

Minutes of Authority meeting 24 January 2018

Strategic delivery:

Safe, ethical
effective
treatment

Consistent
outcomes and
support

Improving standards
through intelligence

Details:

Meeting Authority

Agenda item 2

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For information or
decision? For decision

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

Resource implications

Implementation date

Communication(s)

Organisational risk Low Medium High

Annexes

Minutes of the Authority meeting on 24 January 2018 held at Church House, 27 Great Smith Street, London SW1P 3NZ

Members present	Sally Cheshire (Chair) Kate Brian Dr Anne Lampe Anthony Rutherford Bishop Lee Rayfield	Yacoub Khalaf Margaret Gilmore Bobbie Farsides Ruth Wilde Andy Greenfield
Apologies	Anita Bharucha	
Observers	Jeremy Mean (Department of Health)	
Staff in attendance	Peter Thompson Nick Jones Paula Robinson Richard Sydee Catherine Drennan	Joanne Triggs Caylin Joski-Jethi

Members

There were 10 members at the meeting, 6 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 2018. As with previous meetings, it was audio-recorded and the recording would be made available on our website to enable interested members of the public who could not attend the meeting to listen to our deliberations.
- 1.2. Apologies were received from Anita Bharucha.
- 1.3. Declarations of interest were made by:
 - Anthony Rutherford (Person Responsible at a licensed centre)
 - Yacoub Khalaf (Person Responsible at a licensed centre)

2. Minutes of Authority meeting held on 15 November 2017

- 2.1. Members agreed the minutes of the meeting held on 15 November 2017, for signature by the Chair of the meeting.

3. Chair's report

- 3.1. The Chair provided members with a summary of events that she attended since the Authority meeting on 15 November 2017.

- 3.2.** On 20 November, the Chair and other members attended a lecture by former Secretary of State for Health, Frank Dobson, at the Speaker's House, on Parliament's response over three decades to developments in embryology and infertility treatment in the UK. The lecture was dedicated to the memory of Lisa Jardine, former Chair of the HFEA. The Chair said that the lecture provided a fascinating overview and she had asked for it to be put on the HFEA website.
- 3.3.** The Chair attended the Royal College of Obstetricians and Gynaecologists' annual dinner on 24 November.
- 3.4.** On 29 November, the Chair attended the Huxley Summit, Chaired by Lord David Willetts. The Summit considered how people's views and behaviour impact on introducing new technologies and how scientists, policy-makers, government and business innovators can understand and better respond to public concerns. The conference brought together scientists, government figures and other key industry influencers and the Chair met Katherine Mathieson, Chief Executive at the British Science Association. The HFEA was referenced by several speakers as a good example of a public body that had successfully engaged the public on new scientific developments.
- 3.5.** On 8 December, the Chair and Chief Executive attended the Progress Education Trust's annual conference. This focused on genome editing and the 14-day limit on human embryo research. An Authority member, Dr Andy Greenfield, also spoke at this event.
- 3.6.** The British Fertility Society annual conference was held on 4 January. The Chair and the Director of Compliance and Information both spoke at this event, the Chair speaking on leadership and our collective ambition for the fertility sector in 2018 and beyond. The Chair and the Chief Executive also met Aileen Feeney, the new Chief Executive of the Fertility Network and Roy Farquharson, the new Chair of ESHRE (the European Society of Human Reproduction and Embryology).
- 3.7.** Lastly, on 12 January, the Chair met Clara Swinson, the Director General for Global and Public Health at the Department of Health.

4. Chief Executive's report

- 4.1.** In addition to events attended with the Chair, on 21 November the Chief Executive chaired the HFEA information project and embryo research workshop in London, which was attended by delegates from the fertility sector. The event brought together clinics and researchers and the afternoon session allowed researchers to explain their work and encourage clinics to participate. The Chief Executive thanked Anna Quinn for leading the organisation of the event and Dr Andy Greenfield for chairing the afternoon session.
- 4.2.** On 23 November, the Chief Executive met with colleagues at the Department for Digital, Culture, Media and Sport. The discussion centred on the HFEA's success in building public trust in a contested area of public policy. Our work is increasingly seen as a model for the various ethical issues raised by developments in artificial intelligence.
- 4.3.** The Chair and Chief Executive conducted interviews for a new Director of Strategy and Corporate Affairs on 24 November. This process was successful, leading to the

appointment of Clare Ettinghausen, who would join the HFEA's senior staff team on 29 January.

- 4.4.** A leadership away day was held on 29 November, attended by all Directors and Heads. This was a positive day, helping to shape the agenda for the all staff away day planned for 29 January.
- 4.5.** On 30 November, the Chief Executive attended a Public Bodies Event organised by the Cabinet Office.
- 4.6.** On 5 December, the Chief Executive attended the Audit and Governance committee meeting, specifically to talk about the possible impact of Brexit on our work. The Commons Health Select Committee is conducting an inquiry into the impact of Brexit on medicines, medical devices and substances of human origin and the HFEA submitted written evidence in January.
- 4.7.** On 7 December, the Chief Executive attended an NHS England-led meeting, to discuss the commissioning of IVF, benchmark pricing and guidance for CCGs.
- 4.8.** On 12 December, the Chief Executive attended a conference at Wellcome in honour of renowned biologist Anne McLaren, at which Baroness Mary Warnock spoke.
- 4.9.** The last quarterly accountability meeting of 2017 with the Department took place on 15 December.
- 4.10.** On 23 January the Chief Executive attended the Health and Care Leaders Scheme Aspiring Directors programme, where he spoke on leadership.
- 4.11.** On staffing and organisational change, the Chief Executive reported on the current risks we were managing about resilience and capacity. Given the freeze (or below inflation increases) in public sector wages since 2010, and the limited opportunities for promotion, there had been higher than normal turnover in the HFEA over recent months. The organisational change programme last year had also involved some redundancies and internal reconfiguration to enable us to provide new services. This period of turnover and churn was now drawing to an end. The Chief Executive thanked the managers who had conducted a large number of recruitments, and particularly Julie Hegarty in the HR team who had supported a great deal of recruitment and other changes.
- 4.12.** A recent staff survey showed that we should now focus afresh on staff learning and development. This, and other topics, would be discussed at the staff away day planned for 29 January. The Chief Executive would keep the Audit and Governance Committee (AGC) apprised of developments. Staff were grateful to members for bearing with them during the pressured period that was now coming to an end.

Press coverage

- 4.13.** The Chief Executive informed members that it had been a busy few weeks in terms of media interest in the fertility sector, with unregulated sperm donation, OHSS, NHS funding and egg freezing the main themes of coverage.
- 4.14.** Our first ever State of the sector report was launched in December, and aspects of it, including multiple birth rates and figures for adverse incidents in clinics were picked up by

the national and local press. The aim for this predominantly sector-facing report was for it to become an annual fixture alongside the more public-facing Fertility trends publication, which is due out in March to coincide with the annual conference. The item on the Intelligence Strategy, later on the agenda, would set out the HFEA's broader ambitions in this area.

- 4.15.** In December, the Chair was interviewed for a Channel 4 documentary on unregulated sperm donation, discussing the risks of looking for a donor outside of a regulated clinic, and what people should consider before they do. This interview was scheduled for broadcast in February, and the date would be communicated to members once it was confirmed.
- 4.16.** We provided a statement to the Times, published on 2 January, about the disparities in the costs of IVF treatment, emphasising that we required clinics to provide patients with costed treatment plans, and, as noted earlier, we remained in discussion with NHS England about setting a benchmark price for NHS treatments. It was hoped that in the future such a public benchmark would help all patients, both NHS and private, make more informed judgements about what is good value for money.
- 4.17.** We also responded to a query relating to an FOI request about the number of embryos disposed of.
- 4.18.** A member asked whether there had been any feedback from the sector on the State of the sector report. The Director of Compliance and Information reported that it had been well received at the BFS Conference, but there was some concern about the press coverage of incidents. In general clinic staff welcomed the more rounded picture provided in the HFEA's report. It was encouraging to see that the majority of the sector was compliant, and successfully reducing multiple births and the associated health risks.

5. Committee Chairs' updates

- 5.1.** The Chair reported that the Appointments Committee met on 20 November to approve the re-appointment of one Appeals Committee member and two members of the Licence Committee that hears representations. All three had served one three-year term and were keen to serve another. Their new terms started on 16 January.
- 5.2.** The Chair of the Statutory Approvals Committee (SAC) reported that the committee met on 30 November and 14 December, and considered one mitochondrial donation application, six new PGD condition applications (five of which were approved and one declined), and approved three special directions applications, one of which was re-issued having expired. The committee also received a paper on the current audit of the PGD list, and conducted its annual review of effectiveness. SAC would next meet on 25 January, to consider two more mitochondrial donation applications and six new PGD conditions.
- 5.3.** The Committee had also met previously on 26 October, as reported at the last meeting, at which time the outcomes had not been publicly available. The Chair reported that the committee had considered one mitochondrial donation application and six PGD applications, all of which were approved.

- 5.4.** The Chair thanked the Executive for the support from staff over an intensive period of work including new item types. The Committee was also grateful for the high quality of papers received.
- 5.5.** The Deputy Chair of the Audit and Governance Committee (AGC) advised members that the committee met on 5 December and, in addition to the usual standing items and updates from internal and external audit, the committee received reports on:
- Strategic risks, from the Business Planning and Risk Manager.
 - Regulatory and Register management, from the Director of Compliance and Information.
 - Handling Brexit, from the Chief Executive, including the possible effects of Brexit on research in the UK, which was a potential area of concern.
 - A data submission project update, from the Director of Compliance and Information.
 - Business continuity, resilience and cyber-security, from the Chief Information Officer.
 - Whistle blowing and fraud, from the Head of Finance.
 - Contracts and procurement, from the Head of Finance.
- 5.6.** The Chair of the Licence Committee advised members that the committee met on 11 January. The minutes were not yet available. The committee considered one renewal inspection report, one research licence renewal, one research project revocation, one research licence variation application, and one interim inspection report. The committee also conducted its annual review of effectiveness. The Chair thanked the Deputy Chair, Lee Rayfield, for Chairing in his absence.
- 5.7.** The Chief Executive advised members that the Executive Licensing Panel (ELP) met four times since the Authority last met; on 17 November, 1 December, 15 December and 19 January. The panel considered one initial inspection report, six renewal applications, five interim inspection reports, three licence variations, two executive updates, and one application for HLA tissue typing. The Licensing Officer also approved five licence variations.

6. Performance report

- 6.1.** The Chief Executive introduced this item, which reported on both organisational performance and progress against our strategy. The Chief Executive also reported on activity and performance within the Strategy and Corporate Affairs directorate.
- 6.2.** In addition to the upcoming staff conference, work was starting on the HFEA's annual conference for the sector. There would be workshops including using better research, improving clinical standards, using patient feedback to support patients, and using data effectively. The conference would also include a celebration of the 40th anniversary of the birth of Louise Brown.
- 6.3.** The intranet for staff was being reviewed to improve the information and format. Members asked whether this could be made open to members and whether it could be used for

reviewing minutes using track changes. The Chief Executive agreed to explore this possibility after the meeting.

- 6.4.** The website was being constantly reviewed and a digital board had been established to oversee future developments. As part of this an editorial board had been established, with three Authority members as part of it. The clinic portal was in use by clinics, with positive feedback. Ongoing bug identification and fixing was in place.
- 6.5.** The Chief Executive explained that in light of the recent organisational changes and an extremely busy period in licensing, a review had been initiated to examine procedural and structural questions. An initial report was expected by Easter, and the Authority would be updated in May. Members recognised that this had been a long period of hard work.
- 6.6.** The Director of Compliance and Information summarised activity and performance within his directorate. There had been a glut of Parliamentary Questions which had proved challenging to respond to, resulting in a red indicator, but the HFEA had still met Parliamentary deadlines. Although PGD processing times were still in the red, this was due to the very high workload in recent months.
- 6.7.** The Director of Compliance and Information also reported on the remaining elements of the Information for Quality programme, being delivered as the data submission project. There was ongoing scrutiny of the progress of this work at each AGC meeting, and excellent progress was being achieved to ensure the submission system for clinics was improved. Engagement with third party suppliers was now under way, so that the majority of clinics that use such systems, rather than a direct link to the HFEA's system, could undertake the necessary development work to link to the new electronic data submission. A six-month window was necessary for third party systems. A beta release was planned for the HFEA conference on 15 March. This would enable clinics to see the navigation and lay-out for the first time.
- 6.8.** There was also steady progress on preparations for data migration to the new Register, which was on track. A decision to revise the original the originally envisaged 'two stage' start-up, whereby those on the HFEA system would start to use it first, with those using third party suppliers starting 6 months later, was being actively considered. Discussions with the sector now indicated that it would be better to allow all clinics 6 months to prepare, and start all clinics on the new system at the same time.
- 6.9.** All of this work would be completed within the capital budget agreed for 2017/18.
- 6.10.** A member asked about whether obsolete data that would not be collected in future would be preserved or archived after data migration. The set of data requirements had been consulted on, and defined the fields included in the new Register. Fields that had been populated in the past but would now cease to be populated would be retained, not deleted, and the 'old' Register would be retained in shadow form.
- 6.11.** There was also a question relating to scrutiny of the third party providers to ensure confidentiality. It was clarified that there is a duty on clinics to ensure that such systems are secure. The security systems the HFEA had developed are extremely robust and require all data to be encrypted during the transfer.

- 6.12.** Delays in the ability to transmit data could be problematic for clinics, owing to the speed at which work could build up. The new system had been designed to ensure the flow of information would be much smoother.
- 6.13.** Members welcomed this report and asked that the Director of Compliance and Information continue to report back on progress.
- 6.14.** The Director of Finance and Resources reported on the latest budget outturns and income figures. For the overall year-end position, an underspend of just over £600,000 was forecast. This was due to a combination of additional income, lower than budgeted for legal costs and staffing costs underspends. Baseline budget assumptions for 2018/19 were also presented. The budget would remove expenditure related to staff exits and would assume lower agency staffing following the conclusion of the data submission project work.
- 6.15.** Based on the modelling work described in the following agenda item, an upward trend in income was anticipated. It was suggested that one option would be for a cap to be placed on expenditure, set at £5.7m. This would help the HFEA to maintain its position as a demonstrably cost-effective public body. This would lead to a surplus of £0.74m for the 2018/19 year. There were additional areas where the HFEA could potentially utilise such funds, but it was felt that specific projects or programmes should be funded via agreed business cases where real value for the sector and patients could be demonstrated.
- 6.16.** The HFEA currently received grant in aid from the Department as part of its annual budget settlement, and there was potential for this to be decreased or even removed if a decision was made that the HFEA should be self-sufficient. There was also an ongoing conversation with the sector about the level of fees to be charged, and there could be potential to reduce fees.
- 6.17.** One member expressed a view that it could be too soon after the recent organisational changes, with an increasingly complex workload, to cap the budget. It may be that difficulties would arise if the freedom to direct the budget to where it was needed was removed. Another member raised concerns about the unpredictable nature of legal costs.
- 6.18.** In general members were keen to ensure that benefit was felt across the sector if fees were reduced, and were strongly of the view that any reduction in fees would be modest and of little value to the individual given the total cost of treatment. Instead, members expressed a preference for keeping fees as present and using any additional revenue to provide benefits for patients. Factors such as Brexit may also alter current budget assumptions.
- 6.19.** On the capping of pay, members recognised the difficulty in retaining good people, and questioned whether the HFEA could respond to this.
- 6.20.** The Chief Executive explained that the HFEA continued to be bound by Government expenditure rules, regardless of its sources of income. The framework was not flexible. Like all regulators, the HFEA was expected to cover all costs of regulation from the fees charged. Grant in aid was a different 'pot' intended for policy development. If the HFEA became self-financing, this would only really be beneficial if it was also agreed that this therefore freed us from Government controls. The overall picture was complex and the HFEA's ability to decide how to spend its budget was very limited.

- 6.21.** The Director of Finance and Resources also reported on a recent joint Resources Directorate review with the Human Tissue Authority (HTA). The review had resulted in ten recommendations, and concluded broadly that the current operation and function of the Directorate provided the outputs and support needed by both organisations. It had been agreed that new HR management systems should be procured jointly across both organisations, if possible, and that there may be further joint working and collaboration that would be advantageous in the future.
- 6.22.** The HFEA would need to relocate in 2020, and opportunities for closer working, especially for corporate services functions, should be considered in this context, alongside plans for more flexible working arrangements. Members noted these future developments and heard that the intention to work jointly would be welcomed by the Department, but that there was currently no pressure for the HFEA to consolidate further, having previously made substantial cost savings through post reductions and an increased use of shared services. The Department were satisfied that the requirements from the last Triennial Review had all been met.
- 6.23.** Following discussion, members noted the latest performance report.

7. Forecast model

- 7.1.** The Director of Finance and Resources presented a report on future income forecasting, developed with the Head of Intelligence, suggesting a model which would allow the Authority to estimate its future income on a more reliable basis. Knowing how treatment activity (and therefore income) fluctuates over time and throughout the year enabled the HFEA to plan efficient use of its resources, both within and across financial years.
- 7.2.** The proposed forecasting model demonstrated that the treatment rate per capita was steadily increasing, and that around 44 women in every 10,000 had a chargeable treatment in 2016, the latest year for which full statistics were available. The income forecasting model was based on forecasting the projected rate from past performance, using one of two possible methods.
- 7.3.** Both methods forecast increases in the number of treatments based on historic data. The model led to a projected increase in the HFEA's income of at least 2% annually. As a result, the income from licence fees would increase by around £90,000 per annum. There was additional regional trend and Office for National Statistics data that could be added to the income model, but this would be primarily for modelling and information purposes rather than materially improving the accuracy of the forecasts.
- 7.4.** The Authority heard that both forecasting methods had achieved a very high accuracy rate for short term forecasting. This exploratory work would inform whether the HFEA should invest further resources into developing more advanced models.
- 7.5.** A member asked if the recent evidence of NHS disinvestment in the provision of fertility services in England had been taken into account when thinking about the model. It was agreed this could be followed up after the meeting, since it was possible that improved funding in some areas was offsetting others. It was also possible that earlier referrals for IVF were having an impact. There could also be a time-lag issue, in that CCGs would

announce that they were withdrawing funding in advance of doing so, which may mean the figures would change in a year's time.

- 7.6.** Members noted that forecasting was not an exact science, but if done correctly, could predict with some accuracy the trends that tend to occur when dealing with volatile metrics such as treatment activity. Members welcomed the report, noting that it provided evidence for the factors affecting treatment rates, in a way not previously analysed. Further data mining would be possible to examine particular factors and their impact, including regional provision, societal trends, different age groups, etc.
- 7.7.** The Authority also noted that the work to date had considered the data in terms of demand. The impact of supply and policy had not yet been studied to see how base demand may translate through to activity. National policy changes, pricing, trends in seeking treatment abroad, and other factors, could affect patterns of activity (eg, NHS commissioning decisions). Increased demand may therefore not lead to increased activity, if barriers to access increased alongside.

Decision

- 7.8.** The Authority agreed:
- To incorporate this model into the HFEA's financial and business planning for 2018/19, testing its validity on emerging 2017 data to determine if the results from the analysis provide realistic estimates of activity and income.
 - To keep fees for 2018/19 unchanged. Members agreed that the sector appreciated stability in terms of our fees and the information presently at hand did not indicate we could reduce our fees materially for 2018/19 based on forecast increased activity.
 - That a further update of the model should be presented to the Audit and Governance Committee in mid-2018, which would allow an improved income forecast model to be combined with the three-year financial plan and proposals for future fees from April 2019.

8. Regulation of groups of clinics

- 8.1.** The Director of Compliance and Information explained that the number of licensed treatments taking place in clinics that form part of a 'group' of clinics had increased markedly over the last few years. These developments had raised questions about the appropriate organisation of the regulatory regime in response to this. It was currently based on a model of separate stand-alone clinics, led by an identified 'Person Responsible' (PR).
- 8.2.** A new approach had already been piloted with some established and integrated groups. It now seemed timely to set out a broad policy position on the regulation of group structures, and move to implement this where there was demand.
- 8.3.** A group approach pays dividends for the group involved, reducing the level of regulatory activity needed for each individual clinic - for example through the multiple assessment of shared quality management systems employed at different clinics in the group.

- 8.4.** Members heard that, of the 87 currently active clinics, 31 were located within NHS trusts, and therefore not in a group structure. Of the 56 clinics in private ownership, 38 were currently in a group structure in some form. Such clinics were undertaking a progressively larger proportion of treatment cycles, collectively delivering 38% of all cycles in 2017.
- 8.5.** There were several types of clinic group in existence, with some fluidity between the types:
- Integrated model – a common operating system with a high degree of central control and common processes
 - Federated model – central services with an autonomous role for the individual clinics
 - Franchise model – a consultant-led model within the independency hospital operating model, with central legal and marketing services but a high degree of local autonomy
 - Location specific model – first seen in research clinics, where different research projects were licensed within the same institution and now also seen in treatment clinics that were located in separate premises, but in the same vicinity.
- 8.6.** While the Act would continue to require a licence for each separate premises, it was still possible to employ a regulatory approach based on ‘earned autonomy’, involving group-wide inspection of shared features, and a simplification of the inspection process so as to reduce duplication and focus on those elements that were particular to each individual clinic. In return, where non-compliances were found we would expect to see these addressed across the whole group. Shared features, based on the sections of the Code of Practice, might include staffing policies, information policies and architecture, facilities management and administration, the approach to record-keeping, and so on. Other aspects of the Code would need local review for compliance in each individual clinic, for example on counselling provision, welfare of the child, embryo testing, donation and surrogacy, and treating people fairly.
- 8.7.** The group approach would operate according to an agreed framework, geared to the circumstances of each particular group. Operating principles would include being intelligence-led, formalised relationship management with one lead inspector for the group, tailored inspections, centring on the patient; meeting our statutory requirements, and promoting effective leadership. It would be important for the HFEA to assure itself that there were sufficient resources within the group to support a clinic’s quality management efforts.
- 8.8.** Following assessment of one clinic, the inspectorate would expect to see improvements identified implemented across the whole group.
- 8.9.** Members noted that all parties needed to be content with the arrangement in order for the model to be implemented.
- 8.10.** Members recognised that the typology may lead to challenges and that the group approach may introduce some complexities. Although at group level there could be some processes in common, it may be that local delivery in the clinics varied considerably, limiting their comparability and their ability to implement the same recommendations in all clinics. The words ‘lighter touch’ were questioned, since something working well in one clinic would not necessarily mean it was working so well in all the clinics in the group. It was confirmed that group-based assessments would be limited to central features, and that we would continue to inspect all clinics to the same depth regardless of whether they

were in a group. It was confirmed that premises and facilities would be inspected in each case, since these would vary greatly.

- 8.11.** It was also questioned whether the inspectors' time could be dominated by large groups, and whether there was a danger of cultural inculcation. It was confirmed that the portfolio of each inspector was rotated regularly. It was recognised that clinics in a group would expect consistency between different inspectors. This was something the inspectorate had worked hard to achieve over the past few years, and this would represent a natural evolution of the existing approach. The Executive were therefore confident that questions of consistency would be no more likely to arise than at present.
- 8.12.** Members asked whether the clinics would be licensed on a group basis, and it was confirmed that this would not be the case, since the Act requires a licence per premises. From a Licence Committee perspective, there would be no additional papers and calibration of outcomes across a group would not be required.

Decision

- 8.13.** Members questioned whether there would be any significant consequences of not pursuing this new model. It was confirmed that there were improvements to be had, some of which may be quite intangible, but that if some of the clinic staff time could be freed up by this approach, this could only benefit patients. Where there may be a problem with one clinic in a group, it would also make the contrast more visible, assisting both us and the clinic in improving the situation.
- 8.14.** Where policies are the same across clinics, the focus would be on implementation of the policy in each clinic. The approach should also give us more intelligence, and therefore more ability to illuminate differences in compliance between the clinics, feeding this back to the clinic.
- 8.15.** Following discussion, members approved the proposal to move to regulating groups of clinics, where there was demand, to promote further improvement in clinic performance. The Authority endorsed the approach set out in the paper and noted that further details would be worked up with the groups, led by the inspectorate. The pace of development would depend on interest from clinics, but this would be approached cautiously at first.

9. Intelligence strategy 2017-2020

- 9.1.** The Head of Intelligence gave an overview of the new intelligence strategy for 2017-2020, which would be integral to several of our key strategic objectives and would enable us to capitalise fully on the improved Register data quality that would follow from the Information for Quality Programme, and to get the most value out of the new clinic portal and website, and enhanced patient feedback mechanisms. Recruitment to the new Intelligence Team had recently been completed, and the Intelligence Strategy would guide its work.
- 9.2.** The strategy placed patient experience at its heart, developing services to enable patients to act as their own advocates and involving them in shaping aspects of sector development. It would also enable us to use the full extent of our organisational knowledge

to ensure robust evidence is used by all stakeholders to drive sustainable self-improvement in clinics. Good use of intelligence would take us beyond compliance, giving the HFEA and the sector alike real opportunities for quality improvement.

- 9.3.** The focus would be on using our data, getting more feedback from patients, and extending our range of engagement and collaboration. Delivery would be achieved through an expanded programme of publications, particular programmes of work on equality of access and treatment fees, partnership working with patients and others affected by fertility treatment, and developing more standardised approaches to information sharing and provision.
- 9.4.** In relation to obtaining more insight from patients, the Head of Intelligence had spoken to some patient support groups, and reported that many of their expectations about care were very practical and realistic. The aim would be to put patient feedback on an equal footing with outcomes data. It would be possible for the HFEA to gain more patient feedback, for example through a national patient survey. There appeared to be an appetite from patients to give more feedback to the HFEA (rather than to their clinic), and for this to be on a range of subjects.
- 9.5.** The strategy also included a proposal for an optional patient care quality mark to be offered, based on the factors that are most important to patients. This would help to recognise outstanding patient care.
- 9.6.** Members welcomed the strategy with enthusiasm and congratulated the Head of Intelligence on the ideas set out in the strategy and its patient focus. It encapsulated evidence-based compassionate regulation, and would lead to exciting possibilities for improving the quality of care received by patients and the quality of information provided by the HFEA to all its stakeholders. The strategy also demonstrated good leadership by the Authority.

Decision

- 9.7.** Following discussion, members agreed the focus of the new intelligence strategy and the suggested approach, which would be rolled out over time. The idea of a national patient survey was supported, as was the possibility of a patient care quality mark. It was recognised that further work would be necessary to work out a full delivery plan over time.
- 9.8.** Members also recommended that a governance structure should be established for this work, to support and guide it, and to oversee the access and use of data.
- 9.9.** Members also commended the Head of Intelligence on her presentation and the new thinking and imagination she had brought to the strategy.

10. Ovarian hyperstimulation syndrome (OHSS)

- 10.1.** The Director of Compliance and Information explained that OHSS is a potentially serious side effect developed by some patients in reaction to the drug treatment necessary for IVF. Licensed clinics must report all severe or critical cases of OHSS to the HFEA. In May

2017, a national newspaper had alleged under-reporting of OHSS by clinics, based on a wide disparity between the number of OHSS reports to the HFEA and the number of hospital admissions apparently due to OHSS.

- 10.2.** Members were reminded that an initial assessment of the issue had been presented to the Authority in September 2017. The Authority agreed to work with NHS Digital to analyse available data to establish how many of the reported 865 hospital admissions for OHSS arose from IVF treatment, and to set up an arrangement for regular updates on such hospital admissions. The Authority also agreed to meet with the Royal College of Obstetricians and Gynaecologists and the British Fertility Society to discuss the key professional issues, and to consider updating the Code of Practice in terms of the information clinics should provide to patients on OHSS. It was also agreed that we may wish to review what inspectors ask clinics about their application of the OHSS adverse incident definitions.
- 10.3.** The current Authority paper provided an update on the actions taken since September.
- 10.4.** Analysis of data from NHS Digital showed that the majority of hospital admissions for OHSS were for mild or moderate OHSS, which does not need to be reported to the HFEA. It was also apparent that not all cases labelled as OHSS were subsequently diagnosed as such. NHS coding limitations also meant that the data varied in accuracy and did not capture information that would be more relevant for the HFEA's purposes. Clinics were aware of what 'severe' and 'critical' cases of OHSS looked like, and there was good awareness of reporting requirements. However, we could not assume that the number of cases reported was always accurate.
- 10.5.** The 'green top' guidelines produced by the RCOG is currently out of date, and while there is good general awareness of reporting requirements, it could not be assumed that reporting was always accurate.
- 10.6.** An audit had indicated that incorrect coding could arise from inexperience, and that the NHS coding system does not appear to be a reliable method of identifying cases that meet the criteria for reporting. Systematic under-reporting was not found, but the study recommended further such audits across a number of acute trusts. It was now proposed that such audits should also be conducted across a number of volunteer clinics.
- 10.7.** To improve reporting, it was proposed that a change should be made to reporting requirements under General Directions 0011, such that clinics would be asked to report all severe and critical cases of OHSS to the HFEA, regardless of whether these involved a hospital admission. Stakeholders also agreed that a new pro forma specifically for severe or critical OHSS reviews should be developed, asking for more detail than was currently recorded.
- 10.8.** Since hospitals do not necessarily inform clinics when patients are admitted with OHSS, it may be possible for clinics to develop relationships with their local hospitals to allow follow up of at risk patients. This idea could be explored further with the sector. The next review of inspection themes could also consider whether to target clinics with high success rates and few reported OHSS incidents, or cases of patients with a high number of follicles, to check for under-reporting on inspection. Other suggestions in the paper included improved information for patients, encouraging them to report adverse outcomes to their clinic,

awareness raising of the RCOG guidelines on the grading of cases, and encouraging better patient follow-up. We could also consider whether the risk of hospital admission is adequately and accurately reflected on our website.

- 10.9.** The professional bodies were keen to play a role in reducing OHSS to the extent possible. The BFS planned to survey its members on the measures they currently took to prevent OHSS, and both the BFS and RCOG planned to promote the 'green top' guidelines through their various publications. The wording in the Code of Practice would be checked to ensure it is sufficiently clear that clinics should have protocols in place for the prevention of OHSS.
- 10.10.** Members recognised that reporting is a means to an end, and even if there is no under-reporting, OHSS is still a serious issue for affected patients. Clinics must have a strategy to deal with it. All critical cases would be admitted to hospital; however lesser cases may not, and staff in a general hospital may not readily diagnose OHSS even in serious cases. There may also be no direct correlation between the area in which someone is admitted to hospital and the location of their clinic. Improved monitoring and follow-up by clinics would be important to bring about improvements. One member suggested that this should be a requirement in the Code of Practice.

Decision

- 10.11.** Members welcomed the update on progress, and endorsed the range of measures being taken by the HFEA, the NHS, and professional bodies to improve the safety of patients. Further work on data analysis and the steps proposed to improve the situation were supported. It was recognised that OHSS, and the fear of it, were big issues to patients.
- 10.12.** Members noted that the next steps would be to review the NHS Digital hospital episode statistics annually, to extend the audit programme to further volunteer clinics, to make changes to Directions 0011, to develop and launch a new reporting pro forma and to give further consideration to the inspection approach to OHSS reporting, through the next thematic review.

11. Code of Practice update

- 11.1.** The Chief Executive presented a summary of the areas of guidance being reviewed as part of the next Code of Practice update, which would be implemented in October 2018, and the plan for stakeholder engagement. The Code provided guidance for licensed clinics and research establishments on how they should carry out licensed activities in line with legislation.
- 11.2.** Members heard that the policy decisions involved in updating the Code could also result in associated changes to other regulatory tools such as General Directions, consent forms and best practice guidance.
- 11.3.** Members noted that the following areas would be reviewed as part of the next update:
- Information provision for patients – to ensure that clinics provide patients with clear, evidence-based, unbiased information about the treatments they offer.

- Donor screening and quarantine requirements – to ensure that clinics are provided with greater clarity, in an area where there is conflicting or unclear guidance from a variety of professional bodies and organisations.
 - Egg sharing – to ensure that the ‘exceptional circumstances’ in which a woman could give all collected eggs from a cycle, rather than sharing them, if undergoing treatment at that time would be harmful to the egg giver. Following concerns raised in 2017, guidance would be reviewed to address inspection observations at that time, such as an overly informal culture about the provision of information to patients in relation to donation treatment and the need to further emphasise the special nature of egg donation and egg sharing.
 - Obtaining and retaining electronic consent – to adapt our guidance to changing practice in clinics, and the paperless NHS planned in 2020.
 - Consent to data research – to increase the proportion of patients that consent to the use of their identifying information in research.
 - Extending storage for gamete providers – to clarify the current guidance, which was sometimes misinterpreted by clinics.
 - Leadership – to review the responsibilities of the PR and leadership more generally in clinics. There would also be other associated work, outwith the Code, including a training programme, revised PR Entry Programme (PREP) test, and updated inspection tools.
 - Implementation of the EU Directive on import and export of gametes or embryos – to ensure the Directive’s purpose of verifying quality standards and the safety of gametes and embryos was met, and that new rules on the approval of importing relationships with overseas clinics are appropriately applied. The policy on compensation and consent requirements for overseas donors would also be reviewed in parallel.
 - Emotional support – to identify the key constituents of good emotional support before, during and after treatment and donation, and to update the Code of Practice accordingly.
 - Other minor issues – to address a range of minor issues identified since the last update, through enquiries received from clinics and inspectors, and from general discussions. Feedback would also be gathered from stakeholders on the Code’s format, structure and usability.
- 11.4.** Members heard that an engagement plan was in place, and noted the timeline through to October 2018. A working group had been established, comprising a range of clinic and laboratory staff, to advise on the development of the new Code. Engagement would also include workshops, a stakeholder survey, and the circulation of a draft in April for comment.
- 11.5.** The Authority would receive an update on stakeholder feedback in May, and all proposed changes would be presented in June for approval. Following this, Department of Health and Ministerial sign-off would be necessary prior to publication.
- 11.6.** Members were invited to attend the regional workshops where possible. This could be helpful in hearing the views of staff in clinics on issues such as leadership and culture.

Decision

- 11.7.** Members welcomed the update, and noted the areas of guidance being reviewed as part of the next Code of Practice update, and the plan for stakeholder engagement.

12. Any other business

- 12.1.** The Chair of the meeting confirmed that the next meeting will be held on Wednesday 14 March at Church House, London, SW1P 3NZ. Members were asked to confirm their attendance to the Executive Assistant to the Chair and Chief Executive as soon as possible.

13. Chair's signature

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

Signature

Chair

Date

Performance report

Strategic delivery:

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

Details:

Meeting	Authority
Agenda item	6
Paper number	HFEA (14/03/18) 870
Meeting date	14 March 2018
Author	Helen Crutcher, Risk and Business Planning Manager

Output:

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

1. Introduction

- 1.1.** The attached paper mainly summarises our performance up to the end of December 2017, with financial data covering January 2018.

2. Reviewing performance

- 2.1.** The Corporate Management Group (CMG) reviewed the November and December data at its February performance meeting.
- 2.2.** Overall performance is good. Four indicators are currently classified as red. There is a full discussion of these in the performance report, provided in the annex to this paper.
- 2.3.** As part of its rolling review of all indicators, CMG also reviewed the detailed key performance indicators for HR, Information (IT, Register, OTR) and public enquiries, to ensure that these best reflect actual performance and provide useful oversight. This has not led to substantive changes in the Authority's summary report but further information about this discussion is provided in the annex.

3. Recommendation

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

HFEA performance scorecard

Dashboard – December data

People – capacity

Establishment leavers per month

(% turnover for the year).

KPI: 5 - 15% establishment turnover



Leavers: 1
(21.2%)

Overall performance – RAG status (all indicators)



Engagement – Website traffic

Website sessions this month

Arrow tracks performance since last month
(baseline to be established once the website has been active for a year)



31,271
sessions

Licensing end-to-end

Length of the whole inspection and licensing process

KPI: ≤ 70 working days



49 working
days

Money – budget

Summary Financial Position - January 2018

	Year to Date			Full Year		
	Actual £'000	Budget £'000	Variance £'000	Forecast £'000	Budget £'000	Variance £'000
Income	5,113	4,967	146	6,324	6,230	94
Expenditure	4,649	5,074	425	5,695	6,062	367
TOTAL Surplus / (Deficit)	464	(106)	571	629	168	461

Commentary

The above tables show our YTD position as at 31 January (period 10) as a surplus against budget of £571k. There are underspends in most areas of the organisation as explained in the detailed management commentary.

Our forecast position takes into account the current YTD underspends with an expected surplus of £629k at year end. We do not anticipate any significant changes although there could be some minor cost increases related to the Information Systems project this year as we agree which elements should be expensed as part of the year end process.

Overall performance – December 2017

We reviewed the overall performance picture at the CMG meeting on 21 March. There were 4 red indicators.

In February, CMG reviewed all enquiries, Information and HR indicators, to ensure that they are meaningful measures that allow management to address performance. Key changes are:

- CMG will receive metrics on the timeliness of enquiry responses (this was previously only done at a management level) and we will investigate recording enquirer satisfaction and adding this as an indicator.
- CMG will receive tracking metrics on IT support for the external facing systems EDI and Portal support. A metric on supporting the new submission system will be reported to CMG once this is live.
- HR will provide more detailed metrics to CMG at six-monthly intervals (in line with reporting for the annual report and an additional report six-months afterwards, both of which will come to AGC). CMG will review themes from exit interviews annually to consider wider organisational learning (more detailed reviews are already done with line managers and SMT).

These changes do not directly affect this Authority report.

Overall, December performance is generally good and represents a positive position as we move closer to the end of the financial year.

The 4 red key performance indicators (KPIs) shown in the 'overall status - performance indicators' bar chart on the dashboard are as follows:

People and capacity – one red indicator

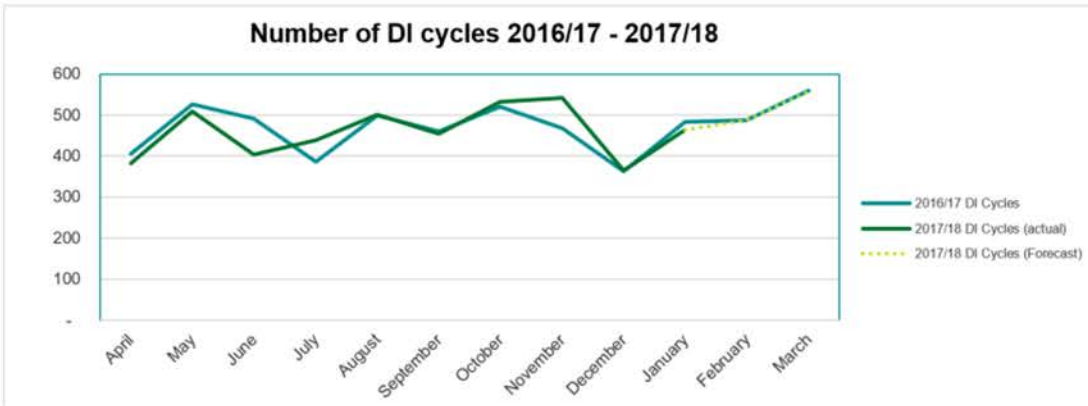
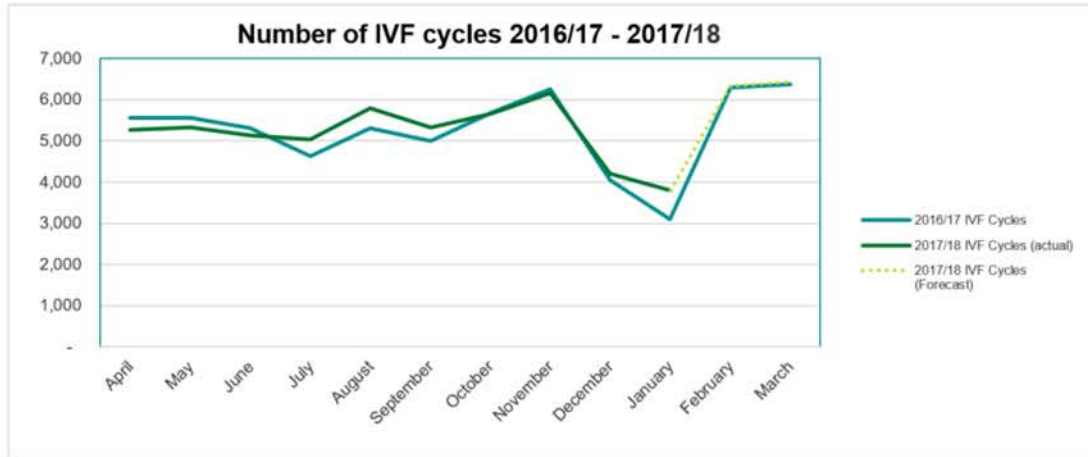
- 'Unplanned' leavers. Our target is to remain within 5 - 15% headcount turnover for the year. Performance is the same as in October at 21.2%. This is still above target and the overall planned and unplanned leavers for the year has increased to 30.99%. December included the final two redundancies that were part of the organisational change which accounts for the increase in total turnover from November to December.

Inspection and licensing processes – three red indicators

- Average number of working days from day of inspection to the day the draft report is sent to the PR. Our target is for 90% of reports to be sent within 20 working days of inspection. In December, performance was 40% in 20wd, this was based on five reports. The average was 23 working days.
- Percentage of PGD applications processed within three months. Our target is 100% to be processed (ie, considered by SAC) within three months (66 working days) of receipt of completed application. In December we were only due to finish processing three items, but all failed the KPIs, in part because of the complexity of the items under consideration. One item was paused by the centre.
- Three month rolling average figure – Percentage of all PGD applications processed within 3 months for the three months to date. Our target is for 100% of applications to be processed within 3 months to date. Performance in December was 15%. However, the 3-month average of time taken was only slightly above the target, at 69 working days (target 66 working days).

Budget status – January data

2017/18 Income



IVF Cycles

	YTD		YE / Forecast	
	Volume	£	Volume	£
2016/17 IVF Cycles	47,350	3,787,974	63,111	5,048,854
2017/18 IVF Cycles	47,883	3,830,640	64,452	5,156,156
Variance	533	42,666	1,341	107,302

As of Q3 2017, IVF Cycles are increasing at a rate of 0.11% against those reported in 2016/17. The 'drivers' for volumes of IVF are currently being assessed with report-back in 2018/19.

Our forecast for the whole year is showing an increase on that in 2016/17.

DI Cycles

	YTD		YE / Forecast	
	Volume	£	Volume	£
2016/17 DI Cycles	4,604	172,650	5,651	211,913
2017/18 DI Cycles	4,590	172,125	5,634	211,268
Variance	14	525	17	644

DI cycles appear to be increasing all be it at a slower rate of 0.01% when compared to 2016/17.

	Year to Date			Full Year		
	Actual £	Budget £	Variance £	Forecast £	Budget £	Variance £
Income						
Grant-in-aid	704	704	-	933	938	(5)
Licence Fees	4,354	4,259	95	5,324	5,286	38
Other Income	4	5	(1)	5	6	(1)
Seconded Salary reimbursed	52	-	52	62	-	62
Total Income	5,113	4,967	146	6,324	6,230	94
Revenue Costs						
Salaries (excluding Authority)	3,270	3,139	(132)	3,839	3,778	(62)
Staff Travel & Subsistence	135	168	34	171	200	29
Other Staff Costs	69	121	52	111	151	41
Authority & Other Committees costs	202	253	51	268	301	33
Facilities Costs incl non-cash	493	569	76	623	689	66
IT Costs	87	104	17	123	125	3
Legal / Professional Fees	274	585	311	353	638	286
Other Costs	119	135	16	208	180	(28)
Total Revenue Costs	4,649	5,074	425	5,695	6,062	367
TOTAL Surplus / (Deficit)	464	(106)	571	629	168	461

Management commentary

Income.

At the end of M10 (January) our Treatment fee income is above budget by £94k or 2%. This is in line with the volume levels shown in the graphs.

Expenditure.

Year-to-date we are operating 8% (£425k) below our budget. This includes £165k for accrued restructuring costs which, if excluded, would increase our underspend on expenditure to 11.6% (£590k). Key areas of underspends remain the same as that reported for Q3 (Training, Recruitment, Facilities and Legal fees).

Forecast

We are forecasting an underspend of revenue costs against budget of 6.8% £367k which reflects the continuing underspends in the areas highlighted above. We do not envisage this position changing significantly by year end.

Spend against Digital Projects for the year are forecast to exceed budget by £9k. We will continue to review these costs over the last two months of the year and manage expenditure in order to remain within the control total delegated to us by DHSC for this year.

People – key performance and volume indicators

Indicator	Score	RAG	Recent trend ¹	Notes																		
Current headcount by month Staff in post/headcount/	63/66	↔	<p>Headcount vs establishment</p> <table border="1"> <thead> <tr> <th>Month</th> <th>Establishment</th> <th>Headcount</th> </tr> </thead> <tbody> <tr> <td>Aug</td> <td>66</td> <td>57</td> </tr> <tr> <td>Sep</td> <td>66</td> <td>61</td> </tr> <tr> <td>Oct</td> <td>66</td> <td>62</td> </tr> <tr> <td>Nov</td> <td>66</td> <td>63</td> </tr> <tr> <td>Dec</td> <td>66</td> <td>63</td> </tr> </tbody> </table>	Month	Establishment	Headcount	Aug	66	57	Sep	66	61	Oct	66	62	Nov	66	63	Dec	66	63	Overall volume (capacity) indicator. We are now using the new post-organisational change headcount of 66.
Month	Establishment	Headcount																				
Aug	66	57																				
Sep	66	61																				
Oct	66	62																				
Nov	66	63																				
Dec	66	63																				
Turnover: Establishment ('unplanned') leavers (% establishment turnover for the year). This is done monthly for the rolling year to date.	21.2%	↔	<p>Turnover vs target range (5-15%)</p> <table border="1"> <thead> <tr> <th>Month</th> <th>Turnover (%)</th> </tr> </thead> <tbody> <tr> <td>Aug</td> <td>22.7%</td> </tr> <tr> <td>Sep</td> <td>21.2%</td> </tr> <tr> <td>Oct</td> <td>21.2%</td> </tr> <tr> <td>Nov</td> <td>19.5%</td> </tr> <tr> <td>Dec</td> <td>21.2%</td> </tr> </tbody> </table>	Month	Turnover (%)	Aug	22.7%	Sep	21.2%	Oct	21.2%	Nov	19.5%	Dec	21.2%	KPI range: 5-15% turnover for the rolling year The public-sector average is 10.9% (Xpert HR 2017) which therefore forms the basis of our target.						
Month	Turnover (%)																					
Aug	22.7%																					
Sep	21.2%																					
Oct	21.2%																					
Nov	19.5%																					
Dec	21.2%																					
Staff sickness absence rate (%) per month.	1.28%	★	<p>Sickness absence</p> <table border="1"> <thead> <tr> <th>Month</th> <th>Sickness absence (%)</th> </tr> </thead> <tbody> <tr> <td>Aug</td> <td>0.53%</td> </tr> <tr> <td>Sep</td> <td>0.78%</td> </tr> <tr> <td>Oct</td> <td>2.30%</td> </tr> <tr> <td>Nov</td> <td>1.58%</td> </tr> <tr> <td>Dec</td> <td>1.28%</td> </tr> </tbody> </table>	Month	Sickness absence (%)	Aug	0.53%	Sep	0.78%	Oct	2.30%	Nov	1.58%	Dec	1.28%	KPI: Absence rate of ≤ 2.5%. Average rate of public sector sickness absence is 2.9% versus 1.7% for the private sector. (Source: ONS data 2016)						
Month	Sickness absence (%)																					
Aug	0.53%																					
Sep	0.78%																					
Oct	2.30%																					
Nov	1.58%																					
Dec	1.28%																					

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

Information – key performance and volume indicators

Indicator	Score	RAG	Recent trend	Notes																		
Number of emailed public enquiries received (compared with same month last year)	154	↓	<table border="1"> <caption>Number of emailed public enquiries received</caption> <thead> <tr> <th>Month</th> <th>This year</th> <th>Last year</th> </tr> </thead> <tbody> <tr> <td>Aug</td> <td>143</td> <td>232</td> </tr> <tr> <td>Sep</td> <td>165</td> <td>248</td> </tr> <tr> <td>Oct</td> <td>166</td> <td>244</td> </tr> <tr> <td>Nov</td> <td>172</td> <td>238</td> </tr> <tr> <td>Dec</td> <td>154</td> <td>160</td> </tr> </tbody> </table>	Month	This year	Last year	Aug	143	232	Sep	165	248	Oct	166	244	Nov	172	238	Dec	154	160	Volume indicator. We are now tracking telephone enquiries as well as those via email. These are reported to CMG in more detail. We are in the process of integrating the enquiries team with website development, to ensure it meets user needs.
Month	This year	Last year																				
Aug	143	232																				
Sep	165	248																				
Oct	166	244																				
Nov	172	238																				
Dec	154	160																				
Percentage of Opening the Register requests responded to within 20 working days	100%	★	<table border="1"> <caption>Percentage of Opening the Register requests responded to within 20 working days</caption> <thead> <tr> <th>Month</th> <th>Number of requests</th> <th>% within 20 days</th> </tr> </thead> <tbody> <tr> <td>Aug</td> <td>25</td> <td>100%</td> </tr> <tr> <td>Sep</td> <td>30</td> <td>100%</td> </tr> <tr> <td>Oct</td> <td>19</td> <td>100%</td> </tr> <tr> <td>Nov</td> <td>20</td> <td>100%</td> </tr> <tr> <td>Dec</td> <td>15</td> <td>100%</td> </tr> </tbody> </table>	Month	Number of requests	% within 20 days	Aug	25	100%	Sep	30	100%	Oct	19	100%	Nov	20	100%	Dec	15	100%	KPI: 100% of complete OTR requests to be responded to within 20 working days (excluding counselling time)
Month	Number of requests	% within 20 days																				
Aug	25	100%																				
Sep	30	100%																				
Oct	19	100%																				
Nov	20	100%																				
Dec	15	100%																				
Number of requests for contributions to Parliamentary questions	0	↓	<table border="1"> <caption>Number of requests for contributions to Parliamentary questions</caption> <thead> <tr> <th>Month</th> <th>PQs dealt with</th> <th>Same month last year</th> </tr> </thead> <tbody> <tr> <td>Aug</td> <td>0</td> <td>0</td> </tr> <tr> <td>Sep</td> <td>0</td> <td>0</td> </tr> <tr> <td>Oct</td> <td>17</td> <td>6</td> </tr> <tr> <td>Nov</td> <td>5</td> <td>5</td> </tr> <tr> <td>Dec</td> <td>0</td> <td>2</td> </tr> </tbody> </table>	Month	PQs dealt with	Same month last year	Aug	0	0	Sep	0	0	Oct	17	6	Nov	5	5	Dec	0	2	Volume indicator.
Month	PQs dealt with	Same month last year																				
Aug	0	0																				
Sep	0	0																				
Oct	17	6																				
Nov	5	5																				
Dec	0	2																				

Indicator	Score	RAG	Recent trend	Notes																		
Number of Freedom of Information (FOI) requests	6	↓	<table border="1"> <caption>FOI Data</caption> <thead> <tr> <th>Month</th> <th>FOIs dealt with</th> <th>Same month last year</th> </tr> </thead> <tbody> <tr> <td>Aug</td> <td>13</td> <td>14</td> </tr> <tr> <td>Sep</td> <td>2</td> <td>4</td> </tr> <tr> <td>Oct</td> <td>5</td> <td>1</td> </tr> <tr> <td>Nov</td> <td>8</td> <td>4</td> </tr> <tr> <td>Dec</td> <td>6</td> <td>3</td> </tr> </tbody> </table>	Month	FOIs dealt with	Same month last year	Aug	13	14	Sep	2	4	Oct	5	1	Nov	8	4	Dec	6	3	Volume indicator.
Month	FOIs dealt with	Same month last year																				
Aug	13	14																				
Sep	2	4																				
Oct	5	1																				
Nov	8	4																				
Dec	6	3																				

Inspection and licensing process – key performance and volume indicators

Indicator	Score	RAG	Recent trend ²	Notes																		
Average number of working days taken for the whole licensing process, from the day of inspection to the decision being finalised (signed off by the chair)	49	★	<table border="1"> <caption>Working Days Data</caption> <thead> <tr> <th>Month</th> <th>Working days</th> <th>Target</th> </tr> </thead> <tbody> <tr> <td>Aug</td> <td>46</td> <td>70</td> </tr> <tr> <td>Sep</td> <td>73</td> <td>70</td> </tr> <tr> <td>Oct</td> <td>40</td> <td>70</td> </tr> <tr> <td>Nov</td> <td>39</td> <td>70</td> </tr> <tr> <td>Dec</td> <td>49</td> <td>70</td> </tr> </tbody> </table>	Month	Working days	Target	Aug	46	70	Sep	73	70	Oct	40	70	Nov	39	70	Dec	49	70	KPI: Less than or equal to 70 working days.
Month	Working days	Target																				
Aug	46	70																				
Sep	73	70																				
Oct	40	70																				
Nov	39	70																				
Dec	49	70																				
Monthly percentage of PGD applications processed within three months (66 working days).	0% (0/3)	↔	<table border="1"> <caption>Performance Data</caption> <thead> <tr> <th>Month</th> <th>Performance</th> <th>Target</th> </tr> </thead> <tbody> <tr> <td>Aug</td> <td>100%</td> <td>100%</td> </tr> <tr> <td>Sep</td> <td>33%</td> <td>100%</td> </tr> <tr> <td>Oct</td> <td>50%</td> <td>100%</td> </tr> <tr> <td>Nov</td> <td>0%</td> <td>100%</td> </tr> <tr> <td>Dec</td> <td>0%</td> <td>100%</td> </tr> </tbody> </table>	Month	Performance	Target	Aug	100%	100%	Sep	33%	100%	Oct	50%	100%	Nov	0%	100%	Dec	0%	100%	<p>KPI: 100% processed (i.e. considered by SAC) within three months (66 working days) of receipt of completed application.</p> <p>See commentary above.</p>
Month	Performance	Target																				
Aug	100%	100%																				
Sep	33%	100%																				
Oct	50%	100%																				
Nov	0%	100%																				
Dec	0%	100%																				

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

Indicator	Score	RAG	Recent trend ²	Notes												
Average number of working days taken (in the month).	72 (average for 3 reports)	↓	<p>Working days</p> <table border="1"> <tr><th>Month</th><td>Aug</td><td>Sep</td><td>Oct</td><td>Nov</td><td>Dec</td></tr> <tr><th>Value</th><td>62</td><td>63</td><td>62</td><td>76</td><td>72</td></tr> </table>	Month	Aug	Sep	Oct	Nov	Dec	Value	62	63	62	76	72	
Month	Aug	Sep	Oct	Nov	Dec											
Value	62	63	62	76	72											
Cumulative 3 month (rolling average) percentage of PGD applications processed within three month KPI (66 working days)	15% (2/13)	↓	<p>Performance</p> <table border="1"> <tr><th>Month</th><td>Aug</td><td>Sep</td><td>Oct</td><td>Nov</td><td>Dec</td></tr> <tr><th>Value</th><td>81%</td><td>53%</td><td>55%</td><td>25%</td><td>15%</td></tr> </table>	Month	Aug	Sep	Oct	Nov	Dec	Value	81%	53%	55%	25%	15%	KPI: As above. We are now reporting against a three-month rolling average rather than an annualised average, since this will allow us to see trends, without being affected by negative performance from a year ago which has been addressed.
Month	Aug	Sep	Oct	Nov	Dec											
Value	81%	53%	55%	25%	15%											
Average number of working days taken (cumulative 3 month picture).	69	↓	<p>Working days</p> <table border="1"> <tr><th>Month</th><td>Aug</td><td>Sep</td><td>Oct</td><td>Nov</td><td>Dec</td></tr> <tr><th>Value</th><td>64</td><td>70</td><td>68</td><td>72</td><td>69</td></tr> </table>	Month	Aug	Sep	Oct	Nov	Dec	Value	64	70	68	72	69	
Month	Aug	Sep	Oct	Nov	Dec											
Value	64	70	68	72	69											

Business plan 2018/19

Strategic delivery:

Safe, ethical
effective treatment

Consistent
outcomes and
support

Improving standards
through intelligence

Details:

Meeting	Authority
Agenda item	7
Paper number	HFEA (14/03/18) 871
Meeting date	14 March 2018
Author	Paula Robinson, Head of Planning and Governance

Output:

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

1. Strategic delivery – year two

- 1.1. Our business plans are designed to help us deliver our overall strategy, year by year. This business plan, attached at Annex A, will deliver the second phase of our three year strategy for 2017-2020.
- 1.2. We will start the new business year with a new set of tools and capabilities, and an intelligence strategy to enable us to capitalise on the work done through the Information for Quality Programme and the organisational restructuring we completed in 2017. We will be well positioned to begin to make better use of the data we hold – to assist clinics towards better performance, to make targeted regulatory interventions when this is merited, and to provide a range of improved information for patients and our other stakeholder audiences.
- 1.3. Our people strategy for 2018-2020 sits alongside our organisational strategy, and sets out how we will ensure that we have the capacity and capability to deliver our vision. We aim to foster a culture of high performance and attract, develop, reward and retain highly skilled and innovative people. This will best serve our overall vision for high quality care and support for patients.
- 1.4. Our mid-year assessment of delivery of this new business plan (at the end of quarter two) will mark the mid-point of our current strategy, and this will be a good time to take stock of progress towards our vision. In the second half of the business year, we will also begin to consider the process for developing a new strategy from 2020 onwards.

2. Finalising the business plan

Year-end content

- 2.1. Some content can only be added after 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 and Social Care (DHSC) approval.

Sign-off and publication

- 2.2. The DHSC have given positive initial feedback on the earlier draft of the business plan. The budget will be discussed in more detail during this Authority meeting, and the financial section of the business plan will then be finalised prior to submission of the final draft to the Department.

3. Recommendation

- 3.1.** The Authority is asked to approve the business plan for 2018/19, and to note that year-end information will be added in April.
- 3.2.** We anticipate receiving DHSC 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

2018/19

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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.

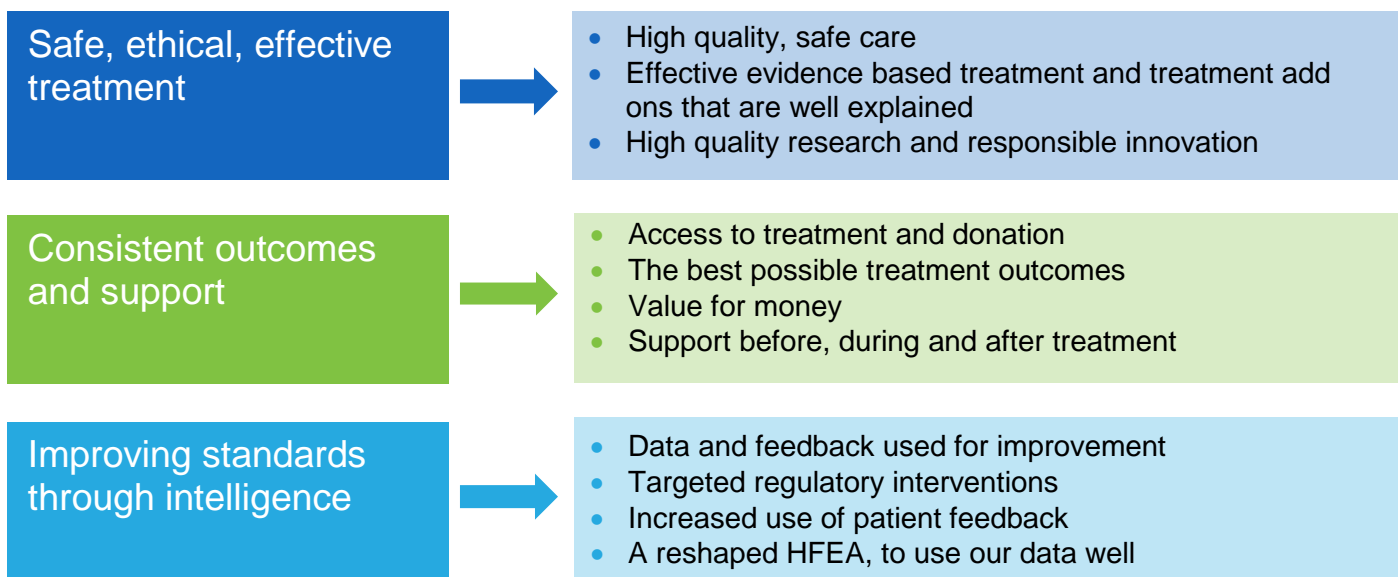
Patients, donors and donor-conceived people are at the heart of our strategy, and our work. We want them all to receive high quality care and support, at every stage in their journey through fertility services.

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 2018/19.

Our legislation and functions

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

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

Under this legislation our main statutory functions are:

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

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

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

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

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

What we did in 2017/18

Delivery of the 2017/18 business plan

Overview

In the past year, we began to deliver our three year strategy for 2017-2020, with an emphasis on making full use of our clinic portal, website and data so as to improve quality for patients.

Our new clinic portal and website were launched in 2017, as part of our Information for Quality Programme. When the new Register and electronic data interchange systems are also fully complete, in autumn 2018, we will be even better equipped to collect and use our data in new and exciting ways.

Our aim, throughout our activities, has been to collect and use our data, and to communicate with our audiences, as effectively as possible. In order to capitalise fully on the advancements achieved through the Information for Quality Programme over the past three years, we restructured the HFEA's staffing, in April 2017, creating a new Intelligence team and re-shaping other functions. This reconfiguration will ensure we have the right skills and capacity in place to enable us to make full use of our new tools and to implement a newly agreed intelligence strategy in 2018/19 and beyond.

Following the restructuring, we involved our staff in the development of a people strategy setting out how we will attract and retain the skills and talent we need in order to deliver the Authority's strategic vision. Our people strategy describes our core values, which are:

- We care about our people
- We are expert and are knowledgeable about our business
- We are professional. We take pride in our work and act in an accountable way.

Our people strategy acknowledges that our success as an organisation depends on having skilled and motivated employees.

Safe, ethical, effective treatment

We carried out a full programme of clinic inspection, audit and licensing activities, increasing our emphasis on consistent standards and safety. We carried out additional inspections at a number of clinics after a Daily Mail investigation alleged poor practices in a number of clinics. We also began a conversation with the sector about clinic leadership, with the aim of putting in place new incentives to encourage and support excellent clinic leadership.

We maintained our strong focus on learning from incidents, adverse events and complaints from patients, and published our annual review of clinic incidents in November 2017.

Throughout the year, our licensing committees considered inspection reports and applications for preimplantation genetic diagnosis (PGD), human leukocyte antigen (HLA) testing, and, for the first time, mitochondrial donation.

Our website includes a wide range of up to date scientific information, so as provide clear and unbiased information for patients about treatments or add ons. And our annual horizon scanning process helped to ensure that our policy developments and website material are informed by expert input and an understanding of current scientific issues and future developments.

We seek to encourage an enquiring culture and responsible innovation in clinics, and to improve the overall quality of treatment by engendering world class data and embryo research and clinical trials. Last year we completed two projects on research – one to ensure that clinics explain data research well to patients, and record consent accurately, and the other to promote and explain embryo research findings and improve the explanatory material available to patients about donating unused embryos for research purposes. We also continued to respond to requests from researchers for access to Register data for research purposes.

Consistent outcomes and support

We provided advice and information to patients about accessing treatment and donation, via our website. We also worked with professional stakeholders (such as the British Fertility Society, BFS) to put patients in touch with better information and services when they first realise they may have a fertility issue.

Through our inspection activities, we maintained our focus on quality and safety, focusing in particular on shortcomings in the taking and recording of consents, learning from incidents, medicines management, data submission, multiple birth rates, and the information clinics publish on their own websites. We also began to work with commercial groups of clinics, so as to improve quality, consistency and compliance on a group-wide basis, as relevant.

We have worked with NHS England on a piece of work led by them on price benchmarking, with the aim of assisting NHS commissioners in securing fair prices and effective fertility services for patients. This collaborative work will continue in 2018/19.

We began a project on the emotional experience of care before, during and after treatment, working with professional stakeholders to bring about improvement. Proposed changes will be incorporated into the next edition of the Code of Practice in 2018. We also evaluated the second year of a three year pilot of counselling support services for applicants to the Register.¹

With the aim of improving the chances of successful treatment, we have been publishing more information in our annual Fertility Trends report, and focusing on success rates through inspection reports and risk tool alerts. In the coming year we plan to do further work on success rates.

At the end of the business year, we implemented new EU requirements relating to the import and coding of donor eggs and sperm. The introduction of new processes and certifications to ensure we are fully compliant will be in place by October 2018.

Improving standards through intelligence

In January 2018, the Authority approved a new information strategy, setting out how we will analyse, publish and use our data to improve the quality of the information we produce and, ultimately, to provide a sharper focus in our regulatory work. This followed on from the creation of a new Intelligence team in our organisational re-shaping in 2017. The information strategy sets out much of our strategic delivery in 2018/19.

We maintained our role as the UK's competent authority for ART in the European Union, participating in two meetings and implementing associated EU decisions such as the new requirements on certifying imports of eggs, sperm and embryos.

In addition to our programme of improvement work on the Register infrastructure, which will conclude this year, we maintained the Register of treatments and outcomes throughout the year, and worked with clinics to ensure accurate reporting of data. We also continued to publish the information we hold, and to respond to a range of enquiries from patients, clinics and central Government.

¹ 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.

Delivering our strategy in 2018/19

Delivering the strategy

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

High quality care for everyone affected by fertility treatment.

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

In this area...	We will...
Safe, ethical, effective treatment	1. Ensure that all clinics provide consistently high quality and safe treatment
	Our aim: <ul style="list-style-type: none"> patients know clinics provide a high quality, consistent, safe service
	2. Publish clear information so that patients understand treatments and treatment add ons and feel prepared for treatment
Consistent outcomes and support	Our aim: <ul style="list-style-type: none"> increase patients' understanding of the science and evidence base behind treatments and added extras known as add ons, and of their safety and effectiveness.
	3. Engender high quality research and responsible innovation in clinics
	Our aim: <ul style="list-style-type: none"> improve the quality of treatment, by encouraging world class research and clinical trials.
Improving standards through intelligence	4. Improve access to treatment
	Our aim: <ul style="list-style-type: none"> provide advice and information about access to treatment and improve access to donor conception treatment.
	5. Increase consistency in treatment standards, outcomes, value for money and support for donors and patients
Improving standards through intelligence	Our aims: <ul style="list-style-type: none"> higher birth rates, without adverse outcomes. patients and NHS commissioners receive good value fertility services improve the emotional experience of care by clinics before, during and after treatment or donation
	6. Use our data and feedback from patients to provide a sharper focus in our regulatory work and improve the information we produce.
Improving standards through intelligence	Our aims: <ul style="list-style-type: none"> use our data and intelligence to drive quality improvements for patients. targeted and responsive regulatory interventions in the interests of quality and consistency. increase insight into patient experience in clinics and encourage good practice based on feedback. work more smartly with our resources, and capitalise on recent systems improvements.

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

We will start the year with a new set of tools and capabilities, and an intelligence strategy to enable us to capitalise on the work done through the Information for Quality Programme and the organisational restructuring we completed in 2017. We will be well positioned to begin to make better use of the data we hold – to assist clinics towards better performance, to make targeted regulatory interventions when this is merited, and to provide a range of improved information for patients and our other stakeholder audiences.

Our people strategy for 2018-2020 sits alongside our organisational strategy, and sets out how we will ensure that we have the capacity and capability to deliver our vision. We are proud of our people and the work we do, and we want to be recognised as an Employer of Choice. Through our approach to people management and organisational development, we aim to foster a culture of high performance and attract, develop, reward and retain highly skilled and innovative people. This will best serve our overall vision for high quality care and support for patients.

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

Activities for 2018/19

The focus of delivery in 2017/18 was to complete the programme of work known as Information for Quality, and to commence work on the aims set out in our strategy. There are three main areas of focus in the strategy:

- safe, ethical, effective treatment
- consistent outcomes and support
- improving standards through intelligence.

Following the building of our new Register and electronic data submission system, we will now focus on making full use of the resulting tools and data to provide an enhanced range of information for patients and clinics on a range of topics, including access to treatment, treatment add ons, and success rates. We will also work with the sector to improve the leadership culture within clinics, encouraging them to be more responsive to patients' emotional needs, as well as their treatment.

The activities set out over the next few pages will help us to deliver our strategic objectives in 2018/19, in the interests of high quality care for everyone affected by fertility treatment.

Activities for 2018/19

Aims	Methods and channels	Benefits and outcomes	Timescale
Safe, ethical, effective treatment			
Strategic objective 1: Ensure that all clinics provide consistently high quality and safe treatment			
<p>Ensure that clinics are well regulated and provide a high quality, consistent service.</p>	<p>Full programme of clinic regulation, encompassing all of our inspection, audit and licensing activities, with an increased emphasis on consistent standards across the sector, and between inspections. We will be clearer about what good performance looks like and will use our skills and our data to help clinics to be more compliant, more of the time.</p>	<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>October 2018</p>

Aims	Methods and channels	Benefits and outcomes	Timescale
	Continued strong focus on learning from incidents, adverse events and complaints from patients, in dialogue with the sector. This will include a focus on incidents and clinics' learning culture during inspections, and publication of our annual review of clinical incidents.	<p>Publication of 'State of the Sector' report for 2016/2017, including information about clinical incidents.</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>Better understanding of factors contributing to particular types of adverse event.</p>	<p>November 2018</p> <p>Throughout year</p>
	Proactively encouraging and supporting leadership in clinics, on inspection and through wider engagement with the sector and professional bodies.	<p>Revised guidance in the Code of Practice setting clear expectations for clinics.</p> <p>Redesigned PR Entry Programme (PREP).</p> <p>Enhancements in the clinic portal and through other channels to encourage a quality-focused culture of learning and research throughout clinics.</p> <p>Improvements in standards and consistency over time, both between one inspection and the next, and between clinics – so that more clinics perform at the level of the best clinics.</p>	<p>October 2018</p> <p>March 2019</p> <p>March 2019</p> <p>Throughout year</p>
	Major revision of the Code of Practice.	Guidance for clinics is up to date and reflects latest scientific developments and policy decisions.	October 2018

Aims	Methods and channels	Benefits and outcomes	Timescale
Ensure that licensing decisions and other approvals are well governed.	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
	Processing applications for the licensing of preimplantation genetic diagnosis (PGD), human leukocyte antigen (HLA) and mitochondrial donation.	Growing area of work dealt with effectively and efficiently, with applications processed according to performance indicator timelines. Public confidence assured in the regulation of mitochondrial donation. Decisions on whether to authorise such treatments made, and communicated, in a proper and timely manner for the direct benefit of patients waiting for treatment.	Throughout year
	Policy project to review the current list of PGD conditions and ensure that all listed conditions still meet the statutory tests regarding seriousness and significance.	The list of conditions will be up to date and reflect latest developments in treatment for genetic diseases.	September 2018

Strategic objective 2:

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

Make use of our website and other channels to increase patients' understanding of the science and evidence base behind treatments and added extras known as 'add ons', and of their safety and effectiveness.	Inclusion of up to date scientific content in our website so as to maintain our expanded range of information about current and future treatment options and treatment add ons, and the scientific evidence base for these.	Patients and others turn first to the HFEA for up to date, clear unbiased information. Prospective patients have clear information on which to base decisions about treatment or add ons. Patients feel safe, knowing they can expect certain standards in clinics, and are more aware of the potential risks of new/different treatments or add ons as well as the possible benefits.	Throughout year
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Aims	Methods and channels	Benefits and outcomes	Timescale
	Guidance for clinics on what information they should publish on their own websites about the add on treatments they offer to patients.	Improved guidance in the Code of Practice. Information on clinics' websites is clear and transparent. Consensus statement with professionals setting out the appropriate way to introduce new techniques into treatment, through responsible innovation.	October 2018
	Refine the way we publish treatment information on our website, based on feedback from users.	Our information and site navigation better meets users' needs and preferences.	March 2019
	Responding to new scientific developments and associated reporting, correcting myths and misunderstandings where necessary.	Balance and accuracy provided when media coverage on scientific evidence is misleading or inaccurate.	Throughout year
	Conducting our annual horizon scanning exercise to ensure we identify relevant new scientific developments.	The Scientific and Clinical Advances Advisory Committee meets to discuss issues identified through horizon scanning three times per year. The horizon scanning panel meets once per year. Policy developments and website material are informed by expert input and an understanding of scientific issues and future developments. Future work planning is facilitated by early identification of upcoming issues.	Throughout year June/July 2018 Throughout year Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
Strategic objective 3: Engender high quality research and responsible innovation in clinics			
Improving the overall quality of treatment, by encouraging world class data and embryo research and clinical trials.	<p>Further work on embryo research, following the project in 2017/18 to produce better information about embryo research, streamline the application process and encourage collaboration between clinics and research centres.</p> <p>In 2019 we will carry out a review of embryo research, including the numbers of embryos donated, and whether the number of collaborations has increased.</p>	<p>Improvements in research information quality, applications and collaboration.</p> <p>To assess whether the decisions made at the June 2017 Authority meeting are having a positive impact.</p>	<p>September 2018</p> <p>Spring 2019</p>
	<p>Focus on ensuring clinics explain research data consent adequately, record such consent properly, and report consents accurately to the HFEA.</p>	<p>The quality of research consent-taking, and the recording and reporting of consent, are improved.</p> <p>Higher rate of consent to research from patients.</p>	<p>March 2019</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
Consistent outcomes and support			
Strategic objective 4: Improve access to treatment			
Providing advice and information about access to treatment, and improving access to donor conception treatment.	<p>Publishing information and advice about accessing services, through various channels, and keeping this under review, taking into account user feedback.</p> <p>Providing information for those considering going abroad for treatment on how they might 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>	March 2019
	Collaborating with NHS Choices to put new patients in touch with better information about services when they first realise they may have a fertility issue.	<p>New patients find relevant signposting and advice more easily.</p> <p>Quality and amount of information aimed specifically at new patients is increased.</p> <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>	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
Improving access to donation, support for patients and donors and information about access to donor conception treatment.	<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>Considering available data regarding 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>	March 2019
<p>Strategic objective 5:</p> <p>Increase consistency in treatment standards, outcomes, value for money and support for donors and patients</p>			
Using our outcome data to improve the chances of successful treatment	<p>With the aim of increasing birth rates while avoiding adverse outcomes, we will analyse Register data on success rates, and work with our professional stakeholders to define and establish the factors that lead to successful outcomes, publishing our findings.</p> <p>Continuing to publish the annual fertility trends report.</p> <p>Using data more on inspection and in inspection reports.</p>	<p>More information published so that clinics can compare themselves more easily, based on different factors such as patient age.</p> <p>Fertility trends in 2017 report published.</p> <p>Patients' chance of a live birth is maximised.</p> <p>Redesigned inspection reports focusing more on outcomes.</p>	<p>March 2019</p> <p>March 2019</p>
	As part of the Code of Practice update for 2018, we will review the outcomes information on clinics' own websites, and provide revised guidance.	<p>Revised guidance for clinics on the publication of outcomes data on their own websites.</p> <p>Clarity for the sector about how such data should be presented to prospective patients.</p>	March 2019

Aims	Methods and channels	Benefits and outcomes	Timescale
Identifying and implementing ways of improving the quality and safety of care.	Continuing our focus on quality and safety of care in inspection activities – in particular through focusing on shortcomings in the taking and recording of consents, learning from incidents, medicines management and multiple birth rates. There will also be a greater focus on clinics' management of information responsibilities including meeting data submission and data security requirements, and ensuring information provided to patients generally and on clinics' websites is accurate and not misleading.	<p>Improved compliance and a positive impact on the quality of care, outcomes and safety of patients.</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>	Throughout year
	Continuing to evaluate areas of regulatory concern and identifying performance levers.	<p>Improved levels of compliance.</p> <p>Inspection recommendations and advice or alerts targeting relevant issues, for maximum impact on quality of care, outcomes, and the safety of patients.</p>	Throughout year
Improved Register data quality, as a result of work done previously under the Information for Quality (IfQ) programme.		<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>Fewer data submission and data accuracy related non-compliances found on inspection and audit.</p>	March 2019
To further develop the inspection regime to be more efficient and effective in the regulation of groups of clinics.		A clinic group's central Quality Management System (QMS) can be used to best effect across the whole group.	March 2019

Aims	Methods and channels	Benefits and outcomes	Timescale
		<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>	
<p>Improving value for money, for both patients and NHS commissioners.</p>	<p>Make use of benchmarking information on price, working in collaboration with NHS England.</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>	<p>March 2019</p>
<p>Improving the emotional experience of care before, during and after treatment or donation.</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. (This will be implemented in the October 2018 Code of Practice update).</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>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>Clinics more aware of their responsibilities to patients beyond the immediate treatment setting.</p>	<p>March 2019</p>

Aims	Methods and channels	Benefits and outcomes	Timescale
<p>Evaluating the counselling support pilot for donor-conceived people wishing to access information held on the HFEA Register.</p>	<p>Evaluation of the third and final year of the pilot of counselling support services for Register applicants, including an assessment of provision and take-up.</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 2018</p>
<p>Implementing new EU requirements relating to the import and coding of donor eggs and sperm.</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>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>April- October 2018</p>

Aims	Methods and channels	Benefits and outcomes	Timescale
Improving standards through intelligence			
Strategic objective 6: Use our data and feedback from patients to provide a sharper focus in our regulatory work and improve the information we produce			
Driving quality improvements in treatment standards and outcomes by using our data and regulatory intelligence.	Developing our intelligence team and our analytical capability to extract more value from the data we hold, using the intelligence strategy developed in 2017/18.	Intelligence strategy delivery commenced. More outcome and other data published. Fertility Trends 2017 (for data up to 2016) published. Donor information report for 2013-2016 published. Egg freezing report published (data up to 2016). State of the Sector report published for 2017/18 Increased exposure of statistics and research using our new website.	Throughout year
Making more targeted and responsive regulatory interventions, in the interests of quality and consistency, based on our data.	Applying the intelligence available to us from inspections, the sector, patient feedback, and analysis of our data to make more targeted and responsive interventions.	Ability to make earlier and more responsive regulatory interventions, without the need to wait for the next inspection point. Regulatory performance is more consistent across the inspection cycle.	March 2019
	Reviewing our risk tool, to improve clinics' access to feedback about their own performance.	Risk tool brought up to date with latest benchmarks and available clinic data (entered through the HFEA's data submission system). More clinic data published for clinics' own use, using the clinic portal.	March 2019

Aims	Methods and channels	Benefits and outcomes	Timescale
Maintaining the Register of Treatments and Outcomes and working with clinics to ensure they are accurately reporting their data.	Register data and forms continue to be processed and quality assured, through liaison with clinics on errors and omissions and through validation and verification of Register entries.	High quality data available to develop patient information and respond to information requests. Risk-based regulation and evidence-based policy-making.	Throughout year
Publishing and supplying the information we hold, for the benefit of stakeholders.	Regularly updating Choose a Fertility Clinic (CaFC) information to assist patient choice.	Provide more up-to-date, and accurate, information to patients.	Throughout year
	Continued publication of inspection reports on CaFC.	Inspection reports continue to be published via CaFC, providing patients with an independent assessment of the quality of services offered by each clinic.	Throughout year
	Further develop and improve the presentation of clinic comparison information and user experience scores on CaFC, guided by patient feedback.	Published outcome data is more useful and easier to understand and sets up positive incentives for improvements. Patient feedback enables us to evaluate the effectiveness and usability of the new presentation, and to plan future improvements.	Throughout year
	Continuing to facilitate timely access to information from the Register for those who are entitled to it.	Opening the Register requests continue to be met in a sensitive manner and within required time limits (20 working days, excluding time for counselling).	Throughout year
	Facilitating access to information under various statutory regimes and fulfilling Government requirements such as quarterly disclosure of information on procurement.	Legal and Parliamentary requirements continue to be met within time limits.	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
	To continue to publish statistical and other reports.	<p>'Fertility trends' report.</p> <ul style="list-style-type: none"> - Provides the public, patients, clinic staff and others with up-to-date, high quality information about treatment outcomes. - Provides important information to those affected by donor conception, to patients seeking treatment and to us, to help us to enhance the quality of care that patients and donors receive in clinics, through our regulatory work. - Report carries 'official statistics' status. 	March 2019
		<p>'State of the fertility sector' report -2017-18</p> <ul style="list-style-type: none"> - Provides the public and the sector with the most up-to-date information about the performance of clinics. - Contributes to a culture of openness and information sharing where clinic staff are empowered to report mistakes and learn from each other. - Increases transparency and maximises opportunities for learning from incidents to improve quality of care for patients. 	November 2018

Aims	Methods and channels	Benefits and outcomes	Timescale
Responding effectively to specific enquiries from individuals.	Continuing to respond to the many individual patient and public enquiries we receive each year.	<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>	Throughout year
Maintaining our role as the UK's competent authority for ART in the European Union ² .	Gain intelligence through participation in competent authority events and implementation of associated EU decisions.	<p>We participate in approximately 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>Twice annually</p> <p>Throughout year</p>
Gaining insight into the patient experience in clinics and encouraging good practice based on feedback.	<p>Collecting more patient feedback through various channels, including our website and social media.</p> <p>Establish additional channels and methods for obtaining patient experience information.</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>	Throughout year

² For as long as the UK remains in the EU.

Aims	Methods and channels	Benefits and outcomes	Timescale
	Surveying stakeholders about our performance as a regulator.	Stakeholder input obtained to inform future developments and improvements.	March 2019
Ensuring the HFEA is a good value organisation and makes best use of its limited resources.	Working smartly with our limited resources, capitalising on improvements in our information systems and ensuring that our infrastructure and central systems are efficient and responsive.	<p>Resources are deployed in the interests of high quality care for everyone affected by fertility treatment.</p> <p>Achieving measurable 'added value' and internal efficiency.</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> <p>Updated staff intranet.</p>	Throughout year
	Ensuring that we retain the staff we need in order to operate a good quality service, and implement our People Strategy for 2017-2020.	<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
	Reviewing our internal records management and information governance arrangements.	<p>HFEA's records management system updated and reviewed to ensure that records are securely held and that good practice is followed.</p> <p>Information governance arrangements comply with latest requirements and roles and responsibilities and are clearly set out for staff.</p>	January 2019
	Use available data to understand the factors driving treatment activity and develop an income forecasting model to inform the future setting of treatment fees.	<p>Model developed for use in future fee review exercises.</p> <p>Best value for money for patients.</p>	March 2019

Aims	Methods and channels	Benefits and outcomes	Timescale
Ensuring the HFEA is easy to deal with and offers a professional service.	<p>Full realisation of the benefits of HFEA's improved Register function and processes (including the data submission system and the Clinic Portal).</p> <p>Continuation of engagement arrangements with clinics on fees charged.</p>	<p>System fully bedded in with Clinics and EPRS providers.</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 2018</p> <p>Throughout year</p>
Responding as appropriate to government requirements on transparency, better regulation and the new General Data Protection Regulation (from May 2018 onwards).	<p>Ongoing compliance with government requirements, including:</p> <p>Reporting in our Annual Report on the growth duty and compliance with the Regulators' Code .</p> <p>Complying with the Business Impact Target by identifying and reporting any 'in-scope activity'.</p> <p>Complying with the new General Data Protection Regulation.</p>	<p>The HFEA responds to government requirements and new initiatives in a manner consistent with its legal status, and proportionately within our small resource envelope, carefully recognising our duties.</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>June 2018</p> <p>Throughout year</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.	Continued participation in the collaborative regulatory advice service for regenerative medicine, to provide advice to those working in the life sciences industry.	<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 can quickly and easily navigate the different regulators and allow them to access the right advice more quickly.</p>	Throughout year

Aims	Methods and channels	Benefits and outcomes	Timescale
	<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>	<p>Throughout year</p>
	<p>Collaborative and partnership working with other ALBs and health regulators UK wide, such as the CQC, NHS England, MHRA, UKAS, HRA, GMC and the devolved nations, maintaining the close positive working relationships that have been developed over the past several years.</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>	<p>Throughout year</p>
<p>Maintaining our previously established collaborative information management relationships.</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 2017/18

The following facts and figures give a wider picture of the type and volume of our work in the past year, between 1 April 2017 and 31 March 2018.

[Note: this material and updated KPIs will be added in early April, prior to publication.]

Number of:	2016/17	2017/18
Active clinics and research establishments	132	
Clinics and research establishments inspected	71	
Licences inspected	72	
New licence applications processed and presented to the Licence Committee/ Executive Licensing Panel	6	
Licence renewals processed and presented to the Licence Committee/Executive Licensing Panel	36	
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	45	
Incident reports from clinics processed	558	
Alerts issued	0	
Formal complaints about clinics	10	
Opening the Register requests closed within 20 working days	255	
Donor Sibling Link applications processed	38	
Licensed Centres Panel meetings held	2	
Meetings with patient organisations held	2	
Public and stakeholder meetings	8	
Freedom of Information (FOI) requests dealt with	82	
Environmental Information Regulations (EIR) requests dealt with	0	
Enquiries responded to under the Data Protection Act (DPA)	1	
Parliamentary questions (PQs) responded to	55	
Information for researchers requests received	0	
Unique visits to our website	1,271,686	
Most popular/viewed page on our website	Fertility treatment options – Surrogacy	

Required HR benchmarking information

In common with other ALBs, we are required to maintain a record of the following standard benchmarking data:

[Note: this material will be added in early April, prior to publication.]

Executive senior manager (ESM) to staff complement ratio

Number of staff earning more than £142,500 now and any planned change during the next planning period

HR staff to employee ratio

Training budget as a percentage of pay bill

Projected reductions in non payroll staff

Key performance indicators for 2018/19

[Note: This section will be added in early April, when year-end results are known, using a selection of the current metrics from the performance report that is regularly considered by the Authority.]

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 and Social Care, 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 consistently increased, primarily through increased treatment activity within the sector. We have just completed a piece of work to model, for the first time, the likely activity in future years. This is based on a combination of historic trend data and ONS population forecasts. Our lower confidence interval within the model suggests activity growth of c2% per annum through to 2020, as such we anticipate an increase of c£90k in income for 2018/19.

This modelling work is still in development and we will look to monitor how closely actual activity follows our projections.

Our grant-in-aid funding from the Department of Health and Social Care has reduced by over 50% since 2010 and we anticipate it will remain constant through to 2020 and the end of the current SR period. Over the years, we have managed our expenditure to ensure we spend within budget wherever possible. We have also used our reserves to reduce the draw on GIA and have demonstrated this by use of our reserves to fund our recent Information for Quality (IfQ) programme.

[DN: Budget information for 2018/19 will be added here following discussion at this Authority meeting]

Other required information

Introduction

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

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

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

Better regulation and innovation

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

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

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

Organisational structure and establishment

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

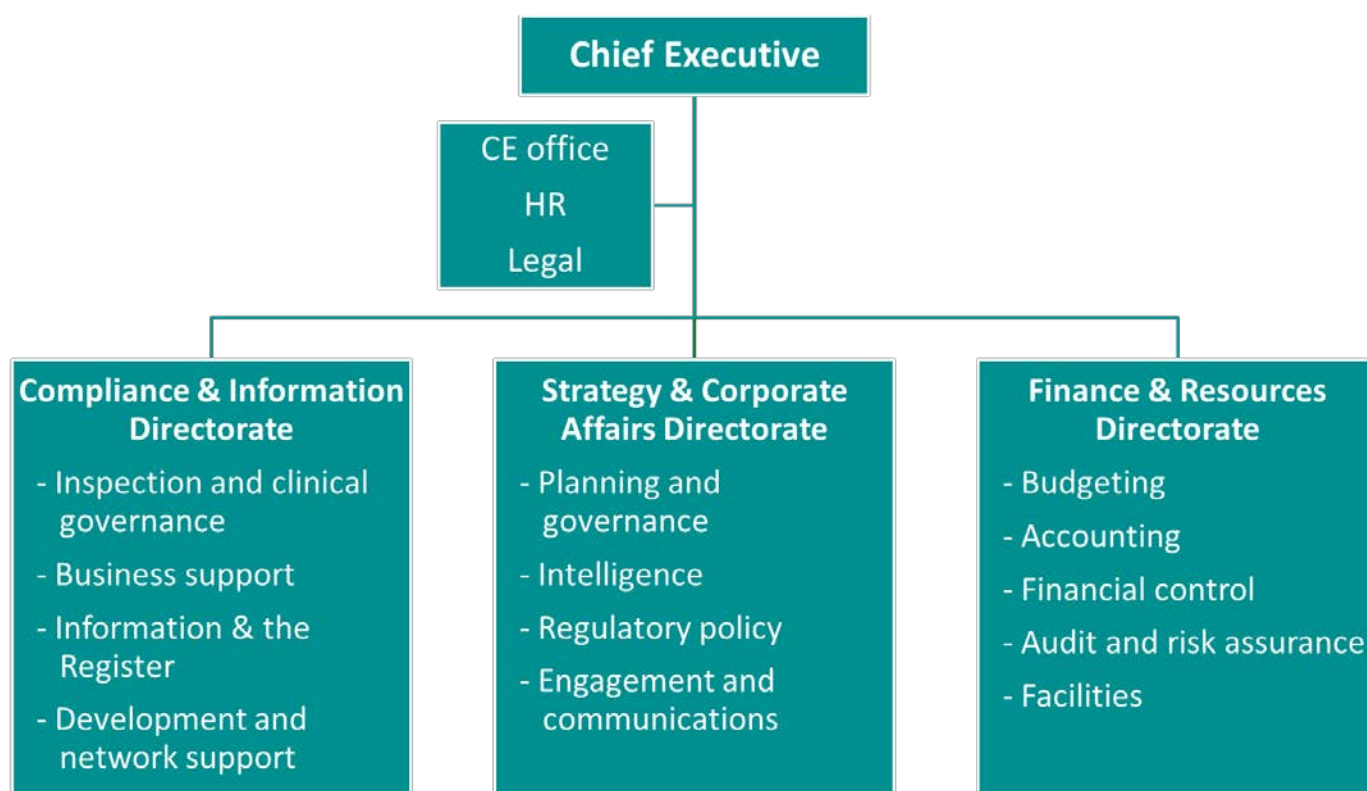
Having made considerable savings, our size will now need to remain stable for the foreseeable future. We need to ensure we retain the capability and capacity to deliver our overall strategy for 2017-2020.

We have a people strategy, referenced earlier in this business plan, which sets out how we will ensure we attract and retain the capacity and skills we need in order to deliver our vision of high quality care for everyone affected by fertility treatment. Our learning and development activities continue to equip our staff with the skills they need. Services are procured in accordance with continuing Government requirements to ensure value for money, using Civil Service Learning, and their associated suppliers, or other ALB provision, as appropriate.

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

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

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



Financial management systems

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

Internal audit

We continue to be part of the Department of Health group assurance framework and to work with the co-sourcing provider on delivering the annual internal audit plan for each year. The programme of internal audits has been streamlined to meet the HFEA's needs and to make best use of the group audit arrangement, which helps to improve the overall levels of assurance for the group.

Assurance framework

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

Equality Act 2010

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

Whistleblowing policy

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

Transparency requirements

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

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

Information technology (IT) and data security

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

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

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

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

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

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

Business continuity

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

Estates strategy

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

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

Sustainable development

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

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

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

Procurement

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

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

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

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

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

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

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Movement of gametes and embryos across borders

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

Details:

Meeting Authority

Agenda item 8

Paper number HFEA (08/03/2018) 872

Meeting date 08 March 2018

Author Niamh Marren, Regulatory Policy Manager
Nick Jones, Director of Compliance and Information

Output:

For information or decision? For information

Recommendation To note the arrangements for implementing the two Directives
To approve the amendments to General Direction 0006 in relation to the application of the Single European Code
Note the arrangements for amending General Direction 0006 in relation to importing that will be brought forward in April 2018.

Resource implications Within existing resources

Implementation date April 2018

Communication(s) Implementation to be communicated through Clinic Focus in March and April 2018. Also, Code of Practice review for October 2018 implementation.

Organisational risk Low Medium High

Annexes Annex A: Application for import relationship between UK clinic and third country supplier (for information)
Annex B: Process for reviewing import relationship applications (for comment)
Annex C: Template certificate (for information)
Annex D: Amendments to General Direction 0006 in relation to the introduction of the Single European Code (for approval)

Annex E: Standard licence conditions - compliance with the requirements – (for comment)

1. Introduction

- 1.1.** This paper sets out the requirements for the implementation of the EU Directives on import, and coding. The import Directive deals with the importing of tissue and cells into the European Union (EU) from outside the European Economic Area (EEA) and Gibraltar. The coding directive sets out the procedures to ensure the traceability of tissue and cells following movement within the EU.
- 1.2.** The import requirement refers to the EU Commission Directive 2015/566 implementing Directive 2004/23/EC regarding the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells. The coding Directive 2015/565 sets out standards of quality and safety for donation, procurement, testing, processing, preservation and distribution of all human tissue and cells intended for human application.
- 1.3.** These requirements have been transposed into the HF&E Act 1990 (as amended) by regulations (the Human Fertilisation and Embryology (Amendment) Regulations 2018) passed by Parliament on 27 February 2018. The regulations come into force on 1 April 2018, and guidance on their implementation will be included in the HFEA Code of Practice, Directions and standard licence conditions.
- 1.4.** We have been in dialogue with the sector for some time and it was originally expected that the implementation would take place in October 2018. Implementation in the UK has been brought forward to 1 April 2018 due to a speedier passage of the Regulations through Parliament.

2. Import Directive

- 2.1.** The purpose of the import Directive is to ensure that there are procedures for verifying the standards of quality and safety of gametes and embryos that are imported into the UK from non-EEA and Gibraltar establishments. These establishments are classified as “third country” suppliers.
- 2.2.** In deciding how to implement the Import directive we have reviewed the Human Fertilisation and Embryology (Amendment) Regulations 2018 alongside the EU Directive and taken external legal advice.
- 2.3.** The requirements laid out in the Directive and the Regulations means that the HFEA will need to amend the Code of Practice requirements in ‘guidance note 16: imports and exports’ on factors that the licensed centre will need to reassure themselves of before applying for the requisite certificate, Schedule 3 of General Directions 0006, and the decision tree.
- 2.4.** The scale and origin of imported gametes into the UK can be summarised as follows. In 2017 there were 1099 import events from

outside the EEA, 989 of which were from the USA. However, there are only four centres in the USA that UK clinics currently import from.

2.5. The other non-EEA countries that UK clinics imported from in 2017 include:

- Australia (incl Cocos Island/Christmas Island)
- Canada
- Hong Kong
- New Zealand (incl Chatham Island)
- Panama
- Samoa (Formerly known - Western Samoa)
- Singapore
- South Africa
- Tanzania
- Ukraine

2.6. In 2017 some 65 UK clinics imported gametes from one or more non-EEA country. However, the scale of their import activity varies hugely, from 1 import event to 151. Of the 65 importing clinics that year, only 14 did so on more than 20 occasions.

2.7. For the purposes of the EU Directive any clinic that imports gametes or embryos from a third country supplier is referred to as an Importing Tissue Establishment (ITE). In order to import from a Third Country supplier (i.e. any supplier in a country which is outside the EEA), a UK centre needs to apply to the relevant regulatory body (in the case of the UK the HFEA) for a certificate to allow them to make qualifying imports. This can be for a one-off import or for ongoing imports. The application form (attached for information at annex A) that UK clinics will use to apply to the HFEA for a certificate sets out the requirements that clinics will have to meet.

2.8. The process works like this. The responsibility of considering/approving any such application lies with the executive Licensing Officer (the delegation by the Authority is proposed in the updated Standing Orders elsewhere at this meeting). In cases where a Special Direction is required for any import, the decision would continue to rest with Statutory Approvals Committee. Annex B sets out the draft process for review of the certificates issued to clinics.

2.9. The regulations give the HFEA a new power to revoke the clinic's licence on grounds that the premises of any clinic in a third country from which the UK clinic imports are not considered suitable. As a result, changes need to be made to the decision tree for the refusal or revocation of a licence. This is the statutory incentive for UK clinics to

ensure that any third country clinic that they import from does indeed meet the standards of quality and safety that the Directive requires.

- 2.10.** The EU Directive provides a template certificate to be issued to those clinics that import from third country suppliers. This certificate is provided at Annex C to this paper, for information.
- 2.11.** Under the Directive, HFEA licensed clinics are required to establish third party agreements (TPA) with all third country suppliers. They will then have to apply to the HFEA for a certificate which allows them to import from those named establishments provided those establishments meet the requirements of quality and safety.
- 2.12.** The importing HFEA licensed clinic must notify us of the following:
 1. if the UK centre ceases to import from a third country supplier.
 2. if there are any serious adverse events or serious adverse reactions as notified by the third country supplier.
 3. if there are any changes in circumstances of the third country supplier that the person responsible (PR) is aware of.
 4. if it changes its importing relationship with the third country supplier for example it starts importing embryos where it previously only imported gametes from the supplier.
- 2.13.** The HFEA must consider the application for any importing certificates and the licensing officer will determine whether to grant the certificate. We then monitor compliance through the process of engaging with clinics to work on TPAs
- 2.14.** To give effect to the directive the HFEA will need to amend the import/export General Direction 0006. Given the challenging time constraints and the complexity of the requirements these are being drafted and will need to be agreed by the Authority (delegated as appropriate) during April 2018, coming into effect as soon as possible thereafter.

3. Coding Directive

- 3.1.** The coding Directive is designed to facilitate traceability by establishing a unique identifier applied to tissues and cells (including reproductive cells) by way of a Single European Code (SEC) providing information on the main characteristics and properties of those tissues and cells. This traceability is for tissues and cells distributed between EU, EEA and Gibraltar (hereafter referred to as EU).
- 3.2.** The SEC is applied to the movement of donor gametes and embryos between licensed clinics (or 'tissue establishments' in EU terms) within and outside the UK (partner gametes and embryos are excluded). A clinic importing gametes and embryos from a tissue establishment and

not distributing thereafter (that is importing for use in that clinic only) is exempt from applying the code.

- 3.3.** The SEC is the unique identifier for tissues and cells distributed in the EU. It comprises of 40 alpha-numeric characters; it must be 'eye-readable', that is, if a bar code is used, it must be accompanied by the SEC. Ideally it will be attached to the container of the tissue/cell but where that is not possible due to its size it is attached to the documentation accompanying and linked to the tissue/cell. That is likely to be the case for many reproductive products, for example straws of sperm.

3.4. The SEC is made up of the following (six) features.

Donation identification sequence			Product identification sequence		
ISO Country code	Tissue Establishment code	Unique Donation Number	Product code	Split number	Expiry date
2 alpha characters	6 alpha-numeric characters	13 alpha-numeric characters	1+7 alpha-numeric characters	3 alpha-numeric characters	8 numeric characters Yyyy/mm/dd
GB	000123 00 then HFEA licensed centre number	0000000000456 Clinic's donor registration number – submitted to HFEA now	E0000059 1 of 5 for reproductive cells (EUTC system), 00000 then -Embryos (56) -Sperm (59) -Oocytes (57) -Ovarian tissue (58) -Testicular tissue (60)	001 If sperm, for example, is distributed to more than one TE	20181231 Date of expiry of consent, for example, 31 December 2018
SEC GB0001230000000000456 E000005900120181231					

3.5. It enables the recipient tissue establishment to trace the primary distributing tissue establishment if there is an issue (now and in the future) relating to the quality or safety of the gametes or embryos, for example a child develops a genetic condition associated with the use of donor sperm.

3.6. The Human Fertilisation and Embryology Act 1990 (amended) requires licensed clinics to ensure full traceability. Our requirements are set out in the HFEA Code of Practice, (General) Direction 0006, and standard licence conditions (SLC 99-104). We also already require clinics to register a unique donor registration code with the HFEA through the data submission system.

3.7. The requirements introduced by the Directive are additional to our extant requirements, but are not substantially different – the format of the code is prescribed and incorporates the current clinic donor code. It will necessitate additional work for clinics, particularly for those distributing gametes and embryos to other clinics, either within the UK or elsewhere. We are not requiring clinics to submit the SEC to the HFEA.

3.8. The necessary changes we need to make to ensure licensed clinics meet the requirements of the Directive are comprised of three main components:

1. Instructions to clinics with detail as to their obligations in meeting the requirements of the Directive, by way of a Chair's letter

2. The Regulations stipulate, amongst other things, that Directions (from the HFEA to licensed clinics) must specify the system to be adopted for the identification of gametes and embryos intended for human application, together with the information that must be provided to the Authority. This stipulation will be met by way of amendments to General Direction 0006 – Annex D
 3. Consequential amendments to standard licence conditions, affecting treatment and storage clinics (standard licence condition T100 and T101) - Annex E
- 3.9.** As the UK Competent Authority for reproductive tissues and cells, the HFEA has other obligations (including ensuring compliance by licensed clinics) to ensure that the SEC system works effectively, as follows and in summary:
- Ensure that all UK licensed clinics' details (name, licence number, and contact details) are held (and updated) in the EU tissue establishment compendium (EU web-based database). This is currently up to date, and as new licences are granted and the details of existing clinics change it will need updating in line with our own Register of licensed clinics;
 - Inform another country's competent authority where a tissue establishment in that country is not shown on the Compendium or its details are erroneous;
 - Monitor the implementation of the SEC by licensed clinics – at inspection, checking that the SEC has been incorporated within the documentation.
-

4. Recommendation

- 4.1.** The Authority is recommended to:
- Note the arrangements for implementing the two Directives
 - Approve the amendments to General Direction 0006 in relation to the application of the Single European Code
 - Note the arrangements for amending General Direction 0006 in relation to importing that will be brought forward in April 2018.

Annex A: Application for import relationship between UK clinic and third country supplier

Application to authorise an importing tissue establishment

General information on the Importing Tissue Establishment (ITE)

Name of ITE (centre number)

EU Tissue Establishment Compendium Code

ITE Address and postal address (if different)

Status of the applicant: first accreditation, designation, authorisation or licence as ITE or renewal First time Renewal

Name of the applying unit (if different from the above address)

Address of the applying unit (if different)

Name of the site of reception of imports (if different from the above)

Visiting address of the site of reception

Postal address of the site of reception (if different)

Contact details for the application

Name of PR

Address of PR

Telephone number of PR

E-mail address of PR

URL of ITE website

Details of tissues and cells to be imported

A list of the tissues and cells to be imported, including one-off imports

One-off imports

Product name(s) of imported tissues and cells

The trade name (if different to the product name)

Name of the third country supplier for each type of tissue and cell to be imported

Location of activities

Which activities are carried out prior to import by the third country supplier per type of tissue or cell

Donation	Procurement	Testing	Processing	Preservation	Storage
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Which activities are carried out prior to import by sub-contractors of the third country supplier per type of tissue or cell

Donation	Procurement	Testing	Processing	Preservation	Storage
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

A list of all activities carried out by the ITE subsequent to import per type of tissue or cell

Names of the third countries in which the activities prior to import take place per type of tissue or cell

Details of third country suppliers

Name of the third country supplier

Name of the contact person

Visiting address

Postal address (if different)

Telephone number (including international dialling code)

Emergency contact number (if different)

E-mail address

Documentation to accompany the application

Have you provided the following:

A copy of the written agreement with the third country supplier

A detailed description of the flow of imported tissues and cells from their procurement to their reception at the ITE

A copy of the third country supplier's export authorisation certificate¹. This should include the contact details of the third country's competent authority.²

¹ Or where a specific export authorisation certificate is not issued, certification from the relevant third country competent authority or authorities authorising the third country supplier's activities in the tissue and cells sector including exports.

² Where this documentation is not available, alternative forms of documentation shall be provided such as reports of audits of the third country supplier.

Annex B Process for reviewing import relationship applications

1. Process 1 – first time application, for an import relationship with a third country supplier, has been received

- 1.1.** The UK clinic who receives the relevant paperwork from the third country supplier to satisfy the quality and safety standards
- 1.2.** The UK clinic finds the HFEA application form on the website (Word format)
- 1.3.** The UK clinic sends the paperwork and application form (outlined in Annex A) to a member of the compliance team
- 1.4.** A Compliance team member reviews the paperwork and the application form and develops an executive summary for the Licensing Officer to review
- 1.5.** The paperwork, application form and executive summary are sent to the licensing officer
- 1.6.** The licensing officer will review the executive summary and application form and make the decision whether to allow or refuse the import using a decision tree
- 1.7.** If the relevant requirements are met:
 1. the licensing officer will grant a certificate and issue the certificate in Annex C with the information provided in the paperwork, application form and executive summary;
 2. the third country supplier needs to be added to a spreadsheet which holds all the information of each third country supplier.
- 1.8.** If a certificate cannot be granted, – letter of refusal, setting out the requirements which were not met, to be sent to the UK clinic

2. Process 2 – when an Importing Tissue Establishment (ITE) wants to import from a third country supplier who was approved previously

- 2.1.** The UK clinic checks the HFEA website to check if any other UK clinic has a certificate authorising it to import from the particular the third country supplier.

2.2. If no – follow process 1

If yes – follow process 2

- 2.3.** The UK clinic requests the third country supplier's paperwork from the HFEA.

- 2.4.** The compliance team member provides the paperwork to the UK clinic.
- 2.5.** The UK clinic must complete their own checks to ensure that the third country supplier continues to meet the quality and safety standards and that no changes have occurred at the third country supplier since the HFEA previously issued the certificate naming that third country supplier.
- 2.6.** The UK clinic sends the updated paperwork and application form to the Compliance team.
- 2.7.** Compliance reviews the paperwork and application form and develops an executive summary for the licensing officer.
- 2.8.** The executive summary and the application form are sent to the licensing officer.
- 2.9.** The licensing officer makes a decision, using the decision tree, whether to grant the certificate.
- 2.10.** If a certificate is granted,
1. the licensing officer completes the certificate in Annex C with the information provided in the paperwork, application form and executive summary and
 2. issues the certificate to the UK clinic.
- 2.11.** If a certificate is not granted,
1. letter of refusal to be sent the ITE setting out the reasons for the refusal;
 2. other ITE's need to be notified to cease import and an updated certificate will need to be issued, removing the third country. This will happen if the certificate is not granted because of concerns about the quality and safety standards of that supplier;
 3. the third country supplier needs to be removed from the spreadsheet where all approved certificates are captured.

Annex C: Template Certificate

Certificate of authorisation of an importing tissue establishment

Importing Tissue Establishment (ITE) Details

Name of ITE (centre number)

EU Tissue Establishment Compendium Code

ITE Address and postal address (if different)

Site of reception of imports
(if different from the above address)

Name of PR

Address of PR

Telephone number of PR (optional)

E-mail address of PR (optional)

URL of ITE website

Competent Authority (CA) Authorisation

National accreditation, designation, authorisation or licence number

Legal basis of accreditation, designation, authorisation or licence

Date of expiry of accreditation, designation, authorisation or licence (if any)

First accreditation, designation, authorisation or licence as ITE or renewal

First time

Renewal

Additional remarks

Name of CA

Name of CA Officer

Signature of CA Officer (electronic or otherwise)

Date of accreditation, designation, authorisation or licence

CA Stamp

Annex D – Amendments to General Direction 0006

General Direction 0006 Single European Code (April 1 2018)

- 2.1.** Licensed clinics must apply the Single European Code (SEC) to all tissues and cells before distribution for human application within the EU (including the UK), EEA or Gibraltar.
- 2.2.** The following exemptions to the requirements for a SEC apply:
- Gametes and embryos for ‘partner donation’. This is a term used in the Directive defined as the reproductive cells between a man and a woman who declare that they have an intimate physical relationship
 - Where gametes and embryos are provided at a clinic and are going to be used in treatment at the same clinic remain within the same centre (that is they are not distributed).
 - Where gametes and embryos are imported into the licensed clinic and will be used in treatment in the same clinic remain within the clinic for use in treatment.
 - Tissues and cells already in storage on 29 October 2016 (see transitional period, below).
- 2.3.** The SEC shall be in the form specified in Annex VII of the amended Directive 2015/565.
- 2.4.** The SEC is the unique identifier for tissues and cells distributed in the EU. It is made up of the following (six) features:

Donation identification sequence			Product identification sequence		
ISO Country code	Tissue Establishment code	Unique Donation Number	Product code	Split number	Expiry date
2 alpha characters	6 alpha-numeric characters	13 alpha-numeric characters	1+7 alpha-numeric characters	3 alpha-numeric characters	8 numeric characters Yyyy/mm/dd
GB	000123 HFEA Licensed Centre number	00000000XX456 Clinic’s donor registration ‘number’ – submitted to the HFEA currently in registering the donor, with zeros added	E0000059 1 of 5 for reproductive cells (EUTC system) -Embryos (56) -Sperm (59) -Oocytes (57) -Ovarian tissue (58) -Testicular tissue (60)	001 If sperm, for example, is distributed to more than one TE	20181231 Date of expiry of consent, for example, 31 December 2018
SEC GB00012300000000XX456 E000005900120181231					

Licensed clinics are permitted to use one of three coding platforms to identify the SEC.

1. The EU coding platform is available at <https://webgate.ec.europa.eu/eucoding/reports/te/index.xhtml> and incorporates the EU Tissue Establishment Compendium.
2. ICCBBA ISBT128 <https://www.iccbba.org>
3. Eurocode IBLIS <http://www.eurocode.org/>

- 2.5.** In all cases the 'unique donation number' must be the unique HFEA donor registration number applied by the licensed clinic, and submitted to the HFEA further to the donor registration process, preceded by zero(s) – as necessary such that it is formed of 13 alpha-numeric characters.
- 2.6.** The 'expiry date' shall be the date on which consent to storage and use expires. This date will be sourced from the patient consent form.
- 2.7.** Once the SEC is allocated it must not be altered unless there is an encoding error. If this happens, a new code should be correctly issued and a record should be kept of the error and amended code.
- 2.8.** The SEC must be attached to the container of the tissue/cell or where that is not possible it must be attached to the accompanying documentation and linked to it. It must be 'eye-readable' that is, if a bar code is used, it must be accompanied by the SEC. When printed, the 'donor identification sequence' and product identification sequence must be separated by a space or as two successive lines.
GB0001230000000000456 E000005900120181231
- 2.9.** Transitional period: Tissues and cells in storage on 29 October 2016 are exempt from obligations to attach the SEC where those tissues and cells are distributed, until 29 October 2021, but they must be traceable. After this date the SEC must be attached to accompanying documentation. See (9) above.
- 2.10.** The SEC shall not be submitted to the HFEA as part of a clinic's data treatment data submission obligations set out in General Direction 0005.
- 2.11.** A licensed clinic must inform the HFEA when:
- Information about it held in the EU Tissue Establishment compendium requires updating or correction;
 - The EU Tissue and Cell Product compendium requires an update;
 - It identifies a significant non-compliance with the requirements relating to the SEC concerning tissues and cells received from other EU tissue establishments.

Annex E Standard licensing conditions - compliance with the requirements

The following standard licence conditions have been **amended**:

T100: The documented procedures referred to in licence condition T99 include the following information:

1. the unique and accurate identification of each patient/donor
2. the unique and accurate identification of each set of gametes and embryos, **including the Single European Code applied to each set of gametes and embryos when required by General Direction 0006**
3. date of procurement
4. place of procurement
5. type of treatment
6. description and origin of any and all products associated with the procurement, processing, use and storage of gametes and embryos, and
7. description of all processing steps applied to the procurement, use and storage of gametes and embryos.

T101: The centre must ensure that all containers (dishes, vials, ampoules, tubes etc) used in the course of procurement, processing, use and storage of gametes and embryos are labelled with the patient's/donor's full name and a further identifier. If at some stages (eg, labelling patient/donor sperm) it is not possible to label the dishes or tubes with the patient/donor name then it must be ensured that the patient/donor code used is uniquely identifying. **Containers holding gametes and embryos or the paperwork attaching to any containers must be labelled with a SEC in those circumstances specified in General Direction 0006.**

Choose a fertility clinic - evaluation of patient rating trial

Strategic delivery:

Safe, ethical,
effective treatment

Consistent
outcomes and
support

Improving standards
through intelligence

Details:

Meeting Authority

Agenda item 9

Paper number HFEA (14/03/2018) 873

Meeting date 14 March 2018

Author Yuba Bessaoud, Media and Stakeholder Relations Manager

Output:

For information or
decision? For decision

Recommendation Approve the continuation of the patient ratings scheme and free text
function and further work around understanding and encouraging
participation

Resource implications

Implementation date Work on encouraging participation to begin in Spring 2018

Communication(s) To be developed in light of research

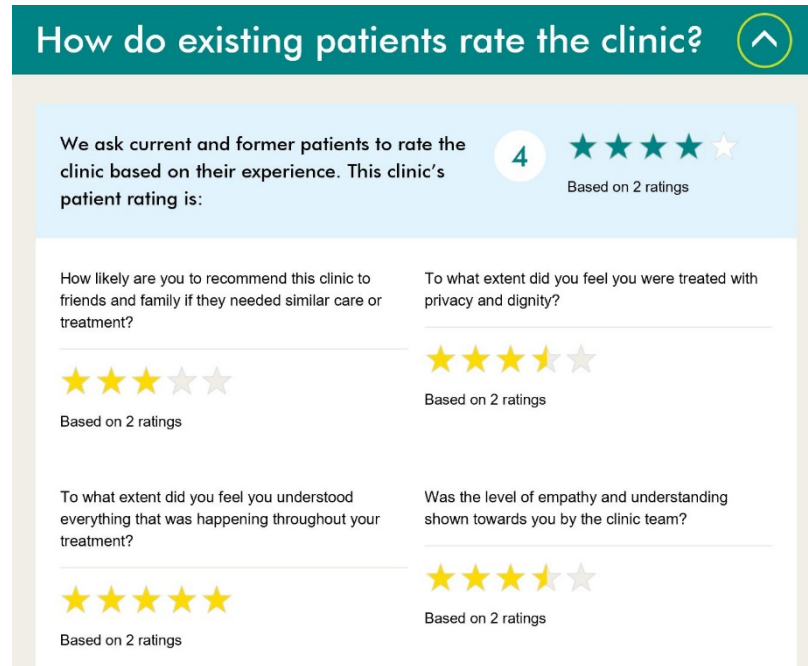
Organisational risk Low Medium High

Annexes Annex A: Patient and clinic case studies

1. Background

- 1.1.** The views of patients are an increasingly important element in the provision of modern health care services in the UK and elsewhere. It has been central to our thinking since the publication of our strategy for 2017-20 and it is a direction which was further emphasised at the last Authority meeting when we approved our first Intelligence strategy, with its proposals for a national patient survey and the development of a voluntary patient charter mark for clinics.
- 1.2.** This paper provides an evaluation of one discrete element of our work on patient voice: the patient ratings function that was launched last year as part of the re-vamped Choose a Fertility Clinic (CaFC) section of the website. The decision to trial the rating system, taken by the Authority in March 2017, envisaged a six-month trial focused on the operation, rather than the principle, of the system. We wanted to ensure that the rating system was fair and robust, and, crucially, that it provided data that was helpful to us, clinics and patients.
- 1.3.** The rating system has two distinct elements: a set of five questions the answers to which are then made available on our website; and a free text feedback mechanism which allows patients to make private comments direct to the clinic's HFEA inspector (a similar feedback feature has been part of our inspections for some time).
- 1.4.** The five questions, each with a five-point range, are:
 1. How likely are you to recommend this clinic to friends and family if they needed similar care or treatment?
 2. To what extent did you feel you were treated with privacy and dignity?
 3. To what extent did you feel you understood everything that was happening throughout your treatment?
 4. What was the level of empathy and understanding shown towards you by the clinic team?
 5. Did you pay what you expected?

- 1.5.** The answers given are used to generate a five-star rating for the first four answers. The average of the four ratings is used to create an overall star rating for the clinic, or what we term a 'patient rating', which is displayed on the relevant clinic page on the CaFC section of our website. We also show the total number of ratings submitted, so patients can see the number of reviews a rating is based on.



- 1.6.** The question about the cost of treatment is not included in the overall score, as around 40% of patients are publicly funded, but patients are still able to access that data.
- 1.7.** The plan approved by the Authority in March 2107 for the trial included a range of elements for the effective promotion, implementation and monitoring of the new system.
- 1.8.** This paper sets out the results of the trial and provides an analysis of how the patient system could be improved going forward.

2. The trial period

- 2.1.** In any new feature it is important to generate awareness and interest. To that end, from its launch in July 2017 we undertook a range of different activities to raise awareness of the new ratings system: direct patient contact; contact through clinics; contact through stakeholder publications.

Direct patient contact

- We used a range of different social media content to promote the system (Twitter and Facebook), with the biggest push coming in November around National Fertility Awareness Week. On average, such messages have reached around a thousand people per month over the course of the trial period, with a peak of 200 per day – or over 6,000 per month – in November. Social media work is continuing, with paid-for promoted content to go out on Facebook in the near future.
- We published a “rate your clinic” page with simple instructions on how to rate a fertility clinic which has been visited 1900 times since it was introduced in November 2017, and we can see its positive impact in that 55% of page visitors move directly on to the clinic search page where they can rate their clinic.
- We handed out leaflets at the London Fertility Show to raise awareness among patients of the new ratings feature.

Contact through clinics

- We designed and printed 175 posters and 5,000 leaflets promoting the ratings system. We initially sent one poster and 30 leaflets to each UK clinic, and have subsequently had requests from a dozen clinics for more leaflets.
- The ratings system has been the subject of two Clinic Focus articles, in September and November 2017, which encouraged clinics to raise awareness of the scheme with patients. The November article also set out best practice hints and tips about how to promote the scheme to patients in a fair and neutral manner.

Contact through stakeholders

- We wrote content promoting both the new website, and the patient ratings system specifically, for FNUK magazine (September 2017 and January 2018), BICA magazine (September 2017) and The Embryologist (August 2017). The system has also been raised at stakeholder meetings.

Security concerns

- 2.2.** A key concern in establishing the rating system was that it was not open to abuse. If patients and clinics are to get the greatest value out of the system they need to be confident that it reflects the views of real patients. However, the system also needed to be easy to use and we were concerned that too many security checks might put off patients from giving their views. Therefore, we took a decision not to add a verification check before launching the trial.
- 2.3.** At the beginning of February 2018, the ratings of 46 clinics were affected by an ‘automated bot’, which randomly added 40-50 ratings on to their CaFC pages (totalling around 2,200 ratings overall) in just over five minutes. The clinics were informed within hours of this being identified and the ratings were removed. It did not affect the genuine ratings submitted before or after

this event. Given this recent event, a verification tool has been added to prevent a recurrence of this.

Assessment and evaluation

2.4. A range of assessment and evaluation exercises have been undertaken:

Patient survey (survey of the ratings system)

- In line with the plan set out to Authority, we set up an online survey for those patients who had filled in the ratings and wished to provide their feedback of the system. To date, we have had 23 responses, the details of which are set out in Annex A.

Patient interviews

- Of the patient survey submissions, six people left their details for future contact. Of those, two patients have been interviewed for their views, details of which are set out in Annex A.

Clinic interviews

- Two clinics were contacted for their views of the ratings system, details of which are set out in Annex A.

2.5. Taken all together, the qualitative and quantitative data so far gathered provide the beginnings of a more rounded understanding of what the patterns of adoption, by both patients and clinics, have been to this scheme.

3. Evaluation

3.1. Any patient rating system takes time to become known. For that reason, we did not approach this six-month trial with an expectation that a specific proportion of patients would complete the questions. Rather our aim was to see whether we could establish a simple and workable system for capturing patient opinion reliably and securely. We also wanted to see whether patients, clinics - and ourselves - found the data useful.

3.2. The total number of patient ratings received each month is set out overleaf (as of 15 January 2018, six months from the launch of the new website).

Table 1: Monthly patient feedback submissions

Month	Monthly total - ratings	Monthly total – free text
July	N/A	N/A
August	97	31
September	200	70
October	150	59
November	223	107
December	148	76
January (Mid-month)	147	47
Total	965	390

- By mid-January 2018, 965 patient ratings had been submitted across all clinics, representing around 1 rating for every 30 treatment cycles performed nationally over the same period.
- Of these 965, the ratings for just five clinics accounted for half (482), with the top two clinics receiving over a third (347) alone.
- Only one of the top five most rated clinics is classified as a large clinic (1,000+ treatments per year), the other four are all medium-sized.
- All the top five clinics had a minimum rating of four and a half, with the top two clinics scoring five.
- Drawing the data out further, we see that only 16 clinics out of the 116 rateable clinics on CAFC had 10 or more ratings submitted over the first six months.
- Of those 16 clinics, seven were large, five were medium and four were small.
- With one exception, the average scores for all 16 were 4.5 and above.
- Combined, the top 16 clinics accounted for 698 (72%) of all ratings submitted.
- Of the remaining 100 clinics, 46 had no rating at all, meaning the remaining 267 ratings were spread across 54 clinics at an average of five ratings per clinic.
- Of the 22 clinics classified by the HFEA as large (1,000+ treatments per year), 16 had five ratings or fewer.
- The free text system appears to be working better than before in terms of the quality and number of responses. Under the previous system inspectors received around 300 free text submissions per year, that

figure now looks set to more than double under the new system, with 390 received under the new system in the first six months.

- 3.3. What conclusions can we draw from this? In terms of the overall numbers of responses, the patient rating system has made slow but steady progress. As noted above we received 965 reviews in total
- 3.4. For the system to work most effectively to the benefit of patients, it would be hoped that the number of ratings being received per clinic would be more or less proportionate to the number of treatments provided; i.e. the larger the clinic, the greater the number of ratings. However, our findings so far show medium-sized clinics buying into the new system most eagerly as they received the highest number of ratings.
- 3.5. Without further research it's difficult to know precisely why the number of ratings varies so widely, or why so few clinics have ten or more ratings. The data suggests that our most intensive period of direct-to-patient promotion of the scheme via social media – in November 2017 around National Fertility Awareness Week – coincided with a spike in submissions, which suggest that further promotional work may help to get the patient ratings firmly established among clinic staff and patients.

Conclusions and next steps

- 3.6. Discussions with staff from clinics with the most ratings (see Annex A) supports the idea that the difference between those with only a few ratings and those with a significant number is the level of promotion being done by the clinics themselves.
- 3.7. For example, we know some clinics have tablet computers in their waiting rooms. Such active promotion is clearly working in terms of achieving high numbers, but it is not without risks around the potential for pressure, however unintentionally, to be placed upon patients. **We may wish to provide more best-practice guidance for clinics looking to encourage patients to provide their ratings in-house.**
- 3.8. It does seem clear that, perhaps inevitably, in-house clinic promotion of the scheme to patients is currently the most effective mechanism for raising awareness and securing participation. **We may wish to consider whether more time and funding be deployed so that we can do more direct marketing to patients.**
- 3.9. Further, with a disproportionate number of ratings being submitted in relation to medium-sized and small clinics, and with comparatively few ratings to the larger clinics, the system is not yet working to the full benefit of patients, and more needs to be done to ensure that ratings are more evenly and proportionately spread across the sector. **Specifically, work should be done to improve our understanding of why larger clinics have not, in the main, embraced the scheme as readily as others. We may wish to attempt to shift attitudes towards participation, in part by explaining**

that as more ratings are entered on the system larger clinics may begin to feel left behind.

4. Outstanding technical issues

Epicentre spreadsheet

- 4.1.** All the patient ratings, including the free text comments, are available to the HFEA inspectors via a spreadsheet in Epicentre. Whilst we know that the free text feedback element of the system is working well, the HFEA inspectorate is looking for improved functionality so that they can access ratings data more easily and in more readily digestible format. IT are aware of this and will work on it as priorities and resources permit.

Gaming and IP addresses

- 4.2.** When the system was being designed, consideration was given to gaming by clinics, spamming by robots, and the rare actions of very disgruntled patients, with plans to minimise the potential for abuse in each case put in place accordingly. In designing the ratings system, the decision was taken to collect IP addresses as a means of identifying issues around potential problems and abuses. The use of IP addresses was useful, for example, in assisting the removal of spambot ratings.
- 4.3.** The usual method for recording IP addresses is recording them through the use of cookies. However, under the General Data Protection Regulation (GDPR), IP addresses are considered identifying information, and the new regulations will allow people to opt out of supplying their IP address, which may have an impact on our ability to fully monitor issues around gaming, duplication, and spambot interference.
- 4.4.** Consideration by IT colleagues will be given as to how this may impact upon the system, and what might be put in place to replace any monitoring deficit that results.

5. Recommendations

- 5.1.** When the Authority agreed to this trial in March 2017, we undertook to develop and implement mechanisms for the promotion, by ourselves and clinics, of the new ratings system, and to monitor and evaluate the results both quantitatively and qualitatively. Though more patient and clinic views would be helpful, we have begun to achieve these aims, identify patterns of behaviour, outstanding issues to be resolved, and possible next steps to further improve the system.
- 5.2.** Moreover, all the patients and clinic staff consulted as part of this trial period felt it was a welcome and useful addition to the website, and very much in-

keeping with modern healthcare and consumer methods for incorporating the patient/consumer voice.

Authority are asked to:

- Approve continuation of the patient rating scheme;
- Approve continuation of the free text mechanism for providing views to inform our inspection activity

Approve further work to:

- Develop best-practice guidance for the promotion of the scheme by clinic staff, and what is acceptable practice in terms of encouraging completion of the ratings scheme in-house;
- Consult with large UK clinics to understand why take-up of the scheme has been slower, and to encourage greater participation.

Annex A

1. Qualitative data – patient survey and case study findings

- 1.1. As part of the trial we set up a small online survey asking patients who had used the system to give us their views (see below). To date, 23 patients, each treated at a different clinic, have responded.
- 1.2. To understand how the ratings system had been raised, discussed and completed, we also undertook four qualitative interviews; two with patients and two with staff working in clinics with good ratings numbers.
- 1.3. The relatively small number of survey responses and interviews mean that the findings should be treated with caution, but they offer a starting point for understanding the perspectives of patients and clinic staff, and raise issues that we may wish to consider in the future.

2. Patient survey

- 2.1. The patient survey consisted of nine questions:
 1. Are you about to start treatment/had some treatment/stopped having treatment/an egg or sperm donor?
 2. Which clinic did you rate today?
 3. What motivated you to give your rating? Information from HFEA/My clinic told me/I heard about it from another patient/Heard about it from another organisation/Looking for somewhere to make a complaint
 4. Do you understand how the rating feature works and how the patient ratings are calculated?
 5. What did you think of the questions you were asked?
 6. How confident are you that the ratings have been provided by real patients, partners and donors at this clinic (very – not at all)?
 7. NHS Choices asks people to give their email address and name before they can give feedback. If we had asked you to register your email address and name would you still use the tool to give your views?
 8. If you needed to request a token from your clinic to prove you were a patient partner or donor (they could not identify your feedback from this) before you could give your feedback then would you still have given your views?
 9. Please give any other feedback about the ratings feature.

The highlights were

- Most people (39%) said they had heard of the ratings system directly, through our website or social media, while (34%) said they had learned

about it from their clinic. 17% found the survey while searching how to make a complaint about their clinic.

- 70% of respondents felt the questions asked were the right ones, 30% did not. Of those that did not, suggestions included a question on professional/clinical expertise; more space for free text; and greater specificity in the questions asked, especially in relation to the emotional, “psychological” support given.
- 74% were very confident/confident that the ratings they saw had been put there by other patients. 17% were somewhat confident, while 9% were not confident. Those who lacked confidence tended to be concerned about the capacity for clinic staff to rate themselves, and for patients to submit repeated ratings.
- Most patients were unconcerned about being identifiable to the HFEA. When asked if they would still have given feedback if they had received a ‘token’ from a clinic that would have proven they were genuine patients, but that might link them to their rating, 91% said they would still have rated their clinic as long as the clinic could not identify them.

3. Interviews:

Patient 1

- 3.1.** Patient 1 is currently having treatment with donor eggs. She had more than one cycle, at the same clinic. She was made aware of the patient ratings system by the HFEA posters in the clinic and clinic staff. The nurse at the clinic, which has many tablet computers in the waiting room, asked Patient 1 to give her rating while she was waiting to go in for the embryo transfer of her first cycle. She completed the ratings form, but in the briefest of terms. The patient feels that the clinic took advantage of this moment of vulnerability to ask for feedback.
- 3.2.** Although no-one at the clinic asked her to rate them again, the patient did so of her own accord, from her own home, after having had some negative experiences at a later date that she wished to give her views about.
- 3.3.** She is a supporter of the ratings system overall, and wants it to stay, but believes the current questions focus too much on the emotional journey and that there should be a question relating to whether the clinic displayed professional expertise. She felt the clinic was focusing on those aspects of treatment covered by the ratings and a question about expertise would ensure they worked hard on all areas of their service.
- 3.4.** While she was aware what would happen to the feedback she gave she was concerned that, in giving the specifics of her case as part of the free text submission, such information would somehow become available to the clinic in a way that would make her identifiable. She felt this might be reflected in the services she received.

Patient 2

- 3.5.** Patient 2 had treatment at two clinics. Having chosen her first clinic because it was close, but then having an unpleasant experience, she next chose a clinic much further away. She is now pregnant following treatment.
- 3.6.** She came across the patient ratings system from her research into the HFEA, it was not mentioned at either clinic. She used it to rate both her first clinic (very negatively) retrospectively and her second (positively) during treatment.
- 3.7.** She felt the questions were the right ones, and captures was what the patient needs, although she too was in favour of a question around clinical expertise. She understood what the purpose of the ratings system was, and felt that “in her mind’s eye” she was speaking both to future patients and HFEA staff as she gave feedback.
- 3.8.** As she had complained directly to the first clinic, she had no concerns about being identifiable to them. She was firmly in favour of the system continuing, as “in a world where you pay so much money clinics should be accountable”.

Clinic 1

- 3.9.** Clinic 1 is a large London clinic, the only one to appear in the top five for ratings submitted. They were very conscious of the system going live, and the low number of ratings they would have to start with, so they took action to address that through promotion. They felt the HFEA website could have more prominently promoted the scheme in its early stages; and that more should be done by us in terms of general promotional materials.
- 3.10.** The clinic has installed tablet computers in waiting rooms and other places in the clinic. They have created a home page featuring the HFEA ratings page that patients can access at any time they wish. Patients are asked to complete their rating at various points across the 20 or so contact points the clinic has with them over the course of their treatment. It forms part of the broader feedback they ask for their own purposes.
- 3.11.** The most common time for completion is the egg collection, or embryo transfer stages, which require long waiting times. Clinic staff mention the possibility of rating (anonymously) - there is no attempt to influence the patients in any way.
- 3.12.** They feel this approach has worked as they have quite a high number – sufficiently high for them to have stopped promoting the HFEA rating. Unless or until the ratings score drop they won’t promote it again.
- 3.13.** They feel the questions are the rights ones, framed in the right way. Patients have no trouble understanding what is required of them. When asked, they were unsure about the usefulness of a possible clinical expertise question, as they’re not sure the patient would be able to answer it They also wonder

whether patients will answer the question on cost intuitively, or based expressly around the costed treatment plan.

- 3.14.** They would “certainly” recommend that the ratings system stays, as they want the opportunity to direct as many people to the HFEA as possible, and their research with patients shows that patients want that too.

Clinic 2

- 3.15.** Clinic 2 is a medium sized clinic with a high number of ratings. They have placed the leaflets and posters around the clinic so that the ratings system is well promoted. At the beginning they found promotion hard work but that it has got easier now that momentum is there. Trying to get the message across that it is for the benefit for all patients.
- 3.16.** The ratings scheme is raised by various staff across the treatment journey from open evenings and consultations onwards, but the theatre manager ensures that a tablet is always passed to patients at the end of their treatment - generally after embryo transfer. They feel this is the best time because patients have completed their journey.
- 3.17.** They feel the questions are the right ones – “the ones patients ask themselves”. Patients don’t tend to ask about clinical expertise. Cost and the commitment of time they’ll need to spend in the clinic is important to patients.
- 3.18.** They combine the feedback received directly from patients with that on the HFEA website and have quarterly meetings about the sort of feedback they are getting.
- 3.19.** They are in favour of the system remaining as it’s an important tool for promoting patient voice.

Beyond fertility trends: the role of intelligence

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

Details:

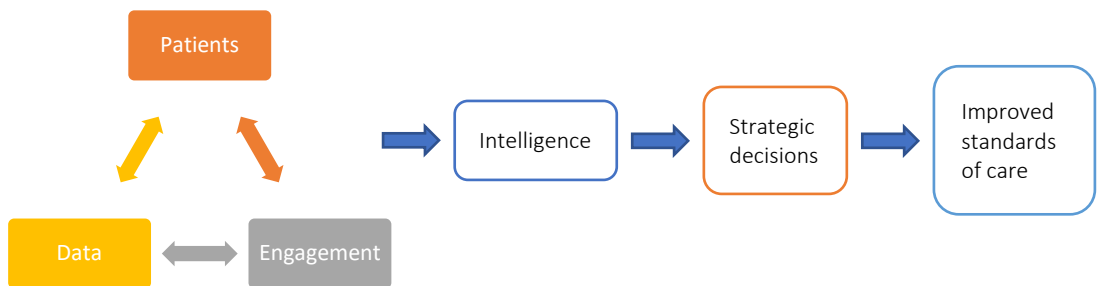
Meeting	Authority
Agenda item	10
Paper number	HFEA (14/03/2018) 874
Meeting date	14 March 2018
Author	Caylin Joski-Jethi, Head of Intelligence Lisa Whiting, Data and Insights Analyst

Output:

For information or decision?	For information
Recommendation	The Authority is asked to: <ul style="list-style-type: none"> Note the key outcomes of the fertility trends 2018 report Comment on possible future areas of work to explore
Resource implications	None
Implementation date	Ongoing
Communication(s)	Full press and stakeholder communication plan for Fertility Trends report
Organisational risk	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High
Annexes	None

1. Our intelligence strategy

- 1.1. Our intelligence strategy, approved by Authority on 24 January 2018, set us on a trajectory to ensure that our information is used to inform strategic decisions which result in improved standards of care.
- 1.2. The January Authority paper focused on the patient-led proposals, whereas this paper focuses on the way we will utilise our Register and other information to improve standards.
- 1.3. Using multiple sources of data, intelligence enables the discovery of new relationships and exploration of new possibilities. This new knowledge will, in turn, help us to use the wealth of information that we hold to improve standards of care. The 'standards of care' we aim to improve relate to the complete breadth of technological advances, public health research, patient care, birth rates, and many others.



- 1.4. We have done work like this in the past. Our 'Fertility Treatment in 2014-2016, Trends and Figures' report is an example of the mechanism we have previously used to assess our outcomes, and how we perform as a sector each year.
- 1.5. This paper aims to take this report one step further, commenting on both our current outcomes and performance, and indicating areas that intelligence could identify for future work.

2. Fertility trends

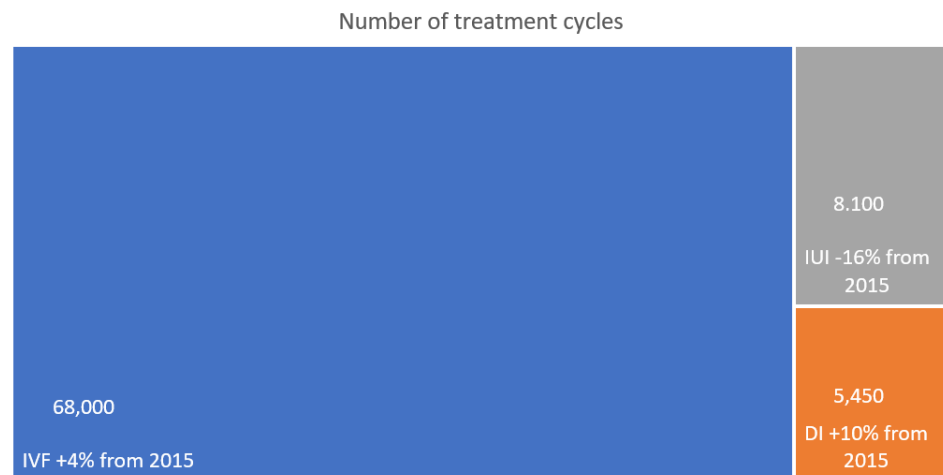
Learning from feedback

- 2.1. Our 'Fertility Treatment in 2014-2016, Trends and Figures' report launched today provides information on birth outcomes for 2014, 2015 and 2016. We have expanded the scope of the report to:
 - Make a greater range of statistics (including surrogacy and IUI data for the first time) available in as much detail as is reliable and practicable
 - Make more current statistics available to inform patients

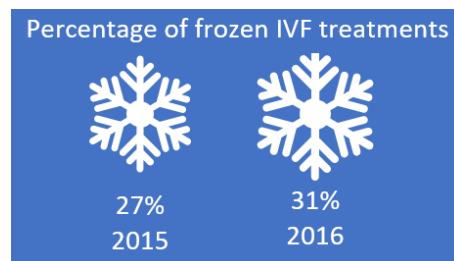
- Provide more commentary and analysis that aids interpretation – particularly with regards to our new definitions (such as per embryo transfer)
- Provide additional detail on outcomes by couple status (in response to frequent PQs on this topic)
- Provide IVF treatment rates for all combinations of donor/own egg, donor/partner sperm and fresh/frozen treatment cycles (in response to patient feedback saying they would like more specific categories)
- Ensure more information about the data we collect is available on our website (in response to feedback from researchers)

What have we learned: key statistics?

2.2. In 2016, there were a total number of 81,550 treatment cycles, the majority of which were IVF.

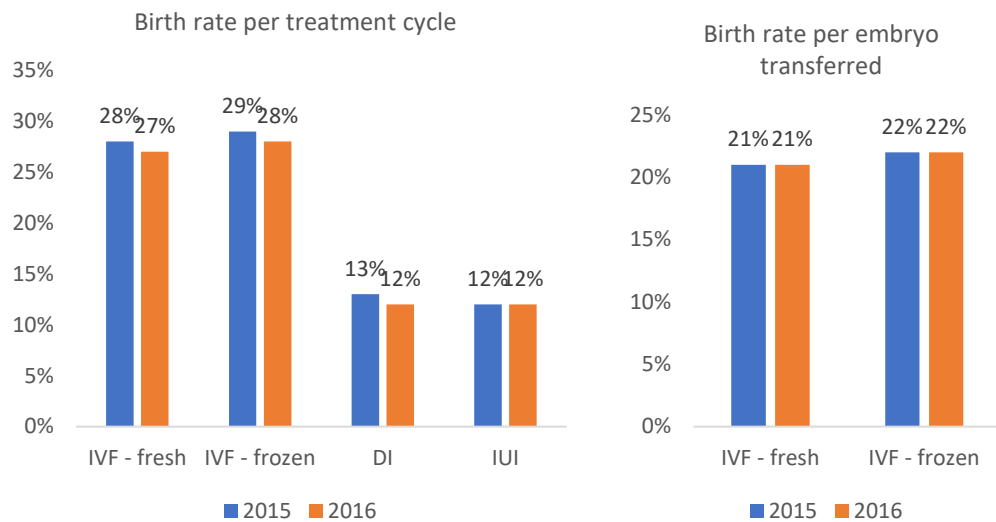


2.3. The proportion of IVF treatments that used frozen embryos increased to 31% of all IVF treatment cycles in 2016.



2.4. Frozen embryo transfer birth rates were above fresh IVF birth rates for the first time in 2015.

2.5. Birth rates for all treatment types remained broadly the same between 2015 and 2016.



Identifying future strategic priorities

- 2.6.** Reports show us what has happened so far and what the current performance is. Intelligence can show us why things happened, identify future areas of work, and adapt our strategic and policy responses to deliver the changes we want to see.
- 2.7.** The remainder of this paper highlights areas of work that could be explored to identify changes in the way that we respond to developments in the sector and to drive improvements in standards. This is not the time for a detailed discussion of the issues raised but any comments at this stage would be useful in helping us to prioritise next steps.

The typical fertility patient

- 2.8.** Our data shows that a significant majority of fertility patients are women with a male partner, undertaking IVF using their own eggs and partner sperm (OEPS). This demographic makes up 88% of around 68,000 IVF treatment cycles. The next most common treatment after OEPS IVF, is IUI at around 8,100 treatments a year. It is important to maintain this context in discussions of more specialist treatments such as egg freezing and PGD which have treatment numbers around 1,170 and 700 cycles respectively.
- 2.9.** Given the bulk of our patient cohort undertake standard IVF using OEPS, we might want to assess whether our policy and communications focus sufficiently on these fertility service users, as well as those who often receive more media coverage, e.g. surrogates, lesbian couples, transgender patients and where policy and practice may be more complex.

Multiple birth rate and frozen embryo transfer

- 2.10.** In 2008 around one in four IVF births were multiples compared to about 2% from natural conception. Over the last decade, we have worked with the sector to reduce the multiple birth rate with the goal of reaching 10%.

- 2.11.** The multiple birth rate has decreased substantially since 2008 for both fresh and frozen cycles, with no reduction in the pregnancy rate. In 2016, 11% of births from IVF treatment cycles were multiple births, down from 13% in 2015.
- 2.12.** Given the continuous downwards trends, it seems sensible to predict that the 10% target will be met in 2017 or 2018. The data prompts us to consider the policy implications for what to do when the target is met; whether we would want to introduce a lower target, or whether we are happy that the 10% goal is the signal that sufficient progress has been made¹. We might also explore further how the frozen outcome data impacts upon the ambition of any future target we set

Egg freezing

- 2.13.** We know more women are freezing their eggs and more women are using previously frozen eggs in treatment, even though overall numbers are still relatively small. Success rates are also improving and, given the public interest in egg freezing, this is valuable information for the public and patients.
- 2.14.** Furthermore, now that there are more patients undertaking egg freezing cycles and using frozen eggs in treatment, it will be possible to begin robust analysis of which factors may influence success rates. Our upcoming egg freezing report (due Spring 2018) will explore these questions in more detail to help inform patients, the public and clinics.
- 2.15.** The emergence of changing messages from the outcome data prompts us to consider reviewing our processes for how we communicate key changes and emerging evidence in developing areas of fertility treatment across our stakeholders.

Success rates for older women

- 2.16.** Currently, NICE recommendations for IVF funding distinguish between women aged up to the age of 40, who are recommended to receive three full cycles of IVF, and women aged 40-42 who are recommended one.² The NICE guidance states this is because “age was found to be the only robust factor in determining IVF success”.
- 2.17.** We know this to be true for older patients using their own eggs. However, when looking at patients using just donor eggs our data demonstrates that age does not influence success rates. This may have implications for funding recommendations or the information we provide to patients around success.
- 2.18.** This prompts us to consider reviewing our processes for how we communicate these significantly different outcomes with all stakeholders, and to explore if we have any responsibility to encourage this emerging evidence to be reflected in

¹ The lowest multiple birth rate in Europe can be found in Sweden at 4.9%:
<https://academic.oup.com/humrep/article/31/2/233/2380245>

² In England individual Clinical Commissioning Groups may then introduce their own eligibility criteria

national commissioning guidance and decisions in which, where donor eggs are used, there is minimal evidence to suggest older women should be denied access to treatment.

NHS funding

- 2.19.** Although regulation of fertility services is UK-wide, commissioning is devolved to the national level. The trend over the past few years has seen a divergence in commissioning policy across the four nations of the UK. Although the picture in Scotland has improved markedly in recent years, many English Clinical Commissioning Groups (CCGs) have reduced their fertility service over the same period. Given the fact the England accounts for the bulk of the UK population, we might expect this to come through in UK-wide trends, however in 2016 41% of IVF treatments were funded by the NHS, a figure which has remained broadly stable since around 2010.
- 2.20.** The obvious explanation for this apparent contradiction is a delay in the impact of commissioning decisions filtering through to the experience of patients. It may therefore be worth exploring the funding data further to help patients and the public better understand the current picture.

3. Intelligence driving our future analysis

- 3.1.** We have developed a timeframe for future reports utilising our intelligence of the types of issues raised through enquiries, PQs, FOIs, and engagement with patients. We have profiled the reports and analysis taking into account both the level of interest and current resource expended on ad-hoc analysis with the resource needed to develop a more thorough publication.

Strategic review of outcomes

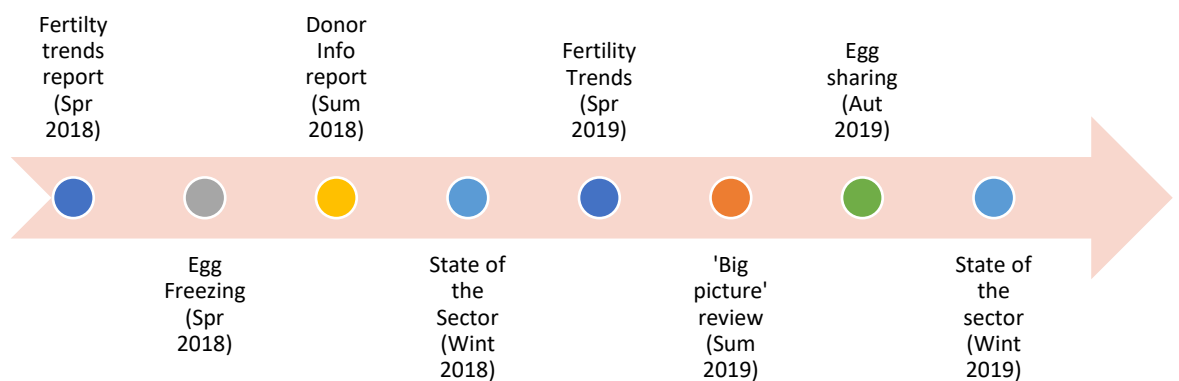
- 3.2.** We recognise that our inspection team have significant expertise in making decisions that drive standards at a local (clinic) level, however, in today's complex operating environment, making sound strategic decisions is more important – and more difficult – than ever, if we aim to account for the full range of demographic, regulatory, market and other factors, and to do this fast enough so there is still time to act.
- 3.3.** The intelligence strategy included an aim to deliver a regular review of enquiries, complaints, FOIs, PQs, incidents, inspection reports, and other qualitative feedback alongside key indicators. This would be used for a sector-level review of outcomes.
- 3.4.** This offers a 'big picture' review of our information to create a solid basis for analysing potential strategic options and guiding effective action across policy, compliance, licensing and communications. We will do this by synthesising information from a wide range of sources to identify the key factors and interactions affecting performance from across the organisation. Importantly, we plan to combine readily captured metrics and quantitative data with softer, more

qualitative information (patient feedback, enquiries, research) that is typically excluded from other analyses.

- 3.5.** This will make it possible to explain the forces driving performance, understand how our current performance was established, and to explore what policies and actions will increase standards in the future.
- 3.6.** We can also use this knowledge to review and build on the early intervention approaches we have developed, such as using the risk tool to provide early warning alerts where performance drops below the expected level. This will enable us to gain the best value from our information on an ongoing basis.

Future reporting timeframe

- 3.7.** Our proposed analysis and reporting timeline to the end of the 2019/20 strategy:



4. Recommendation

- 4.1.** The Authority is asked to:
 - Note the key outcomes of the fertility trends 2018 report
 - Comment on possible future areas of work to explore

Information Provision

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

Details:

Meeting	Authority
Agenda item	11
Paper number	HFEA (14/03/18) 875
Meeting date	14 March 2018
Author	Chris Hall, Interim Head of Information

Output:

For information or decision?	For decision
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Recommendation	<p>The Authority is asked to approve:</p> <p>That we formally advise clinics with third party patient record systems that their suppliers should be given six-months' notice of changes to be made to enable data submission to the HFEA;</p> <p>The proposed changes to General Direction 0005;</p> <p>The proposed arrangements for data confirmation.</p>
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Resource implications	N/A
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Implementation date	Summer 2018
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Communication(s)	Chair's letter attaching Direction will be issued in April 2018, within Clinic Focus. Substantial engagement activity with clinics' patient record suppliers is underway.
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Organisational risk	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High
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Annexes	<p>Annex 1: General Direction 0005</p> <p>Annex 2: Chair's letter</p>
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1. Background

1.1. At the March 2017 meeting of the Authority we brought early thoughts on our information policy for comment. The areas under review were 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

1.2. We explained that to reap the benefits of the investment we have made via the Information for Quality programme we needed to revisit the rules and expectations for data provision (that is the submission of data to the HFEA by clinics) which are currently set out in a mixture of policy, directions and guidance in the Code of Practice, to strike a new information 'bargain' between ourselves and the bodies we regulate. As such, the focus of this paper are areas 1-3 above. Work is underway in the remaining areas through consultation on the Code of Practice; in the newly established intelligence team; and in the Chief Information Officer function.

1.3. By way of reminder, 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.

1.4. We have an information submission policy. This paper highlights two principal changes - to General Direction 0005, and arrangements we put in place for clinics to confirm to us the quality of their data before we publish, for example in Choose a fertility clinic.

2. Introduction of the new data submission system

- 2.1.** We are proposing to introduce clinics to the new system at the HFEA conference in March 2018. Soon after we will be providing clinics with access to a Beta version from April 2018 to enable clinics to familiarise themselves with the new system and to receive training – but not submit data to us.
- 2.2.** At present, however, only a minority of clinics (c.30%) use an HFEA system to submit their data to us. Until we have agreed a timetable for those clinics (the majority, c.70%) who rely on third-party patient record systems to submit data to the HFEA we cannot switch to the new data submission system.
- 2.3.** We have already had discussions with the various third party providers. The next stage in that process is to issue the rules of engagement to clinics - in relation to submission timescales (General Direction) and clinics signing off data prior to their publication by us (verification).
- 2.4.** In normal circumstances when we propose changes to the data submission system we allow clinics that use third party patient record system suppliers a period of grace to implement those changes. This has been based on custom and practice rather than as part of an agreed policy. We wish to formalise this and propose a six-month preparation period for those clinics (and their third-party supplier). We will communicate this ‘starting the clock’ process in a Chair’s letter (draft at annex 2).
- 2.5.** We now seek the approval of the Authority, as we prepare to implement the new system. It is important these requirements are in place prior to then.

3. Changes to General Direction 005

- 3.1.** Following the launch of our new submission system we will have a new set of expectations and arrangements relating to good quality and timely data submission by clinics. We want to provide a transparent framework for clinics (and for the HFEA) about those expectations.
- 3.2.** We seek to do this first by the rules of the proposed new General Direction, backed up by modest changes to the Code of Practice in its October 2018 update.
- 3.3.** General Direction 0005 (at annex 1) sets out mandatory requirements for clinics on collecting, recording and submitting information. The main changes to this version of the Direction are:
 - To reflect the changes in the new submission system we no longer refer to ‘forms’. Instead we refer to ‘Information types’ detailed in the data dictionary, the purpose of each information type, and the deadline for submission;

- A reduction in the period allowed of correction of submission errors from 2 months to 4 weeks;
 - Subtle changes in tone with more use of the word “must”
 - A standardisation of submission deadlines so that they are always expressed in weeks
 - We no longer refer to the person responsible signing off a hard copy of their CaFC data before publication as we expect that this will be done electronically via the Clinic Portal
- 3.4.** Code of Practice (guidance note 32) sets out obligations and reporting requirements of centres (along with presenting mandatory requirements from Licence Conditions and the Act) will be amended to reflect the changes in the new submission system - that we no longer refer to ‘forms’; and the process by which PRs will verify their data ahead of publication on CaFC.
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4. Clinic data confirmation

- 4.1.** One of the advantages of the new system we have been promoting is the benefit to clinics in submitting higher quality data, due to higher standards of validation – making it much more difficult to submit erroneous data.
- 4.2.** The new data submission system allows us to streamline what we currently call the pre-publication CaFC verification process. In short, we ask PRs to confirm all errors have been dealt with for the previous year relating to births, and pregnancies and treatments, and that all relevant records have been submitted to the HFEA.
- 4.3.** We have given much thought to a new data confirmation process, to ensure that we increase the quality of data in the system on an ongoing basis, and can release and use this information to deliver a range of new outcomes. Notably, we see our intelligence team delivering its new strategy and enabling patients to have more current data on which to base treatment decisions.
- 4.4.** Alongside this work we believe that a more frequent confirmation process is necessary to support improved patient choice. In the past we have reduced the frequency of the verification process to reduce the burden on clinics. As such, on the surface more frequent data confirmation (at annex 2) may look counter-intuitive.

However, we believe the new system will be much more user-friendly and this will far outweigh any disadvantages relating to the frequency of the proposed arrangements for confirmation. We will discuss the fine detail of the data confirmation proposal with the sector over the summer.

5. Recommendations

5.1. The Authority is asked to approve:

- that we formally advise clinics with third party patient record systems that their suppliers should be given six-months' notice of changes to be made to enable data submission to the HFEA;
- the proposed changes to General Direction 0005; and
- the proposed arrangements for data confirmation.

Annex 1 Directions given under the Human Fertilisation and Embryology Act 1990 (as amended)

Collecting, recording and submitting information

Ref: 0005Version: 5

These Directions are:	General Directions
Sections of the Act providing for these Directions:	Sections 12(1)(d) and 12(1)(g)
These Directions came into force on:	1 October 2009
These Directions remain in force:	Until revoked
This version was issued on:	1 April 2018]

1. Centres undertaking any licensed treatments, except for IUI using partner sperm (see 7.), must submit information relating to such activities to the HFEA.
2. Centres must submit information via an HFEA approved data submission system. Detailed information on each record type is available within the HFEA's UK ART Data Set Dictionary published on the Clinic Portal:

Information type	Purpose	Submission deadline
Patient registration	To provide identifying information about the female patient having treatment	Before treatment commences.
Partner registration	To provide identifying information about the partner of the patient	Before treatment commences.
Donor registration	To provide identifying, contact, personal information about the donor and why they are donating.	Before first use of donor gametes or embryos or before stimulation to collect eggs from a donor. Pages 3 and 4 of the HFEA Donor Information form must be scanned and attached to the registration record on the HFEA register within 4 weeks of donor registration.
Intended parent registration	To provide identifying information about an intended mother or intended father in surrogacy.	Before first use of intended parent's gametes in treatment.
Surrogate registration	To provide identifying information about a surrogate.	Before the surrogate's treatment commences.
Mitochondrial donor registration	To provide identifying information about the mitochondrial donor. This is required even if the mitochondrial donor is also registered as a patient or egg donor	Before the stimulation to collect eggs from the mitochondrial donor.
Pronuclear only sperm donor registration	To provide identifiable details of a donor whose sperm will only be	2 weeks after sperm is released for use by the clinic, or in the case of

	<p>used in pronuclear transfer mitochondrial donation treatment for fertilisation of the mitochondrial donor's eggs</p> <p>Note: This is not required if the individual is already registered as a sperm donor or is the partner of the woman being treated.</p>	imports, 2 weeks after receipt of the imported sperm
Stimulation	To inform the HFEA when a cycle in which it is intended to collect eggs has started	3 calendar days after the last menstrual period or stimulatory drugs being administered to/taken by a patient with the intention to collect eggs.
Donor insemination treatment	To inform the HFEA when a patient has been inseminated with donor sperm.	2 weeks after the insemination date of the cycle
IVF treatment, and embryo creation and use	To inform the HFEA about the circumstances surrounding egg collection, embryo creation and use (ie, transfer, storage, donation, discard).	2 weeks after the treatment cycle date. Treatment cycle date is the latest of egg collection or collection abandonment date, mixing date, embryo transfer date or embryo storage date.
Frozen embryos	To inform the HFEA of the thawing and use of embryos (i.e. whether they have been used in treatment, stored, donated or discarded).	2 weeks after the thaw date.
Early pregnancy outcome	To inform the HFEA of the early outcome of a treatment	8 weeks after the treatment cycle date.
Pregnancy outcome	To inform the HFEA of the outcome of any early outcome recording 'fetal pulsation seen'	52 weeks after insemination or embryo transfer date.
Mitochondrial donation treatment	To inform the HFEA of a treatment cycle involving mitochondrial donation	To be submitted using a paper* form 2 weeks after the treatment cycle completion date
Embryo and gamete movement – in	To inform the HFEA about the number of embryos, eggs and ampoules, straws or vials of donor sperm transferred from another UK centre or imported from outside the UK.	On the day of receipt for embryos, eggs transferred from another UK centre or imported from outside the UK. 1 week after receipt of ampoules, straws or vials of donor sperm transferred from another UK centre or imported from outside the UK.
Embryo and gamete movement – out	To inform the HFEA of the number of embryos, eggs and ampoules, straws or vials of donor sperm removed from storage at a centre and the	When embryos, eggs and ampoules, straws or vials of donor sperm are removed from storage and transferred to another UK centre or

reason for the removal

exported outside the UK.

* All paper forms submitted should be sent by recorded delivery and addressed to the HFEA's Register Information Team.

1. Where an error is identified, centres must correct the error within 4 weeks.
2. All amendments to data previously submitted by clinic staff to the Authority must be done via an HFEA approved data submission system.
3. The registration record must be updated to record any patient, partner, or donor variation to consent given to disclose register information for research purposes within 2 weeks of the change being made. The consent for disclosure of information related to a child born because of treatment must be notified to the HFEA via within 2 weeks of the decision where it is different to the consent provided by the patient and if appropriate partner. This can be done via the submission of a Consent Variation form available from both the HFEA website and the Clinic Portal.
4. Where a licensed centre marks data as deleted, clearly stated reasons why must be provided.

Other submissions

1. All licensed centres undertaking Intra Uterine Insemination (IUI) with partner sperm must submit an annual return to the Authority no later than 28 February in each calendar year. The annual return must be submitted via the Clinic Portal.
2. All licensed centres undertaking maternal spindle transfer and/or pronuclear transfer must complete and submit to the Authority a copy of the 'Mitochondrial donation follow-up information sheet', available via the HFEA website and Clinic Portal no later than 29 October each year. Licensed centres holding these records must be able to produce copies of those records upon request from an HFEA member or employee.
3. To enable a previously anonymous donor to register as identifiable on the HFEA Register a donor re-registration (also known as a B form) must be submitted. B forms are available on the Clinic Portal and HFEA website.
4. Before centre data is published on Choose a Fertility Clinic (CaFC), the Person Responsible (PR) must satisfy themselves that the data to be published is accurate and confirmed. A PR sign-off sheet for each CaFC publication available within the Clinic Portal and must be submitted by the published confirmation deadline.
5. Persons Responsible must ensure that, before they sign off their data electronically via the Clinic Portal, they are satisfied that:
 - the number of treatment cycles (both generic IVF and DI) completed within the reporting period is 100% accurate;
 - all early outcome relating to cycles in a) above and all outcome data relating to clinical pregnancies in a) above has been submitted to the Authority and have been filled in accurately; and
 - all registration data relating to persons whose gametes are used in treatment in (a) above has been accurately submitted to the Authority.

Sally Cheshire CBE

Chair, Human Fertilisation and Embryology Authority

Annex 2 Chair's letter (draft)

XX/04/2018 - CH (18) X

01 April 2018

Ref CH (18) XX

Dear colleague,

Update to General Direction 0005

I am writing to inform you that General Direction 0005 setting out the mandatory requirements for clinics on collecting, recording and submitting data to the HFEA Register of information has been amended.

The changes are made to support the implementation of our new data submission system. The changes reflect changes to submission timescales and clinic confirmation and sign-off of data prior to publication by us.

The main changes to the Direction are:

- To reflect the changes in our new data submission requirements we no longer refer to 'forms'. Instead we refer to 'Information types' detailed in the data dictionary, the purpose of each information type, and the deadline for submission;
- A reduction in the period allowed of correction of submission errors from 2 months to 4 weeks;
- A standardisation of submission deadlines so that they are with a sole exception always expressed in weeks;
- Subtle changes in tone with more use of the word "must"
- Simplification of some submission requirements to, for example, "before treatment", "before use of donor gametes or embryos"
- We no longer refer to the person responsible signing off a hard copy of their CaFC data before publication as we expect that this will be done electronically via the Clinic Portal.

General Direction 0005 (Version 5) will come into force later this year with the implementation of the new data submission system. You will be informed in advance.

Update of third-party patient record systems used to submit data to the HFEA Register

A key strand in implementing the new system is that all clinics can continue to submit Register data to us in accordance with the new Direction (General Direction 0005 version 5).

Clinics submitting treatment information to the HFEA system directly will move over to the new HFEA system (later in the year). An increasing number of clinics now submit treatment information to us via third-party patient record systems. Providers of those systems now need to make changes such that the benefits are available to all clinics as soon as possible. It is also necessary to minimise disruption to related activity, such as your and our monitoring of your performance, fee billing and so on).

Our usual practice is to allow clinics that use third party patient record systems sufficient notice for their system suppliers to implement proposed changes. We have been in regular contact with most suppliers alerting them to the changes.

We now require clinics with those third-party patient record systems that their suppliers must be given six-months' notice commencing xx/xx/2018 to give them time to make the necessary changes to enable your continued data submission to the HFEA.

We will work closely with suppliers but it is necessary for them to make the necessary changes to ensure compatibility with the HFEA's new data submission system by the end of the six-month preparation period. In the event that changes have not been such that the system is ready for submissions, it will be necessary for you to use an alternative compatible system or the HFEA's own data submission system (PRISM direct-entry) to submit Register data as required by Direction 0005 (Version 5).

Effective governance

Strategic delivery:

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

Details:

Meeting	Authority
Agenda item	12
Paper number	HFEA (14/03/18) 876
Meeting date	14 March 2018
Author	Paula Robinson, Head of Planning and Governance

Output:

For information or decision?	For decision
Recommendation	To approve revised Standing Orders (vote – simple majority; requires two thirds of members (8) to be present) To note a summary of the annual reviews of committee effectiveness
Resource implications	In budget.
Implementation date	1 April 2018
Communication(s)	Standing Orders are published on our website and provided to all members. Our standard pack for licensing meetings is updated whenever a new version is agreed.
Organisational risk	<input checked="" type="checkbox"/> Low <input type="checkbox"/> Medium <input type="checkbox"/> High
Annexes	Annex 1: Standing Orders (revised)

1. Introduction

- 1.1.** As an effective and trusted regulator, the HFEA needs 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 are set out in our standing orders.
- 1.2.** The Authority is committed to an annual review of our governance arrangements, consisting of:
- a self-review of each committee's effectiveness; and
 - a review of our standing orders.

2. Standing orders

- 2.1.** The current standing orders have been active since April 2016, with the only change in 2017 being the addition of mitochondrial donation treatment decisions to the terms of reference for Licence Committee and the Statutory Approvals Committee. This followed the introduction into law of the Human Fertilisation and Embryology (mitochondrial donation) regulations 2015.
- 2.2.** Proposed changes in the standing orders relate to:
- Organisational changes since the last review (updated job titles and role changes reflected).
 - An added delegation to the Licensing Officer, so that we can implement the new EU requirements on imports.
 - Other non-substantive amendments to clarify and improve existing wording.
- 2.3.** Revised standing orders are attached at Annex A for the Authority's consideration. Track changes has been used to show the main changes.
- 2.4.** A 'notice of motion' was sent to members in advance of the meeting, in accordance with the requirements for variation or amendment, set out in section 1.3.1 of standing orders. The Authority may vary standing orders by a majority vote, provided at least two thirds of members are present and that the variation proposed does not contravene any statutory provision or a direction made by the Secretary of State.
- 2.5.** Authority members are also aware that the executive is currently conducting a review of the administrative servicing arrangements for the licensing function. The Senior Management team will consider options in April, and we will report to members at the May Authority meeting, with any recommendations that may require approval by members. It is possible that some changes may require the consideration of further revisions to standing orders.

3. Annual review of committee effectiveness

- 3.1.** All committees are required annually to reflect on their own effectiveness. For this we use a standard checklist framework developed within the HFEA, compiled from a range of available examples of committee review materials used by other bodies. Between October and February, this exercise was conducted by the Licence Committee, the Statutory Approvals Committee, the Executive Licensing Panel and the Scientific and Clinical Advances Advisory Committee.
- 3.2.** There is a specific effectiveness tool for Audit Committees, produced by the National Audit Office. The Audit and Governance Committee conducted its review on 6 March 2018, using the NAO's checklist, and feedback will be provided verbally at the Authority meeting.
- 3.3.** Generally the feedback from committees has been positive, with some improvement points raised. The reviews are summarised below.

Committee	Positives	Areas for improvement
Licence Committee	<p>Role clarity.</p> <p>Effectiveness of membership and skill mix.</p> <p>Quality of meetings and Chairing.</p> <p>Administrative and legal support.</p> <p>Well maintained separation of function between executive and committee.</p>	<p>With Member turnover in the coming year (including the committee's Chair and Deputy), handling and knowledge/expertise management will be important, including particular training for the new Chair.</p> <p>A more balanced workload across meetings is needed – agendas have been extremely variable in size. This leads to congestion and pressure in producing and finalising minutes.</p> <p>Communication between meetings regarding any legal developments.</p> <p>Legal advisers to be asked to volunteer more governance advice.</p>
Executive Licensing Panel	<p>Clear delegations, good role understanding by members.</p> <p>Skill mix and workload distribution.</p> <p>Volume is variable, but manageable.</p>	<p>Refresher legal training.</p> <p>Induction meeting with the Chair and Deputy Chair for new members.</p> <p>Earlier population of agendas to assist in balancing workloads.</p> <p>An annual workshop for members would enable points raised during the year (eg, in relation to consistency) to be shared among all panel members.</p>

Committee	Positives	Areas for improvement
	<p>Quality of discussions and Chairing.</p> <p>Administrative support and meeting organisation.</p>	<p>The scheduling of items could be improved, in relation to licence expiry dates and deadlines for the implementation of recommendations on non-compliances. These are often very shortly after the panel's meeting date, resulting in insufficient information or unnecessary time pressure, which could result in the centre needing to operate under special directions.</p>
Statutory Approvals Committee	<p>Role clarity.</p> <p>Skill mix; robust debates; valued expertise.</p> <p>Quoracy and meeting date management.</p> <p>Chairing and follow-up of issues between meetings.</p> <p>Communication with staff, the Authority and (where applicable) clinic staff; patient input to papers.</p>	<p>Adviser conflict management has been an increasing challenge. Where possible, a new adviser should be identified for the whole meeting.</p> <p>Legal Advisers need more regular experience of the meetings to stay up to date. This may mean using a smaller pool.</p> <p>A wider pool of mitochondrial donation experts is needed, and is being sought. This expertise is still comparatively rare, so building resilience may take time.</p> <p>Various suggestions for the administrative support of meetings, including agenda management, videoconferencing and file sharing improvements.</p> <p>The complex scientific nature of some agenda items has impacted on minuting speed.</p> <p>Senior governance advice would be helpful, particularly on complex matters.</p>
Scientific and Clinical Advances Advisory Committee	<p>Quality of discussions, expert support and papers.</p> <p>Skills and expertise.</p> <p>Frequency of meetings and volume of work.</p>	<p>Facilitate more input for members into the annual horizon scanning meeting at ESHRE.</p> <p>Ensure discussion remains focused.</p> <p>Ensure committee papers are sent to members as early as possible.</p>

Committee	Positives	Areas for improvement
	<p>New traffic light system for add ons working well.</p> <p>Secretariat support and minutes.</p>	
Remuneration, Appointments and Oversight committees	Formal reviews not undertaken due to infrequency of meetings.	
Appeals committee	<p>This committee reports on its activities separately, and in line with business years, in accordance with Regulation 9 of the Human Fertilisation and Embryology (Appeals) Regulations 2009. Its most recent report covers the year ending 31 March 2017. No appeals were heard in that period. In the ensuing year, there has been one appeal, which will be addressed in the next annual report.</p>	

4. Recommendation

The Authority is asked to:

- Approve the revised standing orders, to come into effect from 1 April 2018. (A vote is required.)
- Note the feedback from the annual reviews of committee effectiveness, and that action plans will be put into place for each committee.



Human
Fertilisation &
Embryology
Authority

Annex A

Standing orders

**Draft – to come into effect
1 April 2018**

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, amended and approved by Authority on [15 March 2017](#).

Draft for approval by 14 March 2018 Authority

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Foreword¹

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
 - 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.

¹ This foreword is not part of the standing orders.

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 2018

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 at the meeting 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.

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.

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.

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) any legal update
 - b) any commercially sensitive matters, and
 - c) 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.

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 strategy, the annual business plan and the 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.

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, a 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 such meetings 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.

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; except in the case of the Remuneration and Appointments Committees, whose minutes should be signed off by the Chair as soon as they have been agreed by members following the most recent meeting, 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.

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

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

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:

- e) a Committee Chair (who shall be an Authority member)
- f) a Deputy Committee Chair (who shall be an Authority member)
- g) 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 Planning and 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(4AA) 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 Senior Governance Manager or the Head of Planning and 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.

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.

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.

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 (the Head of Intelligence), and
 - c) the Chief Information Officer.

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.

Standing orders: Annex B

Instrument of delegation in respect of Authority licensing functions

1. Licensing functions delegated to a Licensing Officer

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.
-

Consideration of applications for voluntary revocation of licences under Section 18(1) of the Act

The issuing, revocation, renewal and variation of Certificates of Authorisation of importing tissue establishments in accordance with EU requirements on the import of eggs, sperm and embryos.

2. Licensing functions delegated to the Executive Licensing Panel

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

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 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.

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.

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

The following variations 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.

Consideration of reports of random unannounced inspections.

Consideration of reports of targeted inspections.

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.

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

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

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

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

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.

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.

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

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

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

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

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

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.

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.

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

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

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 Licensing 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 any other required support staff from the Planning and Governance team 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 refer the issue to the Licence Committee for consideration. The panel must record in the minutes of its deliberation the reasons why it was minded to vary or revoke the licence.

11. Reasons for the panel's decision

- 11.1. The panel shall give reasons for each decision that it makes, including any decisions to refer matters to the Licence Committee. 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 shall report to each Authority meeting on the activities of the panel.

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. At the conclusion of every meeting of the Licence Committee, the Head of Planning and Governance shall collate any 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 secretary, any other required support staff from the Planning and Governance team 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 where the committee 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.
- 10.5. 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.
- 10.6. 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.
- 10.7. 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).
- 10.8. 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 report to each Authority meeting on the activities of the Committee.

Standing orders: Annex E

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

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.