMT/CMG additional informal meetings arranged to enable mutual support of managers, to help people retain personal resilience and be better able to support their teams.	In place – Paula Robinson
Levels of service to Authority members may suffer while the changes are implemented, negatively impacting on the relationship between staff and members.	Recognition that we need to communicate the changes clearly to Authority members so that they understand when staff are implementing changes, or are particularly under pressure, and that they will have reduced capacity for a period. Members will also need to be informed when staff are new in post, and to understand that those staff need the opportunity to learn and to get up to speed.	To be implemented – Peter Thompson
Once the changes have been implemented, a number of staff will simultaneously be new in post (either new to the organisation, or in a different role). This carries a higher than normal risk of internal incidents and timeline slippages while people learn and teams adapt.	There will need to be a settling period where staff are inducted and can learn, and teams can develop new ways of working. Formal training and skills development will be provided where required. Knowledge management via records management and documentation	To be implemented – Peter Thompson
Bedding down the new structure will necessarily involve some team building time, the development of new processes, staff away days to discuss new ways of working, etc. This is essential to make the changes work well, but will be challenging to achieve given small organisational capacity and ongoing delivery of business as usual.	Change management will be prioritised so that bedding down occurs and is effective, and does not take an unduly long time.	To be implemented – Peter Thompson
	Continuing programme of leadership development for Heads and SMT.	Being planned – Rachel Hopkins

<p>Over time, particularly once IfQ has finished, some staff may decide the changes are not for them, and that they will move on. Other staff may have different residual responses – some may fail to adapt quickly or warm to the improvements, leading to slower delivery of work and possible negative behaviours.</p>	<p>Processes and policies in place to manage performance and behavioural issues, recruitment, turnover, and induction of new staff, in this scenario as in any other.</p> <p>The people strategy for 2017-2020 will focus on supporting and developing our staff to equip them for delivering the HFEA strategy under the new organisational model.</p>	<p>In place – Peter Thompson</p> <p>To be implemented – Rachel Hopkins</p>
<p>The new model may not achieve the desired benefits, or transition to the new model could take too long. In either case, staff could lose faith in the model and it may require adjustment later.</p>	<p>Management are aware of this risk, and are balancing full consideration of our needs, plus consideration of points raised by staff in the consultation exercise, with well planned phased implementation and ongoing communication throughout. The changes will be made without delay, but not all at once.</p> <p>Communication will be clear as to when each phase of the changes will be implemented. We will continue to explain that change will not be ‘big bang’ or linear.</p> <p>The model will be kept under review following implementation to ensure it yields the intended benefits.</p>	<p>To be implemented – Peter Thompson</p>

## Scoring system

The HFEA uses the five-point rating system when assigning a rating to both the likelihood and impact of individual risks:

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

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

# Business plan 2017/18

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

## Details:

Meeting      Authority

Agenda item      13

Paper number      HFEA (15/03/2017) 833

Meeting date      15 March 2017

Author      Paula Robinson, Head of Business Planning

## Output:

For information or decision?      For decision

Recommendation      To approve the business plan for 2017/18 at its current stage of development.

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

Implementation date      Across the 2017/18 business year.

Communication(s)      The HFEA's business plans, once approved by the Department of Health, are published on our website.

Organisational risk       Low       Medium       High

Annexes      Annex 1: business plan 2017/18 – near-final draft

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## 1. Business planning for strategic delivery

### Three-year overview

- 1.1. The Authority's new strategy for 2017-2020 will be launched at our Annual Conference on 16 March, and will come into effect in April. The 2017/18 business plan is designed to deliver year one of that new strategy, as well as to ensure completion of our goals from the outgoing strategy (which concludes in July 2017).
- 1.2. Our Information for Quality programme will formally end on 31 March 2017. However, we expect the first quarter of the 2017/18 business year to be one of transition and change. We will need to complete work on the new electronic data interchange system, and translate our new systems into 'business as usual'. We will also restructure the HFEA to ensure that we can use our new systems and tools well, in the interests of high quality care for everyone affected by fertility treatment.

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## 2. Progressing our strategy in 2017/18

### Main business plan goals

- 2.1. Our business plan sets out in detail how we plan to deliver our strategy in the coming year.

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### Safe, ethical effective treatment

#### High quality and safe treatment

We want to ensure that patients receive a high quality, safe service. In our regulatory activities, we will increase our emphasis on consistency in quality standards. We will also focus on the learning culture in clinics, ensuring that any incidents, adverse events or complaints are converted into learning and improvement. We will ensure that our own processes for licensing and other decisions remain robust, and that applications for preimplantation genetic diagnosis (PGD) and mitochondrial donation are processed well so that decisions affecting patient care are made in a proper and timely manner.

#### Information about treatments and add ons

Once our new website launches, we want to make full use of this to increase patients' understanding of the science and evidence base behind treatments, and the added extras known as add ons. We will provide up to date scientific information about treatments and add ons, and respond to new developments and associated reporting, correcting media inaccuracies or misunderstandings if we need to. And we will use our annual horizon scanning exercise to identify upcoming issues early.

#### High quality research and responsible innovation

There is a separate item about research on today's Authority agenda.

We think that the overall quality of treatment and treatment outcomes can be improved through research. We will encourage clinics to adopt an enquiring culture and to be more research-focused, leading to more scientific and clinical research in clinics, with

new techniques properly trialled and tested. We will explain embryo and data research projects, and their outcomes, on our website, and we will publish information about the availability of embryos that have been donated for research purposes. On inspection, we will ensure clinics are explaining and recording research consents properly, enabling more patients to participate in data research and donate unused embryos for research.

## Consistent outcomes and support

### Access to treatment

We will publish information and advice about access to fertility services, including information for those considering going abroad for treatment on how they might be able to access services in the UK. We will also provide advice about accessing donor conception treatment, and we will work with clinics, sperm banks and other organisations to improve the availability of donor sperm and eggs in the UK.

### Consistency in standards, outcomes, value and support

In our inspection activities, we will continue to evaluate areas of regulatory concern as necessary, and we will focus in particular on shortcomings in the taking and recording of consents, learning from incidents, medicines management, data submission, multiple birth rates, and information published on clinics' websites.

This year will see the introduction of our new Register data submission system for clinics, and we then expect to see a gradual improvement in data quality.

We will also start a piece of work on success rates, working with our professional stakeholders to establish the factors that lead to successful outcomes for patients.

We will make greater use of benchmarking data on outcomes and price, to assist NHS commissioners in securing fair prices and the most effective fertility services for patients. We will also ask patients whether they paid what they expected to for fertility services.

We also want to improve the emotional experience of care in clinics, before during and after treatment or donation. We will define and encourage best practice for support in clinics, ensuring this is applied to patients, donors and donor conceived people.

## Improving standards through intelligence

### Using our data

We are beginning an organisational change process to re-shape ourselves to make best use of our information. We want to use our regulatory intelligence and other data to drive quality improvements in the sector. We will begin by developing an information strategy describing how we will analyse, publish and use our data. In addition, we will regularly update our new Choose a Fertility Clinic tool, improved as part of the Information for Quality Programme.

We respond to a wide range of information requests and Government initiatives, including responses to Freedom of Information requests, Parliamentary Questions and public enquiries. We will continue to respond to these requests and to collaborate with other bodies in the interests of quality.

We will also collect more patient feedback in the coming year, using the intelligence gained to inform our activities and our messaging to clinics, and sharing the information with professional stakeholders.

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### **3. Finalising the business plan**

#### **Year-end content**

- 3.1.** Some content can only be added at year end. This includes performance data, HR benchmarking information, and various other facts and figures that provide a complete picture of the previous business year. We will add this data in April, before submitting the finalised document for Department of Health approval.

#### **Sign-off and publication**

- 3.2.** The Department of Health have given positive initial feedback on the earlier draft of the business plan. There is a shared delivery plan for all arm's length bodies and the Department, describing objectives and priorities across the whole health system, and this is currently being reviewed. If this review is completed prior to publication, the linkages to it in the activities section of the business plan will be updated accordingly.
- 3.3.** We anticipate receiving budget approval shortly, after which we will be able to finalise the document and seek approval from the Department for publication.

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### **4. Recommendation**

- 4.1.** The Authority is asked to approve the 2017/18 business plan, and to note that year-end information will be added in April.
- 4.2.** We anticipate receiving Department of Health sign-off of the business plan and the associated budget by the end of April, after which the business plan will be published on our website.

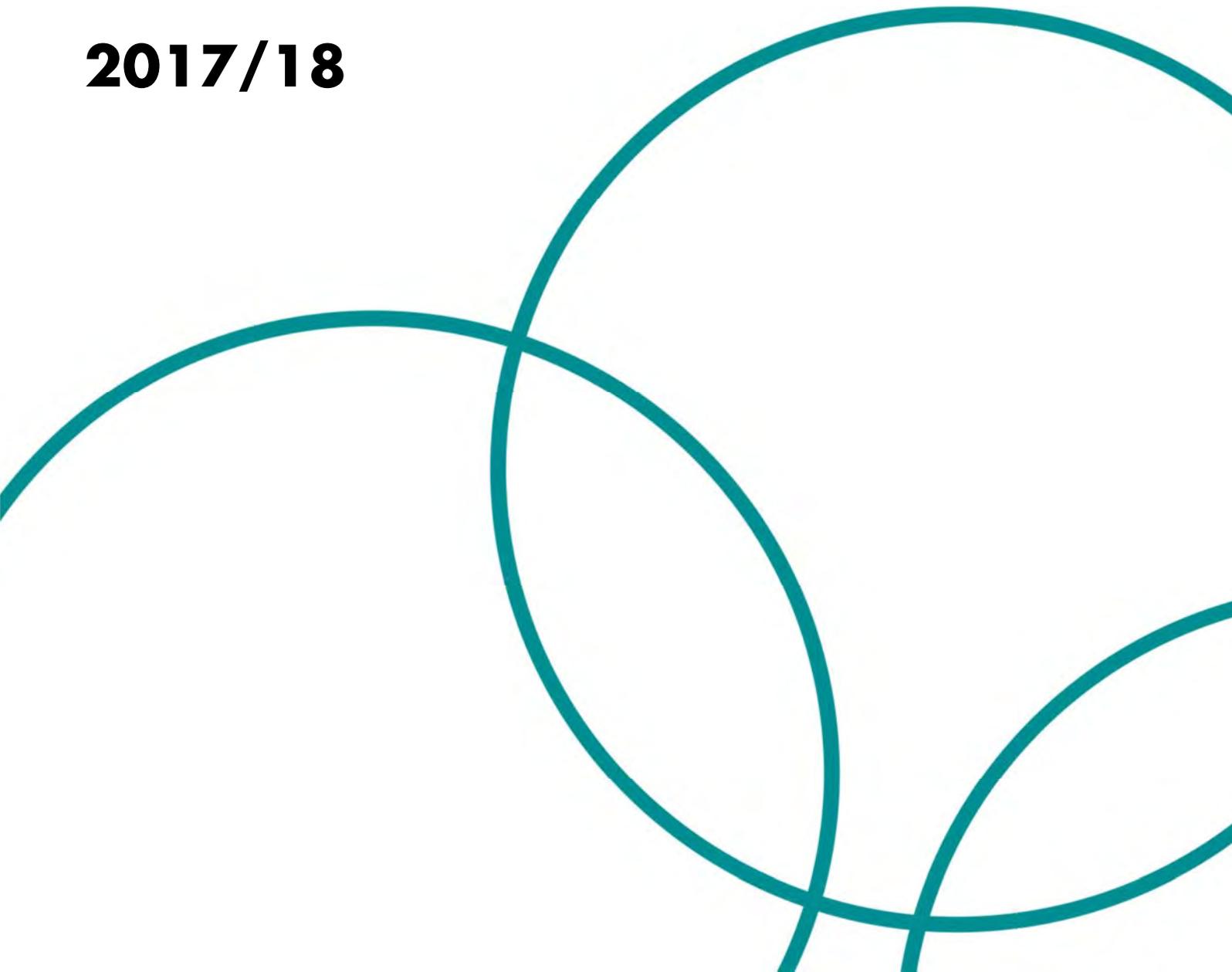


Human  
Fertilisation &  
Embryology  
Authority

## **Annex A: Business plan 2017/18**

# **Business Plan**

**2017/18**



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# Our role and strategic aims

## Who we are

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

Our vision for 2017-20 is:

**High quality care for everyone affected by fertility treatment.**

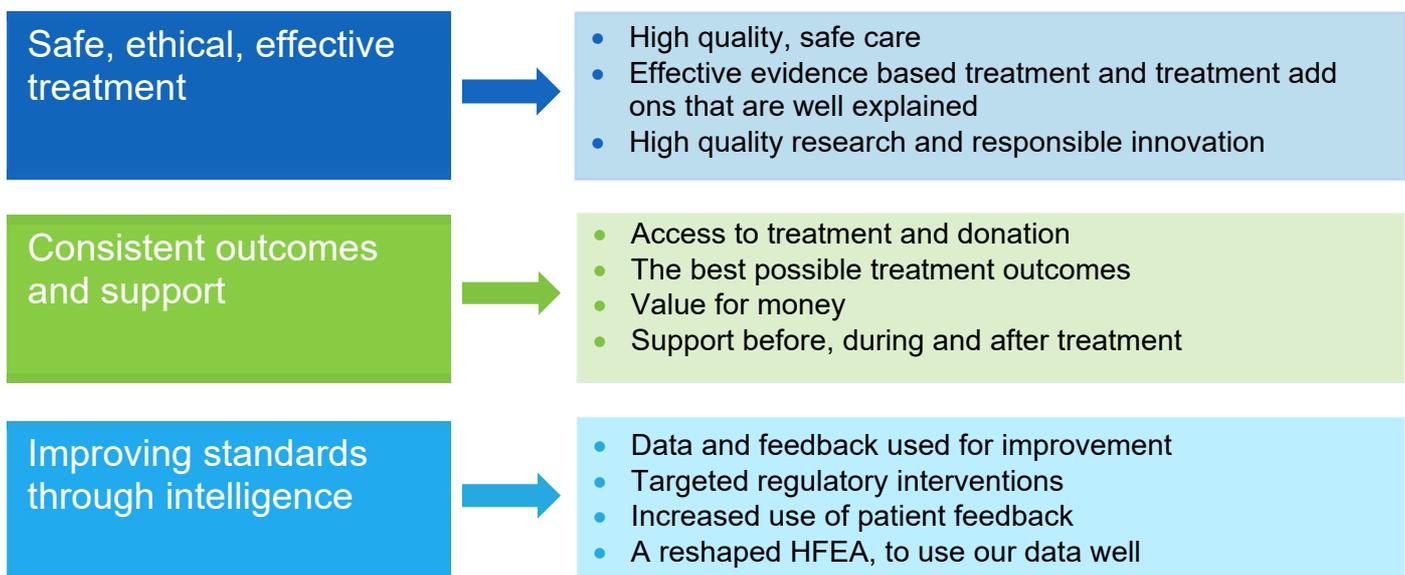
Patients, donors and donor-conceived people are at the heart of our strategy, and our work. We want them all to receive high quality care and support, at every stage in their journey through fertility services.

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

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

## What can we do to achieve high quality care?

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



This business plan sets out how we will work towards our vision in 2017/18.

## Our legislation and functions

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

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

Under this legislation our main statutory functions are:

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

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

- Promoting compliance with the requirements of the 1990 act (as amended), the 2008 act and the Code of Practice.
- Maintaining a statement of the general principles that we should follow when conducting our functions and by others when carrying out licensed activities.

- Observing the principles of best regulatory practice, including transparency, accountability, consistency, and targeting regulatory action where it is needed.
- Carrying out our functions effectively, efficiently and economically.
- Publicising our role and providing relevant advice and information to donor-conceived people, donors, clinics, research establishments and patients.
- Reviewing information about:
  - human embryos and developments in research involving human embryos
  - the provision of treatment services and activities governed by the 1990 act (as amended).
- Advising the Secretary of State for Health on developments in the above fields, upon request.

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

# What we did in 2016/17

# Delivery of the 2016/17 business plan

## Overview

In 2016/17 we formally completed our Information for Quality Programme, known as IfQ. This programme has given us the means to transform how we collect, analyse and publish information. It enabled us to complete our strategic delivery for 2014-2017, and equips us well for 2017-2020. The public, the sector and the HFEA itself can now reap the benefits of our new and improved website, a better Choose a Fertility Clinic feature, and a Clinic Portal which has improved functionality and design.

In 2017, we will also introduce a new data submission system for clinics, which will increase the 'first time' accuracy of the data submitted to us, and decrease the effort required by clinics in submitting data to us for the Register of treatments. This will establish a more modern, effective and reliable technical underpinning for the Register, the Clinic Portal and the website.

Our activities for last year also included a particular regulatory focus on shortcomings in the taking and recording of consents, medicines management, data submission, multiple birth rates, and information published on clinics' websites. In the second half of the year the Authority agreed to allow the new treatment of mitochondrial donation.

We reviewed our embryo research policies and regulation, and responded to various new Government agendas and reports including our Triennial Review **[DN: publication date to be confirmed]** and a range of new Government requirements on transparency, innovation and business impact.

We developed our next strategy, for 2017-2020, retaining our strong vision for high quality care for everyone affected by fertility treatment. We have the staff and the financial resources in place to complete this varied and challenging programme of work.

## Setting standards

### Improving the quality and safety of care through our regulatory activities

#### Delivering the full compliance and licensing cycle to maintain standards for patients

Our compliance activities provide assurance on standards and safety for the public and our other stakeholders. We always aim to have a positive overall impact on the quality of care, on outcomes, safety and support, and on the information clinics publish for their patients (eg, on their websites).

In 2016/17, we carried out our usual full range of inspection, audit and licensing activities. This ensured that clinics were appropriately inspected and monitored against published performance indicators, and issued with licences for up to four years. We also continued our programme of unannounced inspections.

Our governance and licensing work during the year included handling applications for the licensing of preimplantation genetic diagnosis (PGD) and human leukocyte antigen (HLA) testing. This is a growing area of work, which needs to be processed effectively and efficiently so that decisions on whether to authorise such treatments are made, and communicated, in a proper and timely manner for the direct benefit of patients awaiting treatment. We have also recently received our first ever licensing application from a clinic that wishes to offer mitochondrial donation treatment.

Our triennial review report was completed in 2016, but has yet to be published. Our action plan in response to its recommendations has been largely completed, and will conclude the benefits realisation review for the IfQ programme, during the coming year. We continually work to ensure that all our compliance processes encourage quality improvements. We want our regulatory work to have a positive impact and to be effective.

### **Identifying and implementing ways of improving the quality and safety of care**

We continued to focus on the quality and safety of care in our inspection activities – in particular through identifying shortcomings in the taking and recording of consents, medicines management, data submission, multiple birth rates, and information published on clinics' websites.

It is vital that clinics understand, and adhere to, correct consent procedures (including those associated with legal parenthood). Through our regulatory work, we emphasised the importance of getting this right, and helped clinics to improve their practices.

New guidance on consent will be published in April 2017. This will include a new suite of forms for transgender people, which will help clinics to offer a high quality service to this small but growing group of patients.

Our multiple births policy, 'One at a Time', has been a real success. In 2008 24% of all births from assisted reproduction were multiples. Today the average figure is 14%, with many clinics well under the 10% target. Success rates have remained steady and, most importantly, patient understanding of the risks of multiple births and the benefits of single embryo transfer has increased.

We published our latest report on clinical incidents in 2016. We encourage our clinics to have a learning culture, and to share learning throughout the sector so that all clinics are safer and errors are minimised. It is important that any negative patient experiences result in improvements, and that any recurrence is prevented. We developed a collaborative relationship with NHS Improvement, so as to consider wider lessons learned that may have relevance in the fertility sector.

As part of our IfQ programme, we worked with clinics throughout the year to improve the quality of our Register data. Building on that work, we will improve the data submission systems used by clinics so that less remedial work is needed in the future – data submitted will be 'right first time'. The end result will be a better quality service for Opening the Register (OTR) applicants, and fewer data submission and data accuracy related non-compliances found on inspection and audit. In the coming year we will also be in position to extract

better value from the wealth of data we hold, and publish a wider range of information about trends and statistics.

Through our new website, we have published a wider range of reference material for patients, including better information and signposting for patients when they first realise they may have a fertility issue. We want to help patients to feel more equipped to ask the right questions about fertility issues and available treatments, regardless of the level of knowledge of their own particular GP.

### **Acknowledging that treatment is often unsuccessful, and exploring with professional stakeholders how the HFEA and clinics could better address this issue.**

Our new website will contain more information about the chance of a birth following fertility treatment, so that patients to have realistic expectations (both of actual success rates and of what they should expect of clinics in the event that their treatment is unsuccessful). We expect clinics to handle unsuccessful treatment with sensitivity, offering counselling and support as appropriate.

### **Maintaining our role as the UK's competent authority for ART in the European Union.**

As long as the UK remains in the EU we will continue to participate in competent authority events and the implementation of associated EU decisions. We participate in two meetings per year.

These meetings help us to gain up-to-date intelligence about the perspectives of other EU member states, helping to inform the UK approach to patient safety and care. As the competent authority, we continued to ensure that free movement of gametes and embryos was enabled within the UK and that standards upheld in the UK were consistent with those in the rest of the EU.

### **Reviewing our embryo research policies and regulation.**

We reviewed the consent process for donating embryos for research, in collaboration with the Health Research Authority (HRA), the sector and other stakeholders. We also reviewed the relevant

Code of Practice guidance and licence conditions, the end-to-end application and approval process, and the associated paperwork.

As a result, we have made improvements to the application and licensing process, ensuring it remains robust but does not impose unnecessary burdens. We have also improved the forms used by peer reviewers to inform the Licence Committee's decisions about research project licences.

### Improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families

#### Providing information about donor conception directly to patients and donors

Better information has been central to our Information for Quality programme.

We now have a completely redesigned website and Choose a Fertility Clinic (CaFC) tool, with a new headline measure of births per embryo transferred.

We provide up to date information about donation (via the new website) and have improved the information we provide about gamete availability (via CaFC). We want to equip potential donors, recipients and donor conceived people with clear, authoritative impartial information about a range of donor conception issues, so that they feel better informed and supported with respect to the legal aspects and obligations of donation.

#### Ensuring that clinics prepare patients adequately for donation and fully understand their role and importance as a lifelong information provider; and that egg and sperm donors are well supported and understand the lifelong commitment that follows from donation.

We publish information about donation so that clinics, donors and patients could understand all of the issues and legalities associated with donation.

We also emphasised to clinics the importance of their role and performance in relation to donation and the associated information guardianship responsibilities.

#### Evaluating the provision and take-up to date of the counselling support pilot for donor-conceived people wishing to access information held on the HFEA Register

In July 2016, we evaluated the first full year of the three-year pilot of counselling support services for applicants to the Register<sup>1</sup>. Feedback so far has been positive.

Counselling support through the pilot is offered for all Opening the Register (OTR) applicants (those seeking non-identifying information) and for donor-conceived applicants receiving donor identifying information, throughout the pilot period.

Mediation services are also in place for when donors and donor-conceived people meet. Our mediation training and systems assist us in managing the process of identity release to donors and donor-conceived people.

#### Implementing new EU requirements relating to the import and coding of donor eggs and sperm

This year, we were due to complete a set of projects initiated in 2014/15 to implement new EU requirements on the import of donor gametes and new EU coding requirements for human tissue and cells. The aim is to achieve compliance with the new EU directives, improved clarity for clinics, patients and donors, and improved internal clarity and updated procedures for our decision-making committees. The projects will also ensure robust processes are in place to ensure the quality, safety and traceability of imported gametes and embryos.

A Department of Health consultation on the implementation of the directives has been delayed, but is expected to be released shortly. The work will be completed in 2017/18.

<sup>1</sup> Explanatory note: A donor conceived person aged 18 or above is entitled to access identifying information about their

donor, provided the donor has asked for their right to anonymity to be removed.

## Increasing and informing choice

### Using the data in the HFEA Register of Treatments to improve outcomes and research

#### **Maintaining the Register of Treatments and Outcomes and supporting clinics in reporting the data**

Throughout the development work of the IfQ programme, we have continued to ensure that Register data and forms are processed and quality assured, through liaison with clinics on errors and omissions and through validation and verification of Register entries. We are especially grateful to clinics for their cooperation and hard work during the latter part of the IfQ programme while we conducted a more extensive data verification exercise than usual to ensure that the new Register structure contains high quality, accurate data when we migrate from the old system.

#### **Publishing and supplying the information we hold, for the benefit of stakeholders.**

Our focus for much of the 2016/17 year, through IfQ, was to ensure our published outcome data is more useful and easier to understand and provides positive incentives for service improvements.

Our new CaFC will provide a much more rounded picture of quality. For the first time, patients will be able to see at a glance not only the outcome statistics for a particular clinic, but also a rating based on the most recent inspection report and a patient experience rating.

The new CaFC will be subtly different to the beta version we issued for consultation in summer 2016. The consultation response was very strongly against our original proposal to aggregate all treatments and all ages in the headline measure – and the Authority therefore made a decision in November 2016 that the new headline births per embryo transferred measure will be based on stimulated IVF and ICSI involving women under 38 using their own fresh eggs. All the other data for patients that is available on the current CaFC continues to be available on the new CaFC.

While the new version was being developed, we have continued to update the current CaFC periodically with the latest data and inspection reports, so as to assist patient choice and keep the information we provide as up-to-date and accurate as possible.

We will seek ongoing feedback to evaluate the effectiveness and usability of the new CaFC presentation, and to plan future improvements.

One of our most important legal duties is to facilitate timely access to information from the Register for those who are entitled to it, and we have continued to manage Opening the Register requests in a sensitive manner and within the required time limits (20 working days, excluding time for counselling), throughout the year.

We also provide information for researchers requesting access to Register data, and we have continued to do this within the required time limit (90 calendar days from approval). It is important that the information in the Register can be used to best effect, to increase understanding and facilitate good research, and ultimately benefit patients. In our strategy for 2017-2020, we have placed a renewed emphasis on improving the evidence base for both embryo and data research.

We fulfilled a range of access to information requests under various regimes, including regular information publication under various legal and Parliamentary rules.

We published our annual report on clinical incidents and alerts. We encourage a culture of openness and information sharing, with clinic staff empowered to report mistakes and learn from each other. Our report aims to increase transparency and maximise the opportunities for learning from incidents, so as to improve the quality and safety of care for patients.

#### **Maintaining our previously established collaborative information management relationships**

It is important for us to maintain the good working relationships we have established with the relevant bodies, such as the Government Digital Service (GDS), NHS Digital (formerly the Health and Social Care information Centre) and the National Information Board (NIB). Through collaborative

working, we contribute to the objectives of the wider health system, with respect to information management.

Our participation in joint work with such bodies facilitates learning from best practice and easier sharing of expertise, so that we can all make use of each other's strengths and knowledge in data management, systems integrity and security.

### Ensuring patients have access to high quality meaningful information

#### Improved HFEA website information about treatments available, scientific research, embryo and stem cell research and other fertility subjects

The new HFEA website will be released from its beta state to live in Spring 2017 and the old site will then be switched off. The new site is aimed primarily at patients and donors and adopts a tone of voice and level of detail designed for that audience. It is simpler, more direct and – like our new strategy – is organised round the patient's treatment journey.

It has been designed to be read on phones and tablets as increasingly that is people's primary means of accessing information online. And it uses new ways of presenting information – with animations and videos, as well as the traditional text and documents.

The website now provides an expanded range of educative and scientific information about current and future treatment options, the scientific evidence associated with these, and other fertility issues. This includes clearer information for prospective patients, and some useful signposting to external sites and other information resources.

We conducted our annual horizon scanning exercise to ensure we identified possible new scientific developments. Our Scientific and Clinical Advances Advisory Committee (SCAAC) meets regularly to discuss issues identified through this exercise. This helps us to ensure that our future work, our policy developments and our website material are informed by experts and that we maintain an understanding of scientific issues and developments.

#### Working with clinics and scientific experts to publish information about new treatments

As part of our development work for the website, we have established mechanisms for producing and publishing informative and accurate material when new treatment options emerge, working in collaboration with clinics and experts, including SCAAC.

In addition to providing more information about new treatments, we want to increase the public's understanding of emerging new science and future treatment possibilities. We believe this keeps patients better informed and leaves them better placed to make treatment decisions and to judge for themselves the merits or otherwise of any media speculation about potential new treatments.

#### Enhancing the patient voice in all of our work, including information provision

In the course of IfQ, we have greatly developed our communications with, and information provided to, patients, with the aim of making our information as patient-friendly and useful as possible, and to help them to make informed choices about fertility matters. Patient views and needs are now continuously incorporated into our core business, for example through user experience ratings of clinics.

#### Responding effectively to specific enquiries from individuals

We receive many individual patient and public enquiries each year. These are specific and sometimes complex, questions, which receive a tailored and meaningful response within a reasonable timescale.

Analysis of such enquiries also helps us to identify any trends and common themes, informing the development of additional information which could usefully be placed on our website.

## Efficiency, economy and value

### Ensuring the HFEA remains demonstrably good value for the public, the sector and Government

#### Ensuring the HFEA is easy to deal with and offers a professional service

In 2017/18, we will complete the work started in 2015/16 through the IfQ programme to modernise our Register function and processes (EDI, data submission and verification, the clinic portal, and the data dictionary). As well as a range of improvements for patients, this will result in reduced transactional costs for clinics and increased satisfaction for clinic users, whether they are submitting data to us or looking for the latest regulatory guidance.

In January 2017 we released the first stage of the new clinic portal, the primary means by which clinics interact with us between inspections. The portal reminds clinics about actions, offers searchable guidance and regulatory information, gives clinics clearer monitoring and performance information and allows them to apply for licence variations, through a simple online system.

The second stage of the clinic portal will follow later in 2017 and will greatly improve the data submission system. This will allow clinic staff to spend more time treating patients and less time filling in forms or verifying that the submitted data is correct. We have also been working positively with suppliers of patient records systems, used by approximately half of our clinics, so as to make the transition seamless.

The improvements will also allow HFEA staff to spend less time checking data and chasing errors. Instead we will spend more energy on analysing the data we hold, providing clinics and patients with national level intelligence on a range of key issues.

We have also continued our engagement arrangements with clinics on fees charged. This provides both accountability and transparency in respect of the fees we charge clinics.

#### Ensuring the HFEA is a good value organisation and makes best use of its limited resources

We use our strategy as a mean of prioritising our activities and managing our limited resources to best effect.

We aim to provide a speedy service to patients whenever they contact us.

IfQ has provided us with an infrastructure that underpins the delivery of our strategic vision. We will put in place a new organisational structure to enable us to make full use of our data and improved information channels, and a staff consultation on the changes took place at the end of the 2016/17 business year.

It is vital that we can maintain the staff capacity and capability needed to deliver our strategy and our core statutory duties. We ensure our staff have the skills and training they need to perform their roles effectively, and all our staff have access to Civil Service Learning to build their own development plans and enhance their competencies.

#### Responding as appropriate to emerging new government rules on transparency, innovation and better regulation (the Enterprise Bill, the 'growth duty' and the Regulators' Code)

In order to comply with new better regulation requirements, we consulted on an innovation plan in Spring 2016. Encouraging responsible clinical innovation is at the heart of our new strategy for 2017-2020.

We report annually on compliance with the Regulators' Code, and in time, the new growth duty. In addition, during the year we ran a project to introduce the new business impact target, which requires regulators to submit a formal business impact assessment for all qualifying activities and projects.

Our statutory independent appeals mechanism means that we are exempt from the requirement to have a Small Business Appeals Champion.

**Ensuring the HFEA is an effective collaborator and partner in the interests of the efficiency of the wider Department of Health group of ALBs and other health organisations**

Throughout the year, we participated in the collaborative 'one stop shop' for life sciences to provide regulatory advice to those working in the life sciences industry. This is continued joint work between ourselves, the Human Tissue Authority (HTA), the Health Research Authority (HRA) and the Medicines and Healthcare products Regulatory Authority (MHRA).

This year we worked with the MHRA to provide guidance on CE marking, and on the use of non-CE marked goods for mitochondrial donation techniques. We have attended meetings about their new guidance on medical devices and drug-device combination products. We also continue to work with them on related areas, such as medical devices alerts. We will continue to work with the MHRA, and others, to share intelligence and ensure joined up working.

We share services and infrastructure with other organisations as practicable, sharing a Finance

Director and Head with the HTA, and receiving services through service level agreements (SLAs) with relevant other organisations for certain HR services and using Civil Service Learning as our key learning and development provider. We moved to shared premises with NICE in April 2016, helping both organisations to make best use of Crown Estate property, and receive facilities services from NICE.

We work collaboratively, and have various memoranda of understanding with various other ALBs and health regulators UK wide, such as the Care Quality Commission (CQC), the MHRA, the United Kingdom Accreditation Service (UKAS), the HRA, and the General Medical Council (GMC).

We are active members of the National Information Board (NIB) and have good working relationships with regulators in the devolved nations of Scotland, Wales and Northern Ireland.

# Delivering our strategy in 2017/18

## Delivering the strategy

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

High quality care for everyone affected by fertility treatment.

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

In this area...	We will...
Safe, ethical, effective treatment	1. Ensure that all clinics provide consistently high quality and safe treatment
	Our aim: <ul style="list-style-type: none"> <li>patients know clinics provide a high quality, consistent, safe service</li> </ul>
	2. Publish clear information so that patients understand treatments and treatment add ons and feel prepared for treatment
Consistent outcomes and support	Our aim: <ul style="list-style-type: none"> <li>increase patients' understanding of the science and evidence base behind treatments and added extras known as add ons, and of their safety and effectiveness.</li> </ul>
	3. Engender high quality research and responsible innovation in clinics
	Our aim: <ul style="list-style-type: none"> <li>improve the quality of treatment, by encouraging world class research and clinical trials.</li> </ul>
Improving standards through intelligence	4. Improve access to treatment
	Our aim: <ul style="list-style-type: none"> <li>provide advice and information about access to treatment and improve access to donor conception treatment.</li> </ul>
	5. Increase consistency in treatment standards, outcomes, value for money and support for donors and patients
Improving standards through intelligence	Our aims: <ul style="list-style-type: none"> <li>higher birth rates, without adverse outcomes.</li> <li>patients and NHS commissioners receive good value fertility services</li> <li>improve the emotional experience of care by clinics before, during and after treatment or donation</li> </ul>
	6. Use our data and feedback from patients to provide a sharper focus in our regulatory work and improve the information we produce.
	Our aims: <ul style="list-style-type: none"> <li>use our data and intelligence to drive quality improvements for patients.</li> <li>targeted and responsive regulatory interventions in the interests of quality and consistency.</li> <li>increase insight into patient experience in clinics and encourage good practice based on feedback.</li> <li>work more smartly with our resources, and capitalise on recent systems improvements.</li> </ul>

The activities set out over the next few pages describe how we will meet these strategic objectives in 2017/18.

There is also an agreed [shared delivery plan](#) for all arm's length bodies and the Department of Health. This delivery plan gives high level clarity on objectives that reach across the whole health system. Since we are a specialist body, not all of the Department's priorities are relevant to our work, but our activities fit well within them – most notably in relation to the objective of creating the safest, highest quality healthcare services possible. Linkages with specific objectives in the shared delivery plan are indicated in the activities section setting out our plan of work for 2017/18.

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## Activities for 2017/18

Having delivered the majority of our previous strategy (due to conclude in July 2017), we now have a new public website and clinic portal. We will soon migrate our Register of treatment information into a new database. And we are putting in place a new data submission system to collect treatment data in a more efficient and accurate way.

These developments enable us to collect and use our data, and to communicate with our audiences, more effectively and efficiently. In the course of 2017 we will also re-shape our organisation to ensure we have the skills and capacity in place to make full use of our new tools and the new possibilities they open up.

There are three main areas of focus in our strategy:

- safe, ethical, effective treatment
- consistent outcomes and support
- improving standards through intelligence.

The activities set out over the next few pages will help us to deliver our strategic objectives in 2017/18, in the interests of high quality care for everyone affected by fertility treatment.

Aims	Methods and channels	Benefits and outcomes	Timescale
<b>Safe, ethical, effective treatment</b>			
<b>Strategic objective 1: Ensure that all clinics provide consistently high quality and safe treatment</b>			
<p>Ensure that clinics are well regulated and provide a high quality, consistent service.</p> <p>Outcomes in this area of work will contribute to the Department of Health's shared delivery plan (SDP) – objective 2: creating the safest, highest quality healthcare services.</p>	<p>Full programme of clinic regulation, encompassing all of our inspection, audit and licensing activities, with an increased emphasis on consistent standards across the sector, and between inspections. We will be clearer about what good performance looks like and will use our skills and our data to help clinics to be more compliant, more of the time.</p>	<p>All clinics and research establishments in the sector are appropriately inspected and monitored against the requirements of the Act and published performance indicators, and issued with licences for up to four years.</p> <p>Continued programme of unannounced inspections.</p> <p>Assurance of consistent standards and safety for the public and other stakeholders.</p> <p>A clear Code of Practice and other guidance for clinics, that is regularly updated.</p> <p>Positive overall impact on quality of care, outcomes, safety, support, and information clinics provide to the HFEA and publish (eg, on their websites).</p> <p>Patients know that all clinics are safe and appropriately licensed.</p> <p>Reduction in the number of critical, major and other non-compliances.</p> <p>Reduction in the number of clinic incidents, owing to learning from own and others' mistakes.</p>	<p>Throughout year</p>
	<p>Continued strong focus on learning from incidents, adverse events and complaints from patients, in dialogue with the sector. This will include a focus on incidents and clinics' learning culture during inspections, and publication of our annual review of clinical incidents.</p>	<p>Publication of report on clinical incidents 2016.</p> <p>Sector provided with useful information about learning points from incidents and adverse events.</p> <p>Learning gained, to inform future inspections.</p> <p>Patients' negative experiences used to make improvements and prevent recurrence.</p>	<p>November 2017</p> <p>Throughout year</p>

Aims	Methods and channels	Benefits and outcomes	Timescale
		<p>Better understanding of factors contributing to particular types of adverse event.</p> <p>Collaborative relationship established with NHS Improvement to consider any wider lessons learned that may have relevance for the fertility sector.</p>	
	Ensuring governance tools underpinning licensing and other decisions are in place and effective.	Efficient and effective decision-making is maintained. Decisions are evidenced and consistent.	Throughout year
	Conduct an options appraisal for the future handling of representations and appeals processes.	To ensure that the HFEA's processes balance sound governance with cost effectiveness.	December 2017
	Processing applications for the licensing of preimplantation genetic diagnosis (PGD), human leukocyte antigen (HLA) and mitochondrial donation.	<p>Growing area of work dealt with effectively and efficiently, with applications processed according to performance indicator timelines.</p> <p>Public confidence assured in the regulation of mitochondrial donation.</p> <p>Decisions on whether to authorise such treatments made, and communicated, in a proper and timely manner for the direct benefit of patients waiting for treatment.</p>	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
<b>Strategic objective 2:</b> <b>Publish clear information so that patients understand treatments and treatment add ons and feel prepared for treatment</b>			
<p>Make use of our new website and other channels to increase patients' understanding of the science and evidence base behind treatments and added extras known as 'add ons', and of their safety and effectiveness.</p> <p>Outcomes in this area of work will contribute to the Department of Health's <a href="#">SDP</a> – objective 7: enabling people and communities to make decisions about own health and care; and objective 9: improving services through the use of digital technology, information and transparency.</p>	<p>Inclusion of up to date scientific content in our website so as to provide and maintain our expanded range of information about current and future treatment options and treatment add ons, and the scientific evidence base for these.</p> <p>Responding to new scientific developments and associated reporting, correcting myths and misunderstandings where necessary.</p> <p>Conducting our annual horizon scanning exercise to ensure we identify relevant new scientific developments.</p>	<p>Patients and others turn first to the HFEA for up to date, clear unbiased information. Prospective patients have clear information on which to base decisions about treatment or add ons.</p> <p>Patients feel safe, knowing they can expect certain standards in clinics, and are more aware of the potential risks of new/different treatments or add ons as well as the possible benefits.</p> <p>The Scientific and Clinical Advances Advisory Committee meets to discuss issues identified through horizon scanning three times per year.</p> <p>The horizon scanning panel meets once per year.</p> <p>Policy developments and website material are informed by expert input and an understanding of scientific issues and future developments.</p> <p>Future work planning is facilitated by early identification of upcoming issues.</p>	<p>Throughout year</p> <p>Throughout year</p> <p>June/July 2017</p> <p>Throughout year</p>

Aims	Methods and channels	Benefits and outcomes	Timescale
<b>Strategic objective 3:</b> <b>Engender high quality research and responsible innovation in clinics</b>			
<p>Improving the overall quality of treatment, by encouraging world class data and embryo research and clinical trials.</p> <p>Outcomes in this area of work will contribute to the Department of Health's <a href="#">SDP</a> – objective 6: supporting research, innovation and growth.</p>	<p>Encourage an enquiring culture and responsible innovation in clinics.</p> <p>Explaining embryo and data research projects and their outcomes.</p> <p>Encouraging clinics to enable more patients to participate in data research, and to donate unused embryos for research.</p> <p>Publishing information about the availability of embryos donated for research purposes.</p> <p>Ensuring that clinics explain research consent adequately, record consent properly and then report consents accurately to the HFEA.</p>	<p>Clinics become more research-focused, leading to more scientific and clinical research in clinics, with new techniques properly tested.</p> <p>A larger, higher quality evidence base, leading to improved outcomes.</p> <p>Patients are aware of research they could take part in, and how it might benefit future patients.</p> <p>Patients can easily donate embryos to research and research centres have access to those donated embryos for their research projects.</p> <p>Higher rate of consent to research from patients.</p> <p>Improvement in consent-taking and reporting by clinics.</p>	<p>March 2018</p>
	<p>Information provision for researchers requesting access to Register data.</p>	<p>Information for researchers is provided within 90 calendar days of approval.</p> <p>Register information is used to best effect, to increase understanding and facilitate good research, and ultimately patient benefit.</p>	<p>Throughout year</p>

Aims	Methods and channels	Benefits and outcomes	Timescale
<b>Consistent outcomes and support</b>			
<b>Strategic objective 4: Improve access to treatment</b>			
<p>Providing advice and information about access to treatment, and improving access to donor conception treatment.</p> <p>Outcomes in this area of work will contribute to the Department of Health's <a href="#">SDP</a> – objective 7: Enabling people and communities to make decisions about their own health and care.</p>	<p>Publishing information and advice about accessing services, through various channels, including information for those considering going abroad for treatment on how they might access services in the UK.</p>	<p>People understand the possibilities and the hurdles, and can weigh up the options open to them (measured through patient surveys).</p> <p>People can easily find relevant information and signposting on our website, to inform their next steps.</p>	<p>March 2018</p>
<p>Improving access to donation, support for patients and donors and information about access to donor conception treatment.</p> <p>Outcomes in this area of work will contribute to the Department of Health's <a href="#">SDP</a> – objective 7: Enabling people and communities to make decisions about their own health and care.</p>	<p>Providing advice for patients about access to donor conception treatment, and encouraging better donation support for donors and patients, including those considering using unlicensed donor sperm services.</p> <p>Working with clinics, sperm banks and voluntary organisations to improve the availability of donor sperm and eggs.</p>	<p>People understand the process, and are prepared for donation and treatment (measured through patient/donor surveys).</p> <p>Donors and patients are better supported by clinics.</p> <p>An increase in UK-based donation.</p>	<p>March 2018</p> <p>March 2018</p>

Aims	Methods and channels	Benefits and outcomes	Timescale
<b>Strategic objective 5:</b> <b>Increase consistency in treatment standards, outcomes, value for money and support for donors and patients</b>			
<p>Identifying and implementing ways of improving the quality and safety of care.</p> <p>Outcomes in this area of work will contribute to the Department of Health's SDP – objective 2: creating the safest, highest quality healthcare services.</p>	<p>Continuing our focus on quality and safety of care in inspection activities – in particular through focusing on shortcomings in the taking and recording of consents, learning from incidents, medicines management, data submission, multiple birth rates, and information published on clinics' websites.</p>	<p>Improved compliance and a positive impact on the quality of care, outcomes and safety of patients. Clinics have reduced vulnerability to expensive adverse legal risks, and greater awareness of these risks.</p> <p>Tracking of non-compliances, and the responsiveness of clinics in completing actions arising from inspection recommendations, in order to measure our impact (through our internal strategic performance monitoring mechanisms).</p> <p>Clinics' understanding of, and adherence to, correct consent procedures (including those associated with legal parenthood) and their understanding of the importance of getting this right, is improved.</p> <p>Patients and donors have a better experience of being asked for consent, and feel fully informed.</p> <p>If an issue subsequently arises (such as the death of someone with gametes in storage), the correct consents are more likely to be in place and are legally clear and robust.</p>	<p>Throughout year</p>
	<p>Continuing to evaluate areas of regulatory concern and identifying performance levers.</p>	<p>Improved levels of compliance. Inspection recommendations and advice or alerts targeting relevant issues, for maximum impact on quality of care, outcomes, and the safety of patients.</p>	<p>Throughout year</p>
	<p>Improved Register data quality, as a result of work done under the Information for Quality (IfQ) programme.</p>	<p>More 'right first time' data submission from clinics into the Register.</p> <p>Better service quality for Opening the Register (OTR) applicants.</p>	<p>March 2018</p>

Aims	Methods and channels	Benefits and outcomes	Timescale
		Fewer data submission and data accuracy related non-compliances found on inspection and audit.	
	Working with commercial groups of clinics so as to improve quality, consistency and compliance on a group-wide basis, when relevant.	<p>A clinic group's central Quality Management System (QMS) can be used to best effect across the whole group.</p> <p>A benefit in one clinic is shared to others in the group without needing to wait for the next inspection date - for the ultimate benefit of patients.</p> <p>A more efficient, effective and quality-driven way of working for the clinics involved and the HFEA.</p>	March 2018
	Collaborating with professional stakeholders (including the British Fertility Society, the BFS) to put patients in touch with better information and services when they first realise they may have a fertility issue.	<p>More informative signposting on our website, for those who are seeking preliminary information about fertility issues and options.</p> <p>Empowering patients, so they feel more equipped and are able to ask the right questions, regardless of the level of knowledge of their own particular GP about fertility issues and available treatments.</p>	March 2018
<p>Using our outcome data to improve the chances of successful treatment</p> <p>Outcomes in this area of work will contribute to the Department of Health's <a href="#">SDP</a> – objective 2: creating the safest, highest quality healthcare services.</p>	<p>With the aim of increasing birth rates while avoiding adverse outcomes, we will work with our professional stakeholders to define and establish the factors that lead to successful outcomes, and publish our findings.</p> <p>Continuing to publish the annual Fertility Trends report.</p> <p>Focusing on success rates through inspection reports and risk tool alerts.</p>	<p>Evidenced success factors, published on our website.</p> <p>More information published so that clinics can compare themselves more easily, based on different factors such as patient age.</p> <p>Fertility treatment in 2016 report published.</p> <p>Patients' chance of a live birth is maximised.</p> <p>Patients understand the risks of a multiple birth and the advantages of single embryo transfer.</p>	<p>March 2018 and further work in 2018/19</p> <p>March 2018</p>

Aims	Methods and channels	Benefits and outcomes	Timescale
<p>Improving value for money, for both patients and NHS commissioners.</p> <p>Outcomes in this area of work will contribute to the Department of Health's <a href="#">SDP</a> – objective 9: Improving services through the use of digital technology, information and transparency.</p>	<p>Exploring how we can make use of externally generated benchmarking information, and our own outcome data, to assist NHS commissioners in securing fair prices and effective fertility services for patients.</p> <p>Eliciting more feedback from patients as to whether they paid what they expected to for fertility services.</p>	<p>Patients know the price of a treatment at a given clinic at the start of treatment, and pay what they expect.</p> <p>Patients question costs, and particular additional costs, more often.</p> <p>Less variation in the price of treatment.</p> <p>The NHS pays a consistent and fair price for fertility services.</p>	March 2018
<p>Improving the emotional experience of care before, during and after treatment or donation.</p> <p>Outcomes in this area of work will contribute to the Department of Health's <a href="#">SDP</a> – objective 2: creating the safest, highest quality healthcare services.</p>	<p>Improving the emotional experience of care in clinics, by defining and encouraging best practice in clinics, and focusing on support at inspection.</p> <p>Ensuring that best practice is applied to donors and donor conceived people as well as to patients.</p>	<p>Clinics acknowledge how emotionally difficult infertility and treatment can be, and act on this.</p> <p>An improvement in the experience of treatment, with minimal emotional harm.</p> <p>Properly taken consents.</p> <p>Regardless of treatment outcome, but especially if it was unsuccessful, patients know they should expect care and support from the clinic beyond their final treatment.</p> <p>More information on our website for prospective patients, and specific signposting for patients who have experienced unsuccessful treatment.</p> <p>Clinics more aware of their responsibilities to patients beyond the immediate treatment setting.</p>	March 2018

Aims	Methods and channels	Benefits and outcomes	Timescale
<p>Evaluating the provision and take-up to date of the counselling support pilot for donor-conceived people wishing to access information held on the HFEA Register.</p> <p>Outcomes in this area of work will contribute to the Department of Health's <a href="#">SDP</a> – objective 2: creating the safest, highest quality healthcare services.</p>	<p>Evaluation of the second full year of the three year pilot of counselling support services for applicants to the Register<sup>2</sup>.</p>	<p>Counselling support is offered for all Opening the Register (OTR) applicants (those seeking non-identifying information) and for donor-conceived applicants receiving donor identifying information, throughout the pilot period.</p> <p>Mediation services are in place for when donors and donor-conceived people meet.</p> <p>Basic mediation training and systems in place for dealing with identity release to donors and donor-conceived people.</p> <p>OTR applicants feel more supported and will be prepared to deal with the information they receive from us.</p> <p>Second annual evaluation of the pilot provided to the Authority.</p>	<p>Piloting continues through to June 2018.</p> <p>September 2017</p>
<p>Implementing new EU requirements relating to the import and coding of donor eggs and sperm.</p> <p>Outcomes in this area of work will contribute to the Department of Health's <a href="#">SDP</a> – objective 2: creating the safest, highest quality healthcare services.</p>	<p>Completion of projects initiated in 2014/15 to implement new EU requirements on the import of donor gametes and new EU coding requirements for human tissue and cells.</p> <p>(This work continues from the 2016/17 business plan, pending the resolution of Brexit.)</p>	<p>Improved clarity for clinics, patients and donors.</p> <p>Improved internal clarity and updated procedures for our decision-making committees.</p> <p>Compliance with the new EU directives.</p> <p>Robust processes in place to ensure the quality, safety and traceability of imported gametes and embryos.</p>	<p>October 2017</p>

<sup>2</sup> Explanatory note: A donor conceived person aged 18 or above is entitled to access identifying information about their donor, provided the donor has asked for their right to anonymity to be removed.

Aims	Methods and channels	Benefits and outcomes	Timescale
<b>Improving standards through intelligence</b>			
<b>Strategic objective 6:</b> <b>Use our data and feedback from patients to provide a sharper focus in our regulatory work and improve the information we produce</b>			
<p>Driving quality improvements in treatment standards and outcomes by using our data and regulatory intelligence.</p> <p>Outcomes in this area of work will contribute to the Department of Health's shared delivery plan (SDP) – objective 2: creating the safest, highest quality healthcare services.</p>	<p>Publishing an information strategy on how we will analyse, publish and use our data.</p> <p>Re-shaping our organisation to equip us with enough analytical capability to extract more value from the data we hold.</p>	<p>An information strategy setting out our plans. Donors, parents and donor-conceived people understand where their information is stored, the responsibilities of the clinic and the HFEA, and their access rights.</p> <p>Patients have confidence in their clinic as a life-long information guardian with excellent data submission practices.</p> <p>Better outcomes from NHS cycles.</p>	<p>March 2018</p>
<p>Maintaining our role as the UK's competent authority for ART in the European Union<sup>3</sup>.</p> <p>Outcomes in this area of work will contribute to the Department of Health's SDP – objective 2: creating the safest, highest quality healthcare services.</p>	<p>Participation in competent authority events and implementation of associated EU decisions.</p>	<p>We participate in two meetings per year.</p> <p>Up-to-date intelligence gained about the perspective of other EU member states, helping to inform UK approach to patient safety and care.</p> <p>Free movement of gametes and embryos enabled within the UK and standards upheld in the UK that are consistent with the rest of the EU.</p>	<p>June and December, annually.</p> <p>Throughout year</p>

<sup>3</sup> For as long as the UK remains in the EU.

Aims	Methods and channels	Benefits and outcomes	Timescale
<p>Maintaining the Register of Treatments and Outcomes and working with clinics to ensure they are accurately reporting their data.</p> <p>Outcomes in this area of work will contribute to the Department of Health's SDP – objective 2: creating the safest, highest quality healthcare services.</p>	<p>Register data and forms continue to be processed and quality assured, through liaison with clinics on errors and omissions and through validation and verification of Register entries.</p>	<p>High quality data available to develop patient information and respond to information requests.</p> <p>Risk-based regulation and evidence-based policy-making.</p>	<p>Throughout year</p>
<p>Responding effectively to specific enquiries from individuals.</p> <p>Outcomes in this area of work will contribute to the Department of Health's SDP – objective 7: enabling people and communities to make decisions about own health and care.</p>	<p>Continuing to respond to the many individual patient and public enquiries we receive each year.</p>	<p>Individual patients and members of the public are able to ask specific, sometimes complex, questions and receive a tailored and meaningful response.</p> <p>We remain responsive, and continue to be able to handle the range of one-off enquiries raised by individuals, providing a considered and informed response within a reasonable timescale.</p> <p>We are able to identify any trends and common themes in the enquiries we receive, informing the development of additional information which could be placed (for example) on our website.</p>	<p>Throughout year</p>

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

Aims	Methods and channels	Benefits and outcomes	Timescale
	To continue to publish statistical and other reports.	<p>'Fertility treatment in 2016' report covering 2015–2016.</p> <ul style="list-style-type: none"> <li>- Provides patients, clinic staff and others with up-to-date, high quality information about a range of topics.</li> <li>- Provides important information to those affected by donor conception, to patients seeking treatment and to us, to help us to enhance the quality of care that patients and donors receive in clinics, through our regulatory work.</li> <li>- Report carries 'official statistics' status.</li> </ul>	March 2018
		<p>Report on incidents and alerts.</p> <ul style="list-style-type: none"> <li>- Contributes to a culture of openness and information sharing where clinic staff are empowered to report mistakes and learn from each other.</li> <li>- Increases transparency and maximises opportunities for learning from incidents to improve quality of care for patients.</li> <li>- Provides the sector with the most up-to-date information.</li> </ul>	November 2017
<p>Making more targeted and responsive regulatory interventions, in the interests of quality and consistency, based on our data.</p> <p>Outcomes in this area of work will contribute to the Department of Health's shared delivery plan (SDP) – objective 2: creating the safest, highest quality healthcare services.</p>	Applying the intelligence available to us from inspections, the sector, patient feedback, and analysis of our data to make more targeted and responsive interventions.	<p>Ability to make earlier and more responsive regulatory interventions, without the need to wait for the next inspection point.</p> <p>Regulatory performance is more consistent across the inspection cycle.</p>	March 2018

Aims	Methods and channels	Benefits and outcomes	Timescale
<p>Gaining insight into the patient experience in clinics and encouraging good practice based on feedback.</p> <p>Outcomes in this area of work will contribute to the Department of Health's SDP – objective 7: enabling people and communities to make decisions about own health and care.</p>	<p>Collecting more patient feedback through new routes, including our website and social media.</p> <p>Analysing and using this intelligence to inform our activities and our messaging to clinics, sharing the information with professional stakeholders.</p>	<p>Improvement in the quality of services and patient/donor support as a result of patient ratings and other feedback.</p> <p>Quantifiable increase in the amount and frequency of patient feedback available to the HFEA and our professional stakeholders.</p> <p>Patient feedback loop in place to ensure a regular flow of fresh feedback which can be incorporated into our stakeholder interactions and regulatory approach.</p>	March 2018
<p>Ensuring the HFEA is a good value organisation and makes best use of its limited resources.</p> <p>Outcomes in this area of work will contribute to the Department of Health's SDP – objective 3: maintaining and improving performance against core standards while achieving financial balance.</p>	<p>Working more smartly with our limited resources, capitalising on recent improvements in our information systems.</p> <p>This will entail re-shaping our capability and capacity profile, so as to make best use of our new website and Register.</p>	<p>Resources are deployed in the interests of high quality care for everyone affected by assisted reproduction.</p> <p>Achieving measurable 'added value' and internal efficiency.</p> <p>Benefits of Information for Quality Programme realised.</p>	Throughout year
	<p>Maintaining our staff capacity and skills, in line with our people strategy.</p>	<p>We are able to maintain the staff capacity and capability to deliver our strategy and our core statutory duties.</p> <p>Continuing to develop our staff to ensure they have the skills they need, through Civil Service Learning and other means.</p>	Throughout year
	<p>Ensuring internally provided services are efficient.</p>	<p>Our infrastructure is effective and contributes to the delivery of the strategic vision.</p> <p>Central systems, processes and tools are efficiently run, giving good value and service.</p>	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
<p>Ensuring the HFEA is easy to deal with and offers a professional service.</p> <p>Outcomes in this area of work will contribute to the Department of Health's SDP – objective 3: maintaining and improving performance against core standards while achieving financial balance.</p>	<p>Full release of the HFEA's improved Register function and processes (the completed EDI, data submission and verification system, the Clinic Portal, and the data dictionary).</p> <p>Continuation of the engagement arrangements with clinics on fees charged, established in 2014/15.</p>	<p>Reduced transactional costs for clinics and increased satisfaction.</p> <p>'Right first time' data quality and reduction in unnecessary effort by clinics submitting the data.</p> <p>Accountability and transparency in respect of the fees we charge clinics.</p> <p>Fees Group continues to be run effectively, and annual review of fees takes place.</p>	<p>October 2017</p> <p>Throughout year</p>
<p>Responding as appropriate to new government initiatives on transparency, innovation and better regulation (the Enterprise Bill, the 'growth duty' and the Regulators' Code).</p> <p>Outcomes in this area of work will contribute to the Department of Health's SDP – objective 3: maintaining and improving performance against core standards while achieving financial balance, and objective 6: supporting research, innovation and growth.</p>	<p>Complying with better regulation requirements by:</p> <p>Reporting in our Annual Report on the growth duty and compliance with the Regulators' Code .</p> <p>Complying with the Business Impact Target by identifying and reporting any 'in-scope activity' (a new ongoing duty).</p>	<p>The HFEA responds in a manner consistent with its legal status, and proportionately within our small resource envelope, carefully recognising our duties.</p> <p>HFEA innovation plan published March 2017. Innovation has been included in our strategy for 2017-2020.</p> <p>Annual Report publication including additional required information.</p> <p>Compliance with the Business Impact Target for any activities that may be in scope.</p>	<p>Throughout year</p> <p>March 2017</p> <p>June 2017</p> <p>Throughout year</p>

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

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

# Measuring our performance

## Facts and figures

The following facts and figures give a wider picture of the type and volume of our work between 1 April 2016 and 31 March 2017. **[DN: Data follows after year end.]**

Number of:	2015/16	2016/17
Active clinics and research establishments	132	
Clinics and research establishments inspected	88	
Licences inspected	91	
New licence applications processed and presented to the Licence Committee	5	
Licence renewals processed and presented to the Licence Committee/Executive Licensing Panel	42	
Applications for Human Leukocyte Antigen (HLA) testing for tissue match processed and presented to Licence Committee/Executive Licensing Panel	1	
New preimplantation genetic diagnosis (PGD) applications processed and presented to Statutory Approvals Committee	54	
Incident reports from clinics processed	529	
Alerts issued	0	
Formal complaints about clinics	13	
Opening the Register requests closed within 20 working days	275	
Donor Sibling Link applications processed	17	
Licensed Centres Panel meetings held	2	
Meetings with patient organisations held	2	
Public and stakeholder meetings	10	
Freedom of Information (FOI) requests dealt with	99	
Environmental Information Regulations (EIR) requests dealt with	0	
Enquiries responded to under the Data Protection Act (DPA)	0	
Parliamentary questions (PQs) responded to	68 <sup>4</sup>	
Information for researchers requests received	1	
Visits to the anonymised Register download page	465	
Unique visits to our website	1,323,509	
Most popular/viewed page on our website	IUI - What is intrauterine insemination (IUI) and how does it work?	

<sup>4</sup> In 2015, Parliament was dissolved for two months over the General Election period. Parliamentary Questions (PQs) cannot be submitted during such periods, and this resulted in an overall reduction in the number of PQs for the 2015/16 business year.

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## Required HR benchmarking information

In common with other ALBs, we are required to maintain a record of the following standard benchmarking data: **[DN: data to be updated at year end]**

Very senior manager (VSM) to staff complement ratio	1:29
Number of staff earning more than £142,500 now and any planned change during the next planning period	0
HR staff to employee ratio	1:45
Training budget as a percentage of pay bill	1.5%
Projected reductions in non payroll staff	Not applicable

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## Key performance indicators

During 2017, we will revise our in-house strategic performance report so as to enable us to keep track of our performance against our strategic aims for 2017-2020. This document is presented in summary form at every Authority meeting, and the associated papers are published regularly on our [website](#).

The table below shows our performance in 2016/17 for a small sample of our indicators. We will continue to track the same indicators, and more, throughout 2017/18.

**[DN: table to be added after year end]**

# Financial picture

## Our finances and high level budget

We receive funding from two main sources: the majority, around 80%, from clinics and the balance from our sponsors, the Department of Health, as grant-in-aid (GIA).

The vast majority of fee income arises from individual IVF treatments in regulated clinics. In aggregate, together with licence fees, these cover the costs of regulation: evaluating licence applications, making licensing decisions and issuing licences, managing licences, site visit inspections, managing statutory information flows and providing advice and guidance to licensed establishments.

Treatment fee income has steadily increased in the last twelve months. We also removed our eSet (elective single embryo) discount in January 2016 and increased our treatment fee from £75 to £80.

Our grant-in-aid funding from the Department of Health has reduced by over 50% since 2010 and it will remain constant for the next three years. Over the years we have managed our expenditure to ensure we spend within budget where ever possible. We have also used our reserves to reduce the draw on GIA. In the years 2014/15 to 2016/17 we demonstrated this by use of our reserves to fund a significant programme (Information for Quality, IfQ).

The high level budget for 2017/18 is shown below.

	<b>Income</b>	<b>£000s</b>
Department of Health funding		933
Treatment and licence fees		5005
Other income		6
<b>Total income</b>		<b>5944</b>
Operating costs, of which		
Staff costs		3643
Other operating costs		2141
<b>Total operating costs</b>		
Capital charges		160
<b>Total revenue expenditure</b>		<b>5944</b>

# Other required information

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## Introduction

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

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

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

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## Better regulation and innovation

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

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

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

In 2016/17 we consulted on and then published an innovation plan, as part of a Government requirement. The aim of innovation plans is to ensure the UK regulatory framework is working effectively to encourage innovation and that regulators like us are using innovation to deliver our work more effectively and to reduce the burden on business. We are also focusing on responsible innovation in clinics as part of our strategy and business plan.

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## Organisational structure and establishment

Over the past few years the HFEA has significantly reduced its staffing, in keeping with overall pressures on the public sector and Government expectations. Our staff complement has reduced from 86 in 2010/11 down to 67 in 2016/17. We have put in place shared services arrangements with other bodies, where feasible. For example, we share part of our finance and resources team staffing with the HTA, and our facilities management service is provided by NICE (since we now occupy the same premises, having moved offices in early April 2016). We also have a shared services agreement with the Care Quality Commission (CQC) for recruitment.

We believe we have reached a point where, having made considerable savings, our size will now need to remain stable for the foreseeable future. We need to ensure we retain the capability and capacity to deliver our overall strategy for 2017-2020.

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

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

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

The following diagram shows our current organisational structure.

**[DN: to be added shortly]**

## Financial management systems

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

## Internal audit

We continue to be part of the Department of Health group assurance framework and to work with the co-sourcing provider on delivering the annual internal audit plan for each year. The programme of internal audits has been streamlined to meet the HFEA's needs and to make best use of the group audit arrangement, which helps to improve the overall levels of assurance for the group.

## Assurance framework

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

interdependency with the Department of Health or other ALBs and understands the correct dialogue and escalation mechanisms for communicating the issues and relevant mitigations.

## Equality Act 2010

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

## Whistleblowing policy

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

## Transparency requirements

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

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

## Information technology (IT) and data security

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

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

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

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

The robust information security arrangements the HFEA has in place, in line with the information governance toolkit, include a security policy for staff, secure and confidential storage of and limited access to Register information and stringent data encryption standards. All staff complete the annual mandatory

training on information security and new starters complete this on their first day of employment before starting work.

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

## Business continuity

We reviewed our business continuity plan in 2016/17 in light of our office move, to ensure it remains fit for purpose. The plan is regularly updated and periodically tested. There is an operational disaster recovery site available if needed.

## Estates strategy

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

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

## Sustainable development

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

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

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

## Procurement

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

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

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

We are too small to have a procurement pipeline. The only procurement of significance in the previous year, 2016/17, was related to the IfQ programme, which was subject to specific business cases agreed by the Department of Health and the Government Digital Service through various highly robust mechanisms. All related procurement was conducted using CCS frameworks and with close CCS oversight. There will be no procurements over £100,000 in 2017/18. We provide the Department of Health with quarterly reporting on procurement.

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

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

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