

Draft business plan 2016/17

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

Details:

Meeting Authority

Agenda item 7

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Output:

For information or decision? For decision

Recommendation The Authority is asked to approve the draft business plan at its current stage of development, and to note that a draft will be submitted to the Department of Health before the end of December.

Resource implications In budget.

Implementation date Throughout 2016/17 business year.

Communication(s) Publication on HFEA website and Intranet.

Organisational risk Low Medium High

Annexes Annex 1: Draft business plan for 2016/17

1. Background

- 1.1.** The Authority agreed an outline of the new business plan for 2016/17 at its September meeting. Our business plans are designed to help us deliver our overall strategy, year by year, and this will be our second business plan since the strategy was published in August 2014.
- 1.2.** As a reminder, the business planning cycle consists of the following main steps:
- | | | |
|-------------|---|--|
| August | – | Early thinking by CMG (done) |
| September | – | Authority agreed indicative outline (done) |
| October | – | First draft of 2016/17 business plan produced (done) |
| November | – | Draft approved by Authority (this meeting) |
| December | – | Draft submitted to Department of Health (DH) |
| January | – | DH comments received |
| February | – | DH checkpoint meetings and budget discussions |
| March | – | Finalisation with Authority and DH |
| April / May | – | Formal DH approval and publication on website. |

2. Early draft

- 2.1.** This draft follows the same basic template as the current (2015/16) business plan, which was redesigned last year to correspond with our strategy. The content is based on the outline plan agreed in September.
- 2.2.** Some sections of the business plan are not written until later in the business year – these are:
- What we did in 2015/16
 - Measuring our performance
 - Financial picture.
- 2.3.** The activities set out in the main section (delivering our strategy in 2016/17) will still require some further refinement with staff over the next few months.

3. Recommendation

- 3.1.** The Authority is asked to approve the draft at Annex A for submission to the Department of Health in December (or when requested).
- 3.2.** The Authority is asked to note the steps involved in the continuing development of the business plan. If major changes are made to the attached version prior to submission to DH, the new version will be circulated to members for comment.

- 3.3.** The Authority is also asked to note that CMG has reviewed delivery of the current (2015/16) business plan. We always do this after the end of quarter two, and in some business years it is necessary to publish a mid-year revision of the business plan. However this only applies if something of note has changed (additional activities, altered timelines, and so on). This year there is no need for any revision.



Human
Fertilisation &
Embryology
Authority

Annex A

Business Plan

2016/17

www.hfea.gov.uk

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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 2014–2017 is:

High quality care for everyone affected by assisted reproduction.

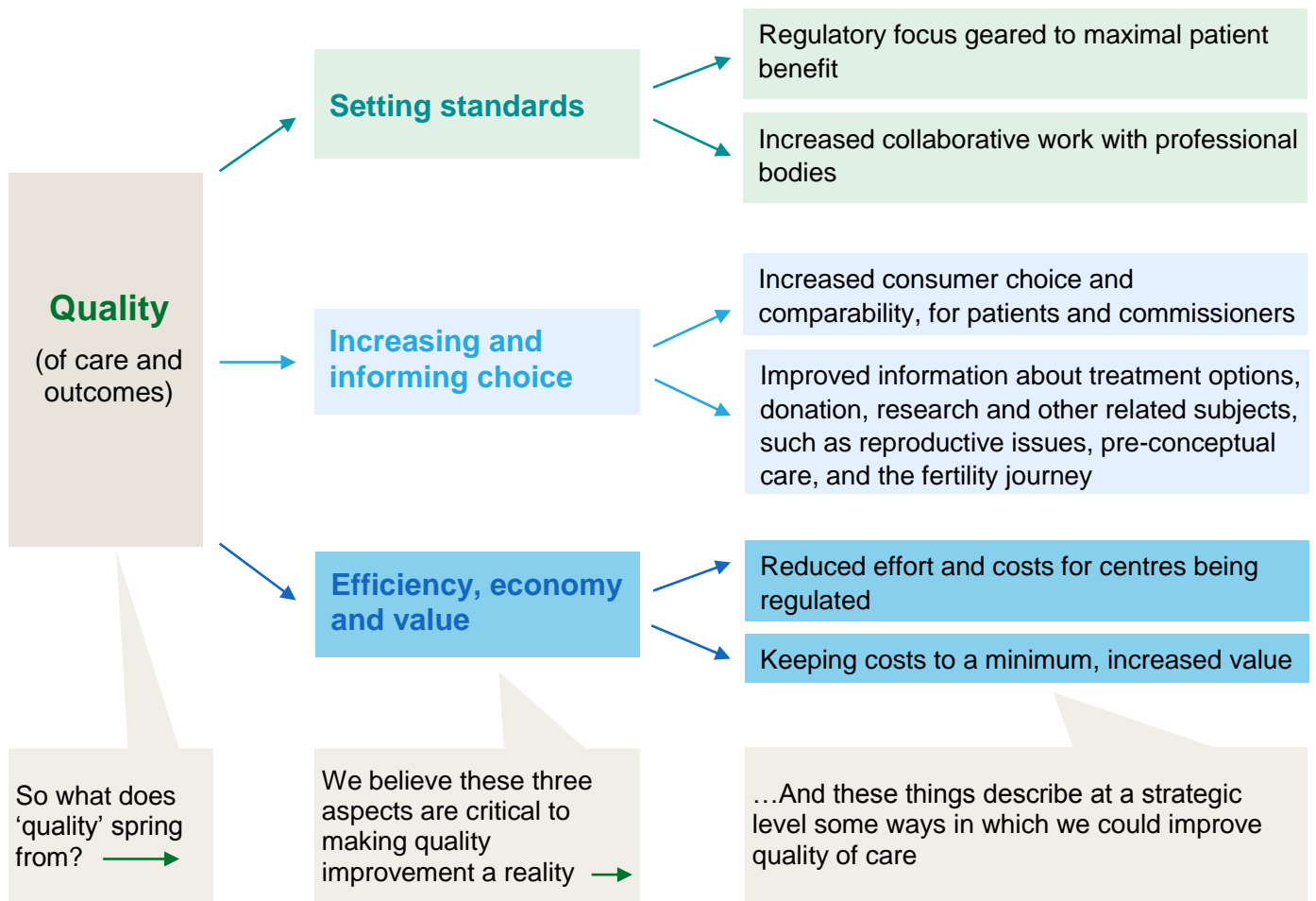
High quality care means...	<ul style="list-style-type: none"> • safe, ethical and effective care and treatment.
Everyone affected means...	<ul style="list-style-type: none"> • patients and parents • all those conceived through assisted reproduction • donor-conceived people • egg and sperm donors • clinic staff.
Assisted reproduction means...	<ul style="list-style-type: none"> • standard fertility treatments • genetic testing and new treatments • innovations in research.

This business plan sets out how we will work towards this vision in 2016/17.

What can we do to achieve high quality care?

We believe that, as the regulator, there are three different means through which we can improve the quality of care:

- Setting standards in clinics and checking compliance with them through inspection.
- Playing a public education role by providing information about treatments and services, so that patients are able to choose better quality care.
- Reducing costs for clinics so that they can focus more of their time on providing care.



HFEA strategy 2014-2017

Our strategy for 2014–2017, published in July 2014, sets out our vision and how we will achieve it by utilising the quality channels available to us, as described above.

We have set out five strategic objectives that will collectively deliver the vision:

Setting standards

We will improve the quality and safety of care through our regulatory activities.

By...

- Making the patient experience integral to the way in which we assess clinics' performance.
- Seeking patients' views, and understanding their perspective, as part of the way we work.
- Publishing more HFEA data to drive improvements in clinic performance.
- Acknowledging that treatment is often unsuccessful.
- Working with professional groups to improve treatment success rates.

We will improve the lifelong experience for donors, donor-conceived people, patients using donor conception and their wider families.

By...

- Providing information about donor conception directly to patients and donors through the Lifecycle campaign.
- Ensuring that clinics prepare patients adequately for donation and fully understand their role and importance as a lifelong information provider.
- Ensuring that egg and sperm donors are well supported and understand the lifelong commitment that follows from donation.
- Collecting and publishing information regarding donor egg and sperm availability in the UK, and addressing impacts for patients (for example, by providing more information about the implications of treatment abroad).

Increasing and informing choice

We will use the data in the HFEA Register of Treatments to improve outcomes and research.

By...

- Improving the presentation of clinic comparison information on Choose a Fertility Clinic (CafC).
- Working with NHS commissioning bodies to ensure that they commission the best services using available data.

Strategic Objectives

We will ensure that patients have access to high quality meaningful information.

By...

- Improving HFEA information about treatments available, scientific research, embryo and stem cell research and other fertility subjects, including reproductive issues, pre-conceptual care.
- Working with clinics and scientific experts to publish information about new treatments.
- Enhancing CaFC by including user experience scores.
- Ensuring that clinics prepare and support patients and donors through the information they give them.
- Collaborating with professional stakeholders to put patients in touch with better information and the right sort of care when they first realise they may have a fertility issue.

Efficiency, economy and value

We will ensure the HFEA remains demonstrably good value for the public, the sector and Government.

By...

- Ensuring we are easy to deal with and that we offer a professional and cost-effective service in all that we do.
- Modifying our ways of working to ensure we are responsive, agile, innovative and effective in achieving our strategic and statutory goals.
- Improving the methods used to submit and verify Register data.

In order to implement the above strategic objectives, we are planning to carry out a number of activities and projects, which are set out later in this business plan.

How we work

Our strategy also sets out our ways of working, which are as follows:

- We will make the quality of care experienced by patients, donors and donor-conceived people our central priority and the primary consideration in our decision making.
- We will consult and collaborate widely – listening to, and learning from, those with an interest in what we do.
- We will communicate more with stakeholders before making decisions and explain those decisions more clearly.
- We will take the time to implement decisions with appropriate stakeholder involvement, piloting new initiatives when appropriate.
- We will keep abreast of scientific and clinical innovations and actively consider what these might mean for the future quality of care.
- We will be a more agile and flexible organisation, changing course if needed in order to be responsive (both to stakeholders and to new priorities).
- We will continue to exercise our statutory functions consistently, proportionately, openly and fairly.
- We will observe the highest standards of integrity and professionalism in putting into effect the law as it governs the fertility sector.
- We will continue to treat people and their information with sensitivity, respect and confidentiality.

Our legislation and functions

The following information is provided to give a complete picture of our purpose and core functions, which are defined in law by the following two Acts of Parliament:

- 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’).

The 2008 Act is primarily amending legislation. It extensively amends the provisions of the 1990 Act, which continues to form the main framework governing our duties and responsibilities. However, the 2008 Act also contained new provisions which were not included in the 1990 Act. In particular, these include provisions relating to legal parenthood.

The 1990 Act (as amended) gives us a number of statutory functions:

- To license and inspect clinics carrying out in vitro fertilisation and donor insemination treatment.
- To license and inspect establishments undertaking human embryo research.
- To license and inspect the storage of gametes (eggs and sperm) and embryos.
- To ensure, where a licensed clinic makes use of an external service which does not hold an HFEA licence, that there is a third party agreement in place which is in accordance with any licence conditions imposed by the Authority, for the purpose of securing compliance with the requirements of technical directives under which the third party procures, tests or processes gametes and/or embryos on behalf of the licence holder, or supplies to them goods or services which may affect the quality or safety of gametes and/or embryos.
- To produce and maintain a Code of Practice, providing guidance to clinics and research establishments about the proper conduct of licensed activities.

- To keep a formal register of information about donors, treatments and children born as a result of those treatments.
- To maintain a formal register of licences granted.
- To maintain a register of certain serious adverse events or reactions (this relates to certain specific activities, which are set out in the amended act).
- To investigate serious adverse events and serious adverse reactions and take appropriate control measures.
- To respond to any request from a competent authority in another European Economic Area (EEA) state to carry out an inspection relating to a serious adverse event or reaction and to take any appropriate control measures.
- To collaborate with the competent authorities of other EEA states.

In addition to these specific statutory functions, the legislation also gives us some 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 its functions effectively, efficiently and economically.
- Publicising our role and providing relevant advice and information to the donor-conceived, 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 2015/16

Delivery of the 2015/16 business plan

[DN: This section is written in March]

Delivering our strategy in 2016/17

Delivering the strategy

Our strategic vision for the three years from August 2014 to July 2017 is:

High quality care for everyone affected by assisted reproduction.

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

1. We will improve the quality and safety of care through our regulatory activities.
2. We will improve the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.
3. We will use the data in the HFEA Register of Treatments to improve outcomes and research.
4. We will ensure that patients have access to high quality meaningful information.
5. We will ensure we remain demonstrably good value for the public, the sector and Government.

These objectives are designed to ensure that we deliver our vision and continue to regulate clinics to a high level of quality, in the interests of patients, donors, donor-conceived people and our other stakeholders. We must manage ourselves effectively as a responsible public body, whilst ensuring that our statutory duties are met, and are met well, for the ultimate benefit of patients and the clinics we regulate. We must also continue to be a reflective and open organisation that constantly seeks improvements and efficiencies. Building on previous work to ensure that we are an efficient and modern regulator, we will continue to review our own performance and effectiveness and to decrease costs where we can.

The activities and projects set out over the next few pages describe how we will meet these strategic objectives in 2016/17.

Activities for 2016/17

Activities	Methods and channels	Benefits and outcomes	Timescale
Setting standards			
Strategic objective 1: improving the quality and safety of care through our regulatory activities			
Delivering the full compliance and licensing cycle to maintain standards for patients.	Inspection, audit and licensing activities.	<p>Clinics are appropriately inspected and monitored against published performance indicators, and issued with licences for up to four years.</p> <p>Continued programme of unannounced inspections.</p> <p>Assurance of standards and safety for the public and other stakeholders.</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>	Throughout year
	Ensuring internal Compliance processes and systems support quality. This may include implementation of any recommendations for the inspection regime resulting from the HFEA's triennial review (in 2015/16).	Consideration of the impact and effectiveness of our regulatory work and identification of further quality improvements that we could make.	September 2016
	Ensuring governance tools underpinning licensing and other decisions are in place and effective.	Efficient and effective decision-making is maintained.	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
	<p>Processing applications for the licensing of preimplantation genetic diagnosis (PGD), human leukocyte antigen (HLA) and mitochondrial donation.</p>	<p>Growing area of work dealt with effectively and efficiently. Public confidence assured in the regulation of the new treatments 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.</p>	<p>Throughout year</p>
<p>Identifying and implementing ways of improving the quality and safety of care.</p>	<p>Continuing our relentless focus on quality and safety of care in inspection activities – in particular through focusing on shortcomings in the taking and recording of consents, medicines management, data submission, multiple birth rates, and information published on clinics' websites.</p>	<p>Improved compliance, with a positive impact on the quality of care, outcomes and safety of patients in clinics.</p> <p>Clinics have reduced vulnerability to expensive adverse legal and reputational risks, and greater awareness of these risks.</p> <p>Tracking of non-compliances in these areas, and the responsiveness of clinics in completing actions arising from inspection recommendations, in order to measure our impact.</p> <p>Clinics' understanding of, and adherence to, correct consent procedures and their understanding of the importance of getting this right, is improved.</p> <p>Patients and donors therefore have a better experience of being asked for consent, and feel fully informed.</p> <p>If an issue subsequently arises (such as the death of someone with gametes in storage), the correct consents are more likely to be in place and are legally clear and robust.</p>	<p>Throughout year</p>

Activities	Methods and channels	Benefits and outcomes	Timescale
	Continuing to evaluate areas of regulatory concern and identifying performance levers.	Improved compliance, with a positive impact on the quality of care, outcomes and safety of patients in clinics.	Throughout year
	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 report on clinical incidents 2015.</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>Collaborative relationship established with the recently established NHS Improvement so as to consider wider lessons learned that may have relevance.</p>	<p>November 2016</p> <p>March 2017</p>
	Improved Register data quality, as a result of work done 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 2017

Activities	Methods and channels	Benefits and outcomes	Timescale
	<p>Working with commercial groups of clinics so as to improve quality and compliance on a group-wide basis, when relevant.</p>	<p>Using a clinic group's central Quality Management System (QMS) to best effect across whole group.</p> <p>A benefit in one clinic is shared to others 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>March 2017</p>
	<p>Collaborating with professional stakeholders (including the British Fertility Society, the BFS) to put patients in touch with better information and services when they first realise they may have a fertility issue.</p>	<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>	<p>March 2017</p>

Activities	Methods and channels	Benefits and outcomes	Timescale
<p>Acknowledging that treatment is often unsuccessful, and exploring with professional stakeholders how the HFEA and clinics could better address this issue.</p>	<p>Improving the chances of success as much as possible, by publishing more HFEA data to drive improvements in clinic performance.</p> <p>Following on from IfQ, publishing a wider range of performance data on our website.</p> <p>Continuing to publish the annual Fertility Trends report.</p> <p>Ensuring our messaging to clinics conveys the importance of handling the issue of unsuccessful treatment with sensitivity, including offering counselling.</p> <p>Ensuring our own information for patients enables them to have realistic expectations (both of actual success rates and of what they should expect of clinics in the event that their treatment is unsuccessful).</p> <p>Continue to apply pressure on success rates and risk tool alerts related to these, through our inspection reports and other means.</p>	<p>Increased transparency to empower and inform patients.</p> <p>Increased visibility for clinics of sector-wide data so that they can assess their own performance against it.</p> <p>Encouragement of best value and treatment outcomes for patients.</p> <p>Better support where treatment is unsuccessful.</p> <p>Prospective patients enter treatment with a realistic understanding that they may not have a baby, even if they undertake many cycles.</p> <p>More information on our website for prospective patients and specific signposting for patients who have experienced unsuccessful treatment.</p> <p>Clinics more aware of their responsibilities to patients beyond the immediate treatment setting.</p>	<p>March 2017</p>
<p>Maintaining our role as the UK's competent authority for ART in the European Union.</p>	<p>Attendance at competent authority events and implementation of associated EU decisions.</p>	<p>We attend two meetings per year.</p> <p>Up-to-date intelligence gained about European perspective, 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>Throughout year</p>

Activities	Methods and channels	Benefits and outcomes	Timescale
<p>Reviewing our embryo research policies and regulation.</p>	<p>Reviewing the consent process in collaboration with the Health Research Authority (HRA), the sector and other stakeholders.</p> <p>Reviewing the Code of Practice guidance and relevant licence conditions.</p> <p>Review the end-to-end application and approval process.</p> <p>Research workshop to identify the barriers to research and innovation.</p> <p>Collaborative work with researchers, peer reviewers and Licence Committee to ensure a common understanding.</p> <p>Establishing clarity on what constitutes ‘a single programme of research’ within the bounds of the Act (which requires a separate licence for every building) to inform a practical review of the licensing model.</p>	<p>No embryos should be allowed to perish where the gamete providers would prefer them to be donated to research.</p> <p>The application and licensing process should be robust but not impose unnecessary burdens. This outcome would help to promote new research for the benefit of the sector and support (or remove barriers to) innovation.</p>	<p>March 2017</p>
<p>Improving the quality of commissioning decisions on fertility services.</p>	<p>Follow-up work with commissioners of NHS services, following road-testing in 2015/16 of the HFEA’s guidance leaflet for commissioners.</p> <p>Wider testing (subject to feedback from the initial group) is planned, and consideration will then be given to the scope for further joint working with commissioners.</p>	<p>Improved understanding by commissioners of the key factors to consider in their decision making.</p>	<p>March 2017</p>

Activities	Methods and channels	Benefits and outcomes	Timescale
Strategic objective 2: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.			
<p>Providing information about donor conception directly to patients and donors.</p>	<p>Through the Lifecycle campaign (and through the IfQ work on Choose a Fertility Clinic, CaFC), we will continue to provide information about donation and gamete availability.</p>	<p>Potential donors, recipients and donor conceived people have better access to clear, authoritative impartial information about a range of issues.</p> <p>Improved information about gamete availability.</p> <p>As a result they feel better informed and supported with respect to the legal aspects and obligations of donation.</p> <p>All involved (including clinics) understand the lifelong commitment associated with donor conception and the associated legal issues that are relevant to them.</p>	<p>Throughout year</p>
<p>Ensuring that clinics prepare patients adequately for donation and fully understand their role and importance as a lifelong information provider; and that egg and sperm donors are well supported and understand the lifelong commitment that follows from donation.</p>	<p>Through the Lifecycle campaign (and through the IfQ work on CaFC), we will continue to provide information about donation.</p>	<p>Clarity of role and performance for clinics in relation to donation and associated information guardianship.</p> <p>Improved experience for donors, donor-conceived people seeking information and patients and their families.</p>	<p>Throughout year</p>

Activities	Methods and channels	Benefits and outcomes	Timescale
<p>Continuing the provision of counselling support for donor-conceived people wishing to access information held on the HFEA Register.</p>	<p>Continuing to run the three year pilot of counselling support services for applicants to the Register. Annual evaluation to Authority.</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.</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>Piloting continues through to June 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 new EU directives.</p> <p>Robust processes in place to ensure the quality, safety and traceability of imported gametes and embryos.</p>	<p>April 2017 (the EU implementation date)</p>

Activities	Methods and channels	Benefits and outcomes	Timescale
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Increasing and informing choice

Strategic objective 3: using the data in the HFEA Register of Treatments to improve outcomes and research

Maintaining the Register of Treatments and Outcomes and supporting clinics in reporting the data.	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 service requests. Risk-based regulation and evidence-based policy-making are better supported.	Throughout year
Publishing and supplying the information we hold, for the benefit of stakeholders.	Regularly updating CaFC information to assist patient choice.	Six monthly verification and publication schedule in place, maintaining provision of up-to-date and accurate information.	Throughout year
	Continued publication of inspection reports on CaFC.	Inspection reports continue to be published via CaFC, providing useful insights for patients.	Throughout year
	Following the revised CaFC, developed through the IfQ programme, continuing to develop and improve the presentation of clinic comparison information and user experience scores, guided by patient feedback.	Published outcome data is more useful and easier to understand and sets up positive incentives for improvements. Acquisition of ongoing feedback enables us to evaluate the effectiveness and usability of the new presentation, and to plan future improvements.	March 2017

Activities	Methods and channels	Benefits and outcomes	Timescale
	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
	Information provision for researchers requesting access to Register data.	Information for researchers is provided within 90 calendar days of approval. Register information is used to best effect, to promote understanding and facilitate good research, and ultimately patient benefit.	Throughout year
	Facilitating access to information under various regimes and fulfilling Government requests.	Legal and Parliamentary requirements continue to be met within time limits.	Throughout year
	To continue to publish statistical and other reports.	<p>'Fertility treatment in 2015' report covering 2014–2015.</p> <ul style="list-style-type: none"> - Provides patients, clinic staff and others with up-to-date, high quality information about a range of topics. - 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. 	November 2016

Activities	Methods and channels	Benefits and outcomes	Timescale
		Statistical report on multiple births. <ul style="list-style-type: none"> - Provides up-to-date, high quality information on progress in reducing the incidence of multiple births following ART. 	June 2016
		Report on incidents and alerts. <ul style="list-style-type: none"> - Contributes to a culture of openness and information sharing where clinic staff are empowered to report mistakes and learn from each other. - Promotes transparency and maximises opportunities for learning from incidents to improve quality of care for patients. - Provides the sector with the most up-to-date information. 	November 2016
Maintaining collaborative information management relationships	Maintaining our good working relationships with relevant other bodies, such as the Government Digital Service (GDS) the Health and Social Care information Centre (HSCIC) and being an active member of the National Information Board (NIB).	We contribute to the objectives of the wider health system, with respect to information management. Learning from best practice and sharing expertise, so that we can make use of each other's strengths and knowledge in data management, systems integrity and security.	March 2017

Activities	Methods and channels	Benefits and outcomes	Timescale
Strategic objective 4: ensuring patients have access to high quality meaningful information			
Improved HFEA website information about treatments available, scientific research, embryo and stem cell research and other fertility subjects.	Continuing the development of new and additional content for our website (redesigned in 2015/16) to provide an expanded range of educative and scientific information about current and future treatment options, the scientific evidence associated with these, and other fertility issues.	<p>Increased information for patients and others.</p> <p>Information is accessible, engaging and meaningful.</p> <p>Patients better informed and better placed to deal with treatment issues and decisions.</p> <p>Patients feel safe and know they can expect certain standards in clinics.</p> <p>Prospective patients have clearer information and signposting.</p> <p>Patients more aware of the potential risks of new/different treatments as well as the possible benefits.</p>	March 2017
	Conducting our annual horizon scanning exercise to ensure we identify relevant new scientific developments.	<p>Policy developments and website material are informed by expert input and an understanding of scientific issues and future developments.</p> <p>Future work planning is improved by early identification of upcoming issues.</p>	March 2017
Working with clinics and scientific experts to publish information about new treatments.	Establishing mechanisms for producing and publishing informative and accurate material when new treatment options emerge, working in collaboration with clinics and experts.	<p>Increased public understanding of emerging new science and future treatment possibilities.</p> <p>Patients better informed and better placed to deal with treatment issues and decisions when emerging new treatments begin to be offered by clinics and better placed to judge the merits of any media speculation about potential new treatments.</p>	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
Enhancing the patient voice in all of our work, including information provision.	<p>Further developing our communications with, and information provided to, patients so as to help them to make informed choices about fertility matters.</p> <p>Ensuring patient feedback is continuously incorporated into our core business, for example through user experience ratings of clinics.</p>	<p>Patient views and needs are better incorporated into our work and are reflected in the style and content of the information we provide.</p> <p>There are increased feedback opportunities for patients via the website, and easier interaction with us.</p>	March 2017

Demonstrating efficiency, economy and value

Strategic objective 5: ensuring the HFEA remains demonstrably good value for the public, the sector and Government

Ensuring the HFEA is easy to deal with and offers a professional service.	Completion of the work started in 2015/16 to modernise the HFEA's Register function and processes (EDI, data submission and verification, the Clinic Portal, and the data dictionary).	<p>Reduced transactional costs for clinics and increased satisfaction.</p> <p>'Right first time' data quality.</p> <p>Reduction in unnecessary effort by clinics submitting the data.</p>	October 2016
	Continuation of the engagement arrangements with clinics on fees charged, established in 2014/15.	<p>Accountability and transparency in respect of the fees we charge clinics.</p> <p>Fees Group continues to be run effectively.</p> <p>Annual review of fees takes place.</p>	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
Ensuring the HFEA is a good value organisation and makes best use of its limited resources.	Using our strategy to prioritise our activities and manage our limited resources to best effect.	Resources are deployed in the interests of high quality care for everyone affected by assisted reproduction. Speedier service to patients when they interact directly with us. Achieving measurable 'added value' and internal efficiency.	Throughout year
	Ensuring internally provided support services run smoothly and are efficient.	Our infrastructure is effective and supports the delivery of the strategic vision. Central systems, processes and tools are efficiently run, giving good value and service.	Throughout year
	Responding to the 2015 Government Spending Review and/or the HFEA's triennial review, as required.	Ensuring the organisation is soundly run, providing best possible value, and compliant with Government targets.	Timescales not yet known
	Building and maintaining our staff capacity and skills, in line with our people strategy.	We are able to maintain the staff capacity and capability to deliver our strategy and our core statutory duties.	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
Ensuring the HFEA is an effective collaborator and partner in the interests of the efficiency of the wider Department of Health group of ALBs and other health organisations.	<p>Continuing to share 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 support services from the landlord of our office premises, via an SLA.</p>	We continue to operate in as efficient a way as possible, extracting maximum value from shared support arrangements and seeking other opportunities.	Throughout year
	Moving to new office premises, alongside other arms length bodies (ALBs).	<p>Best overall use made of Crown Estate property.</p> <p>Overall saving on accommodation achieved for the group of health ALBs as a whole, even if the HFEA's individual accommodation costs have to increase in order to enable this.</p> <p>Further shared services and efficiencies possible for and with other similar organisations in the health ALB family.</p>	April 2017 onwards
	Continued collaborative and partnership working with other ALBs and health regulators (eg, MHRA, UKAS, DH NIB)	Continued ability to address issues that require joint working in an efficient and coordinated way, or to establish the best ways of working if any new areas of regulatory overlap should arise.	Throughout year

Measuring our performance

Facts and figures

The following facts and figures give a wider picture of the type and volume of our work between 1 April 2015 and 31 March 2016. **[DN: Data is added after year end]**

Number of:	2014/15	2015/16
Active clinics and research establishments	127	
Clinics and research establishments inspected	61	
Licences inspected	62	
New licence applications processed and presented to the Licence Committee	6	
Licence renewals processed and presented to the Licence Committee/Executive Licensing Panel	35	
Applications for Human Leukocyte Antigen (HLA) testing for tissue match processed and presented to Licence Committee/Executive Licensing Panel	9	
New preimplantation genetic diagnosis (PGD) applications processed and presented to Statutory Approvals Committee	44	
Incident reports from clinics processed	453	
Alerts issued	0	
Formal complaints about clinics	9	
Opening the Register requests closed within 20 working days	260	
Donor Sibling Link applications processed	23	
Licensed Centres Panel meetings held	2	
Meetings with patient organisations held	1	
Public and stakeholder meetings	48	
Freedom of Information (FOI) requests dealt with	105	
Environmental Information Regulations (EIR) requests dealt with	0	
Enquiries responded to under the Data Protection Act (DPA)	0	
Parliamentary questions (PQs) responded to	136	
Information for researchers requests received	0	
Visits to the anonymised Register download page	462	
Unique visits to our website	1,337,484	
Most popular/viewed page on our website	IUI - What is intrauterine insemination (IUI)	

Required HR benchmarking information

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

[DN: Data is added after year end]

Very senior manager (VSM) 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

In March 2015, we revised our in-house strategic performance report so as to enable us to keep track of our performance, with a particular focus on monitoring strategic delivery. This document is presented in summary form at every Authority meeting, and the associated papers are published regularly on our [website](#).

The table below shows our performance in 2015/16 for a small sample of these indicators. We will continue to track the same indicators, and more, throughout 2016/17.

[DN: Data is added after year end.]

Performance indicator	Target for 2015/16	Performance
Setting standards		
Average number of critical/major recommendations at clinics in inspection reports that were considered by ELP/LC.	This indicator is for monitoring purposes and does not have an associated target. In 2015/16 we plan to focus on the timeliness with which inspection recommendations are met after non-compliances are identified.	xx critical xxx major (from xx inspections during the year)
Percentage of Opening the Register requests responded to within 20 working days.	100% of complete OTR requests to be responded to within 20 working days (excluding counselling time).	xxx% (xx no. of requests)
Increasing and informing choice		
Percentage of finalised Licence Committee, SAC, representations hearing and ELP decisions published on HFEA website within five working days of Chair sign-off.	100% published within five working days of Chair sign-off.	x% (x items published, of which x were published within the target)
Number of emailed public enquiries successfully responded to.	No target, since the nature, volume and complexity of enquiries received varies widely.	X,xxx
Efficiency, economy and value		
Average number of working days taken for the whole licensing process, from the day of inspection to the decision being communicated to the centre.	Less than or equal to 70 working days.	Average for year = xx.x working days Range: xx-xx working days
Cash and bank balance.	To move closer to minimum £1,520k cash reserves.	Year start = £2,038k Year end = £xxxxxxk

Financial picture

[DN: this section is written in December, following initial discussions with the Department of Health.]

The high level budget for 2016/17 is shown below.

Income	£000s
Department of Health funding	x
Treatment and licence fees	x
Other income	x
Total income	x
Operating costs, of which	x
Staff costs	x
Other operating costs	x
Total operating costs	x
Capital charges	x
Total revenue expenditure	x

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 arms length bodies (ALBs).

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

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

Organisational structure and establishment

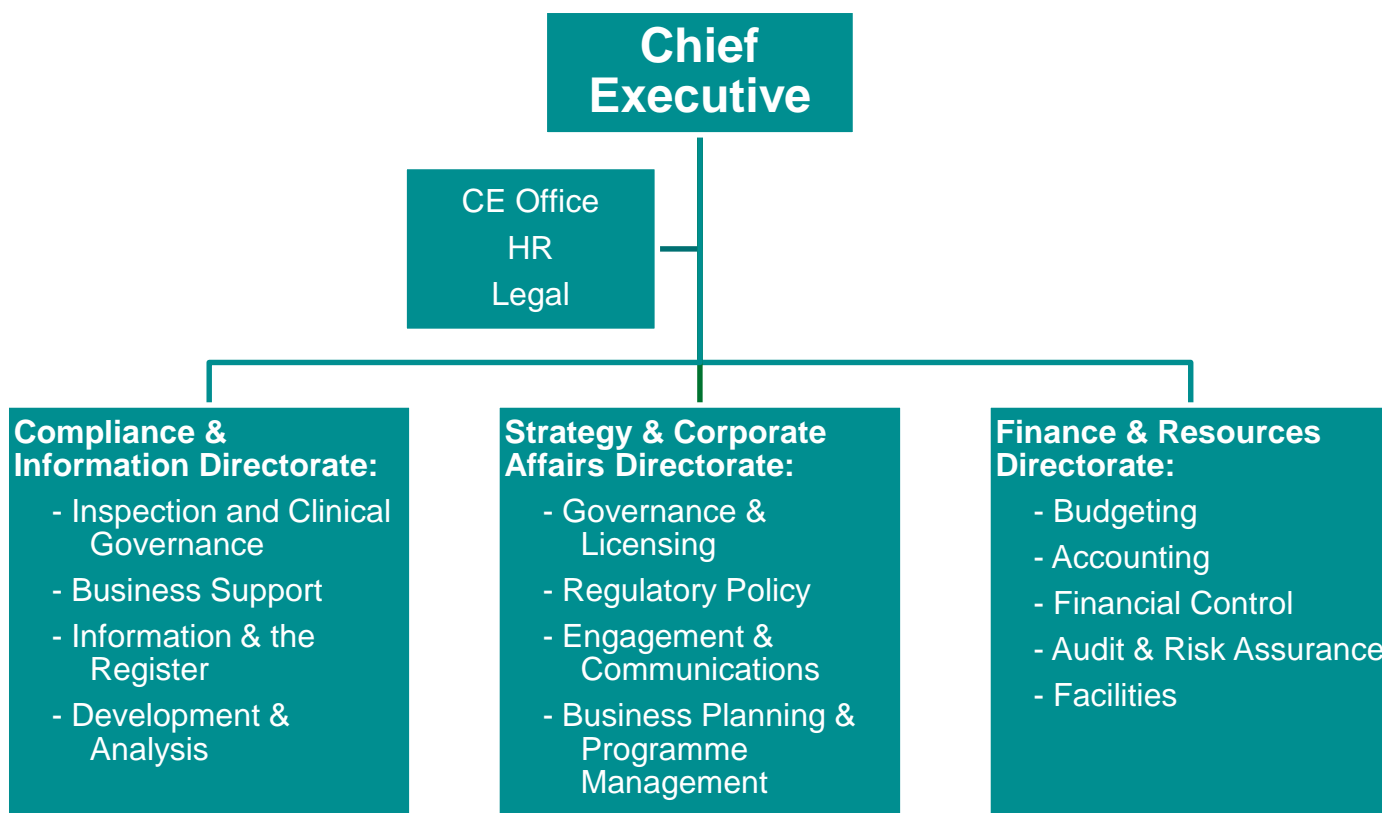
Over the past few years the HFEA has significantly reduced its staffing, in keeping with overall pressures on the public sector and Government expectations. Our staff complement has reduced from 86 in 2010/11 down to 67 2015/16. We have put in place shared services arrangements with other bodies, where feasible. For example, we share part of our finance and resources team staffing with the HTA, our facilities management service is provided by the CQC (since we currently occupy the same premises, although this is likely to change in 2016/17) and we also have a shared services agreement with CQC for recruitment. We believe we have reached a point where, having made considerable savings, our size will now need to remain stable for the foreseeable future. Our people strategy, published in 2015, sets out how we will ensure we retain the capability and capacity to deliver our overall strategy for 2014–2017.

Our learning and development activities continue to equip our staff with the skills they need. Services are procured in accordance with continuing Government requirements to ensure value for money, using Civil Service Learning, and their associated suppliers, or other ALB provision, as appropriate.

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

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

The following diagram shows our current organisational structure.



Financial management systems

We continue to maintain sound financial governance and business planning processes. We will continue to manage our processes efficiently and to 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

interest within the Department of Health 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 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 support the significant databases we hold.

HFEA databases are currently held on highly secure servers within the premises. While we occupy the same premises as the CQC, 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).

Since we are likely to move offices during the course of the coming year, we developed, in March 2015, an IT strategy for the future. This includes making new secure arrangements for our servers, while adhering to any applicable central Government requirements at the time.

The robust information security arrangements the HFEA has in place, in line with the information governance toolkit, include a security policy for staff, secure and confidential storage of and limited access to Register information and stringent data encryption standards. All staff complete the annual mandatory

training on information security and new starters complete this on their first day of employment before starting work.

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

Business continuity

We further developed our business continuity plan in 2014/15 to ensure it remained fit for purpose. The plan is regularly updated and periodically tested. There is an operational disaster recovery site available if needed.

We currently have an interdependency with the CQC with regards to building-related and system matters. Assuming our office move goes ahead early in the 2016/17 financial year, as anticipated, business continuity will be considered afresh in collaboration with other relevant ALBs.

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.

Our current office space of 525 square metres includes flexible hot desking and we previously rezoned the office (in 2013/14) to enable better use of space (with smaller desks).

Our tenancy with the CQC will end when the CQC moves completely from the Finsbury Tower in 2016. Until the resulting office move takes place, the HFEA and the CQC will continue to work together on health and safety services. We have adopted the CQC's online system for individual workplace assessment and meet with the CQC lead on fire evacuation procedures and fire warden liaison. Similarly, new, arrangements will be put in place as appropriate in our new premises.

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) that are pre-set to print on both sides of the paper and in black-and-white. Our IT equipment is re-used and working lives extended where possible and is switched off when not in use. Surplus equipment is either sold or donated. A proportion of our staff are able to work from home, allowing reduced travel impacts.

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. Where we are the purchaser, we procure the mandated procurement categories from Government or other public sector frameworks: energy (N/A), office solutions, travel, fleet (N/A), professional services, eEnablement, property (N/A), ICT, advertising and media, print and print management, learning and development, legal services and conference and events bookings. These frameworks were first established in 2011.

We are aware of the green agenda in relation to procurement. However, we rarely set our own contract terms or purchases 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 public sector procurement target of 18% of procurement spend going to SMEs but we are dependent (as with sustainability) on CCS ensuring that SME suppliers are present on the relevant frameworks in the first place. Where we have a choice of supplier, our criteria do include both sustainability and SME usage.

We are too small to have a procurement pipeline. The only procurement of significance in 2016/17 will relate to the IfQ programme, which has been subject to specific business cases agreed by the Department of Health and the Government Digital Service through various robust mechanisms. All related procurement in 2015/16 has been conducted using CCS frameworks and with close CCS oversight. There will be no procurements over £100,000 in 2016/17.

There is no significant non-pay spend that is not via CCS, CQC 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 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.

Strategic risk register

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

Details:

Meeting Authority

Agenda item 8

Paper number HFEA (11/10/2015) 775

Meeting date 11 November 2015

Author Paula Robinson, Head of Business Planning

Output:

For information or decision? For information

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

Resource implications In budget

Implementation date Ongoing

Communication(s) The risk register is reviewed quarterly by the Corporate Management Group (CMG), and presented at every Audit and Governance Committee (AGC) meeting. AGC reviewed the risk register at its meeting on 7 October.

Organisational risk Low Medium High

Annexes Annex 1: Strategic risk register

1. Latest reviews

- 1.1. CMG reviewed the risk register at its meeting on 2 September. Five of the twelve risks remain above tolerance. CMG reviewed all risks, controls and scores. CMG's specific comments are contained in the risk register at Annex A.
- 1.2. The risk register was also discussed at AGC on 7 October. No changes were proposed. AGC also noted progress towards implementing risk assurance mapping in the HFEA, which will be taken forward early next year as part of the internal audit programme, with the support of the Department of Health internal audit team.

2. Recommendation

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

Annex A - HFEA strategic risk register 2015/16

Risk summary: high to low residual risks

Risk area	Risk title	Strategic linkage ¹	Residual risk	Current status	Trend*
Legal challenge	LC1: Resource diversion	Efficiency, economy and value	15 – High	Above tolerance	↔↔↔↔
Information for Quality	IfQ1: Improved information access	Increasing and informing choice: information	12 – High	Above tolerance	↔↔↔↔
Data	D2: Incorrect data released	Efficiency, economy and value	12 – High	Above tolerance	↔↔↔↔
Financial viability	FV1: Income and expenditure	Efficiency, economy and value	12 – High	Above tolerance	↔↔↔↔
Data	D1: Data loss or breach	Efficiency, economy and value	10 – Medium	At tolerance	↔↔↔↔
Information for Quality	IfQ3: Delivery of promised efficiencies	Efficiency, economy and value	9 – Medium	At tolerance	↔↔↔↔
Donor conception	DC2: Support for OTR applicants	Setting standards: donor conception	9 – Medium	At tolerance	↔↔↔↔
Capability	C1: Knowledge and capability	Efficiency, economy and value	9 – Medium	Above tolerance	↓↔↔↔
Regulatory model	RM2: Loss of regulatory authority	Setting standards: quality and safety	8 – Medium	At tolerance	↔↔↔↔
Information for Quality	IfQ2: Register data	Increasing and informing choice: Register data	8 – Medium	At tolerance	↔↔↔↔
Donor conception	DC1: OTR inaccuracy	Setting standards: donor conception	4 – Low	At tolerance	↔↔↔↔
Regulatory model	RM1: Quality and safety of care	Setting standards: quality and safety	4 – Low	Below tolerance	↓↔↔↔

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

Recent review points:

CMG 20 May 2015 ⇒ AGC 10 June 2015 ⇒ CMG 2 September 2015 ⇒ AGC 7 October

¹ Strategic objectives 2014-2017:

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

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

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

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

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

CMG overview

CMG reviewed the risk register and discussed each risk in detail at its meeting on 2 September.

In addition, CMG recognised that the office move, which will most likely occur in April 2016, will present certain risks, and may interact with risks and controls already listed. As soon as we have confirmation of the move date and location, the move will be explicitly added to the risk register, either as a separate risk, or as a specific source/cause of risk in relation to several of our existing strategic risks. It is already mentioned in several places, but not yet in any detail.

Since CMG met, the Family Court has passed judgement on several cases where consents to legal parenthood were in doubt. That judgement may have administrative consequences for the HFEA. Further cases can be expected over the coming months, although the HFEA is unlikely to participate in legal proceedings directly. Nonetheless, a decision has been taken that the impact of this work ought to be reflected in the legal challenge risk (LC1), and accordingly the risk score for the likelihood component of the residual risk has been increased to 3 (having been briefly reduced to 2 following the conclusion of another outstanding case). This means that this risk, which briefly dipped within tolerance, is now above tolerance.

AGC noted the above information at its meeting on 7 October. Controls and risk management for IfQ were discussed briefly, following an earlier item covering latest IfQ developments in greater depth. No changes were proposed to scores and tolerances.

Criteria for inclusion of risks:

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

Rank

Risks are arranged above in rank order according to the severity of the current residual risk score.

Risk trend

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

Risk scoring system

See last page.

Assessing inherent risk

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

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

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Regulatory model RM 1: Quality and safety of care	There is a risk of adverse effects on the quality and safety of care if the HFEA were to fail to deliver its duties under the HFE Act (1990) as amended.	Setting standards: improving the quality and safety of care through our regulatory activities.	Inherent risk level:			↓ ↔ ↔ ↔	Peter Thompson
			Likelihood	Impact	Inherent risk		
			3	5	15 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			1	4	4 Low		
Tolerance threshold:			8 Medium				
Causes/sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Inspection/reporting failure.		Inspections are scheduled for the whole year, using licence information held on Epicentre, and items are also scheduled to committees well in advance.	In place – Debra Bloor		Below tolerance.		
		Audit of Epicentre to reveal any data errors. All queries being routed through Licensing, who have a definitive list of all licensing details.	Due for completion October 2015 – Sam Hartley (report and recommendations to October CMG)				
		Inspector training, competency-based recruitment, induction process, SOPs, QMS, and quality assurance all robust.	In place – Debra Bloor				
Monitoring failure.		Outstanding recommendations from inspection reports are tracked and followed up by the team.	In place – Debra Bloor				
Unresponsiveness to or mishandling of non-compliances or grade A incidents.		Update of compliance and enforcement policy.	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - Debra Bloor				
		Staffing model changed to increase resilience in inspection team for such events – dealing with high-impact cases, additional incident inspections, etc..	In place – Debra Bloor – May 2015				
Insufficient inspectors or licensing staff		Inspection team up to complement following several recruitments.	In place – Debra Bloor				
		Licensing team up to complement following recruitment.	In place – Sam Hartley				

Recruitment difficulties and/or high turnover/churn in various areas; resource gaps and resource diversion into recruitment and induction, with impacts felt across all teams.	So far recruitment rounds for inspectors and support staff have yielded sufficient candidates, although this has required going beyond the initial ALB pool to external recruitment in some cases.	Managed as needed – Debra Bloor
	Additional temporary resources available during periods of vacancy and transition.	In place – Rachel Hopkins
	Group induction sessions put in place where possible.	In place – Debra Bloor
Resource strain itself can lead to increased turnover, exacerbating the resource strain.	Operational performance, risk and resourcing oversight through CMG, with deprioritisation or rescheduling of work an option.	In place – Paula Robinson
Unexpected fluctuations in workload (arising from eg, very high level of PGD applications received, including complex applications involving multiple types of a condition; high levels of non-compliances either generally or in relation to a particular issue).	Staffing model developed (May 2015), to release an extra inspector post out of the previous establishment. This increased general resilience so as to enable more flex when there is an especially high inspection/report writing/application processing workload (as there is, so far in 2015).	In place – Debra Bloor
	PGD workshop annually (or biannually, as appropriate) with the sector to increase their insight into our PGD application handling processes and decision-making steps; coupled with our increased processing times from efficiency improvements made in 2013 (acknowledged by the sector).	In place – Debra Bloor
Some unanticipated event occurs that has a big diversionary impact on key resources, eg, several major Grade A incidents occur at once.	Addressed by revised staffing model.	In place – Debra Bloor
	Update of compliance and enforcement policy.	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - Debra Bloor

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Regulatory model RM 2: Loss of regulatory authority	There is a risk that the HFEA could lose authority as a regulator, jeopardising its regulatory effectiveness, owing to a loss of public / sector confidence.	Setting standards: improving the quality and safety of care through our regulatory activities.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Peter Thompson
			Likelihood	Impact	Inherent risk		
			3	5	15 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			2	4	8 Medium		
Tolerance threshold:			8 Medium				
Causes/sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Failures or weaknesses in decision making processes.		Keeping up to date the standard operating procedures (SOPs) for licensing, representations and appeals.	In place – Sam Hartley		At tolerance.		
		Learning from recent representations and Appeal Committee experience incorporated into processes.	In place – Sam Hartley				
		Appeals Committee membership maintained – vacancy filled earlier in year; 4 new members recruited in September. Ongoing process in place for regular appointments whenever vacancies occur or terms of office end.	In place – Sam Hartley				
		Staffing structure for sufficient committee support.	In place – Sam Hartley				
		Decision trees; legal advisers familiar.	In place – Sam Hartley				
		Proactive management of quoracy for meetings.	In place – Sam Hartley				
		New (ie, first application) T&S licences delegated to ELP. Delegations to be revisited during 2016 review of Standing Orders. Licensing Officer role to take certain decisions from ELP – implementation due end of 2015.	To be put in place – Sam Hartley Licensing Officer role – December 2015 (postponed from June 2015) Delegations in SOs – April 2016				
		Failing to demonstrate competence as a regulator	Update of compliance and enforcement policy.	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - Debra Bloor			

	Inspector training, competency-based recruitment, induction process, SOPs, quality management system (QMS) and quality assurance all robust.	In place – Debra Bloor
Effect of publicised grade A incidents.	Staffing model changed (May 2015) to build resilience in inspection team for such events – dealing with high-impact cases, additional incident inspections, etc.	In place – Debra Bloor
	SOPs and protocols with Communications team.	In place – Debra Bloor
	Fairness and transparency in licensing committee information.	In place – Debra Bloor
	Dedicated section on website, so that the public can openly see our activities in the broader context.	In place – Debra Bloor
Administrative or information security failure, eg, document management, risk and incident management, data security.	Staff have annual information security training (and on induction).	In place – Dave Moysen
	TRIM training and guidance/induction in records management in place. Head level 6 month contract to be recruited to manage the office move and review records management.	In place – SMT Head post recruitment in progress September 2015 - SMT
	The IfQ website management project has reviewed the retention schedule.	Completed – August 2015 – Juliet Tizzard
	Guidance/induction in handling FOI requests, available to all staff.	In place – Sam Hartley
	Further work to be planned on records management in parallel with IT strategy	Linked to IT strategy work – in progress – Dave Moysen/Sam Hartley
Negative media or criticism from the sector in connection with legally disputed issues or major adverse events at clinics.	HFEA approach is only to go into cases on the basis of clarifying legal principles or upholding the standards of care by challenging poor practice. This is more likely to be perceived as proportionate, rational and necessary (and impersonal), and is in keeping with our strategic vision.	In place - Peter Thompson
HFEA process failings that create or contribute to legal challenges, or which weaken cases that are otherwise sound.	Licensing SOPs, committee decision trees in place. Mitochondria tools in development.	Existing tools in place; mitochondria tools due by October 2015 – Sam Hartley

Update of compliance and enforcement policy.	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - Debra Bloor
QMS and quality assurance in place in inspection team.	In place – Debra Bloor

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
IfQ IfQ 1: Improved information access	If the information for Quality (IfQ) programme does not enable us to provide better information and data, and improved engagement channels, patients will not be able to access the improved information they need to assist them in making important choices.	Increasing and informing choice: ensuring that patients have access to high quality meaningful information.	Inherent risk level:			↔ ↔ ↔ ↔	Juliet Tizzard
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	4	12 High		
Tolerance threshold:			8 Medium				
Causes/ sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Inability to extract reliable data from the Register.		Detailed planning and programme management in place to ensure this will be possible after migration. Migration strategy developed, and significant work being done to identify all of the data that will require correction before migration can be done. Decisions are being made about the degree of reliability required in each data field. For those fields where 100% reliability is needed, inaccurate or missing data will be addressed as part of project delivery.	All aspects – detailed project planning in place – Nick Jones		Above tolerance. Managing these risks has formed an intrinsic and essential part of the detailed project planning and tendering, throughout. Following a lengthy delay, we received formal approval for both the data and digital elements of IfQ in late April 2015. The digital side of the programme has received only partial approval; full delivery will still require additional approvals after the first phase of work. There is a risk that this could lead to further long delays which would have a further		
Unable to work out how best to improve CaFC, and/or failure to find out what data/information patients really need.		Stakeholder engagement and user research is in place as intrinsic part of programme approach. This was elaborated further during sprint 1, in Aug/Sept 2015.	In place and ongoing – Dec 2014 onwards – Nick Jones				
Stakeholders not on board with the changes.		In-depth stakeholder engagement to inform the programme's intended outcomes, products and benefits – including user research consultation, expert groups and Advisory Board.	In place and ongoing – Juliet Tizzard / Nick Jones				
Cost of delivering better information becomes too prohibitive.		Costs were taken into account as an important factor in consideration of contract tenders and negotiations.	In place and now completed – Dec 2014 to June 2015 – Nick Jones				

Redeveloped website does not meet the needs and expectations of our various user types.	<p>Programme approach and dedicated resources in place to manage the complexities of specifying web needs, clarifying design requirements and costs, managing changeable Government delegation and permissions structures, etc.</p> <p>User research done, to properly understand needs and reasons.</p> <p>Tendering and selection process included clear articulation of needs and expectations.</p>	In progress – delivery by end Mar 2016 – Juliet Tizzard	negative impact. This would adversely affect the quality of the final product (rather than the existence of a final product).
Government and DH permissions structures are complex, lengthy, multi-stranded, and sometimes change mid-process.	<p>Initial external business cases agreed and user research completed.</p> <p>Final business case for whole IfQ programme was submitted and eventually accepted.</p>	<p>In place (Nov 2014) – Juliet Tizzard</p> <p>In place (Dec 2014) – Nick Jones (decision received April 2015)</p>	
Resource conflicts between delivery of website and business as usual (BAU).	Backfilling to free up the necessary staff time, eg, Websites and Publishing Project Manager post backfilled to free up core staff for IfQ work.	In place – Juliet Tizzard	
Delivery quality will be very supplier dependent. It is also likely to involve multiple different suppliers and could become very resource-intensive for staff, or the work delivered by one or more suppliers could be poor quality and/or overrun, causing knock-on problems for other suppliers.	<p>Programme management resources and quality assurance mechanisms in place for IfQ to manage (among other things) contractor delivery.</p> <p>Agile project approach includes a 'one team' ethos and requires close joint working and communication among all involved contractors during the Sprint Zero start-up phase. Sound project management practices in place to monitor.</p> <p>Previous lessons learned and knowledge exist in the organisation from managing some previous projects where poor supplier delivery was an issue requiring significant hands-on management.</p> <p>Ability to consider deprioritising other work, through CMG, if necessary.</p>	In place – Juliet Tizzard	
New CMS (content management software) is ineffective or unreliable.	CMS options being scrutinised as part of project.	In progress – December 2015 – Juliet Tizzard	
Communications infrastructure incapable of supporting the planned changes.	Needs to be updated as part of IfQ in order to support the changes.	In place – set out in business case – Juliet Tizzard (Dec 2014)	

Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedding into new ways of working.	In place (June 2015) – Nick Jones
Potential risks associated with the HFEA's likely office move in April 2016, in that this will coincide with the delivery period for some IfQ milestones.	Early awareness of the potential for disruption means that this can be managed through careful planning.	For further thought once there is certainty about the timetable for the move (September 2015) – Nick Jones/Sue Gallone

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
IfQ IfQ 2: Register data	HFEA Register data becomes lost, corrupted, or is otherwise adversely affected during IfQ programme delivery.	Increasing and informing choice: using the data in the Register of Treatments to improve outcomes and research.	Inherent risk level:			↔ ↔ ↔ ↔	Nick Jones
			Likelihood	Impact	Inherent risk		
			2	5	10 Medium		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			2	4	8 Medium		
Tolerance threshold:			8 Medium				
Causes/ sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Risks associated with data migration to new structure, together with records accuracy and data integrity issues.		IfQ programme groundwork focusing on current state of Register. Intensive planning in progress, including detailed research and migration strategy.	In place – Nick Jones/Dave Moysen		At tolerance. This risk is being intensively managed – a major focus of IfQ detailed planning work, particularly around data migration.		
Historic data cleansing is needed prior to migration.		A detailed migration strategy is in place, and a data cleansing step forms part of this (the migration itself will occur later).	In place – Nick Jones/Dave Moysen				
Increased reporting needs mean we later discover a barrier to achieving this, or that an unanticipated level of accuracy is required, with data or fields which we do not currently focus on or deem critical for accuracy.		IfQ planning work incorporates consideration of fields and reporting needs are agreed. Decisions about the required data quality for each field were ‘future proofed’ as much as possible through engagement with stakeholders to anticipate future needs and build these into the design.	In place – Nick Jones				
Reliability of existing infrastructure systems – (eg, Register, EDI, network, backups).		Maintenance of desktop, network, backups, etc. core part of IT business as usual delivery.	In place – Dave Moysen				
System interdependencies change / are not recognised		Strong interdependency mapping being done between IfQ and business as usual.	Done (April 2015) – Nick Jones				
Benefits not maximised and internalised into ways of working.		During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedding into new ways of working.	In place (June 2015) – Nick Jones				

Potential risks associated with the HFEA's likely office move in April 2016, in that this will coincide with the delivery period for some IfQ milestones.

Early awareness of the potential for disruption means that this can be managed through careful planning.

For further thought once there is certainty about the timetable for the move (September 2015) – Nick Jones/Sue Gallone

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
IfQ IfQ 3: Delivery of promised efficiencies	There is a risk that the HFEA's promises of efficiency improvements in Register data collection and submission are not ultimately delivered.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			↔ ↔ ↔ ↔	Nick Jones
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	3	9 Medium		
Tolerance threshold:			9 Medium				
Causes/ sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Poor user acceptance of changes, or expectations not managed.		Stakeholder involvement strategy in place and user testing being incorporated into implementation phase of projects.	In place – Nick Jones/Juliet Tizzard		At tolerance.		
Clinics not consulted/involved enough.		Working with stakeholders has been central to the development of IfQ, and will continue to be. Advisory Group and expert groups have ended, but a stakeholder group for the implementation phase is in place.	In place – Nick Jones/Juliet Tizzard				
Scoping and specification are insufficient for realistic resourcing and on-time delivery of changes.		Scoping and specification were elaborated with stakeholder input, so as to inform the tender. Resourcing and timely delivery were a critical part of the decision in awarding the contract.	In place and contracts awarded – Nick Jones – July 2015				
Efficiencies cannot, in the end, be delivered.		Detailed scoping phase included stakeholder input to identify clinic users' needs accurately. Specific focus in IfQ projects on efficiencies in data collected, submission and verification, etc.	In place – Nick Jones				
Cost of improvements becomes too prohibitive.		Contracts only awarded to bidders who made an affordable proposal.	In place (July 2015) – Nick Jones				

Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedding into new ways of working.	In place (June 2015) – Nick Jones	
Potential risks associated with the HFEA's likely office move in April 2016, in that this will coincide with the delivery period for some IfQ milestones.	Early awareness of the potential for disruption means that this can be managed through careful planning.	For further thought once there is certainty about the timetable for the move (October 2015) – Nick Jones/Sue Gallone	

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Legal challenge LC 1: Resource diversion	There is a risk that the HFEA is legally challenged in such a way that resources are diverted from strategic delivery.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Peter Thompson
			Likelihood	Impact	Inherent risk		
			4	5	20 Very high		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
3	5	15 High					
Tolerance threshold:			12 High				
Causes/sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Complex and controversial area.		Panel of legal advisors from various firms at our disposal for advice, as well as in-house Head of Legal.	In place – Peter Thompson		Above tolerance. One case decided in the HFEA's favour at summary judgement, but is now to be appealed. Appeal completed in September (the decision was to award the licence).		
		Evidence-based policy decision-making and horizon scanning for new techniques.	In place – Hannah Verdin				
		Robust and transparent processes in place for seeking expert opinion – eg, external expert advisers, transparent process for gathering evidence, meetings minuted, papers available online.	In place – Hannah Verdin/Sam Hartley				
Lack of clarity in HFE Act and regulations, leading to the possibility of there being differing legal opinions from different legal advisers, that then have to be decided by a court.		Panel in place, as above, to get the best possible advice.	In place – Peter Thompson		A recent judgement on consents for parenthood may have administrative consequences for the HFEA. Further court cases are also likely, although the HFEA is unlikely to participate in legal proceedings directly.		
Decisions and actions of the HFEA and its committees may be contested.		Panel in place, as above.	In place – Peter Thompson				
		Maintaining, keeping up to date and publishing licensing SOPs, committee decision trees etc. Standard licensing pack completely refreshed and distributed to members/advisers April 2015.	In place – Sam Hartley				

Subjectivity of judgments means the HFEA often cannot know in advance which way a ruling will go, and the extent to which costs and other resource demands may result from a case.	Scenario planning is undertaken at the initiation of any likely action.	In place – Peter Thompson
HFEA could face unexpected high legal costs or damages which it could not fund.	Discussion with the Department of Health would need to take place regarding possible cover for any extraordinary costs, since it is not possible for the HFEA to insure itself against such an eventuality, and not reasonable for the HFEA's small budget to include a large legal contingency.	In place – Peter Thompson
Legal proceedings can be lengthy and resource draining.	Panel in place, as above, enabling us to outsource some elements of the work.	In place – Peter Thompson
	Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise work should this become necessary.	In place – Peter Thompson
Adverse judgments requiring us to alter or intensify our processes, sometimes more than once.	Licensing SOPs, committee decision trees in place.	In place – Sam Hartley.

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

Business continuity issue.	BCP in place and staff communication procedure tested. A period of embedding the policies is now in progress.	In place (January 2015) – Sue Gallone
Register data becomes corrupted or lost somehow.	Back-ups and warehouse in place to ensure data cannot be lost.	In place – Nick Jones/Dave Moysen
Other HFEA data (system or paper) is lost or corrupted.	As above. Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality.	In place – Dave Moysen

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Data D 2: Incorrect data released	There is a risk that incorrect data is released in response to a Parliamentary question (PQ), or a Freedom of Information (FOI) or data protection request.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			↔ ↔ ↔ ↔	Juliet Tizzard
			Likelihood	Impact	Inherent risk		
			5	4	20 Very high		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
	3	4	12 High				
Tolerance threshold:			8 Medium				
Causes/ sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Poor record keeping		Refresher training and reminders about good records management practice. Head level 6 month contract to be recruited to manage the office move and review records management.	In place – SMT Head post recruitment in progress September 2015 - SMT		Above tolerance. Although we have some good controls in place for dealing with PQs and other externally generated requests, it should be noted that we cannot control incoming volumes, which in January 2015 were among the highest we have ever experienced. It is not yet possible to tell if further high volumes will occur during the mitochondria project and the subsequent start-up of applications processing.		
		TRIM review and retention policy implementation work – subsumed by IT strategy.	To sync in with IT strategy – Dave Moysen/Sam Hartley				
		Audit of Epicentre to reveal any data errors. All queries being routed through Licensing, who have a definitive list of all licensing details.	Completed October 2015 – Sam Hartley				
Excessive demand on systems and over-reliance on a few key expert individuals – request overload – leading to errors		PQs, FOIs and OTRs have dedicated expert staff/teams to deal with them. If more time is needed for a complex PQ, attempts are made to take the issue out of the very tightly timed PQ process and replace this with a more detailed and considered letter back to the enquirer so as to provide the necessary level of detail and accuracy in the answer. We also refer back to previous answers so as to give a check, and to ensure consistent presentation of similar data.	In place – Juliet Tizzard / Nick Jones				
		PQ SOP revised and log created, to be maintained by new Committee and Information Officer/Scientific Policy Manager	In place - Sam Hartley				

Answers in Hansard may not always reflect advice from HFEA.	The PQ team attempts to catch any changes to drafted wording that may unwittingly have changed the meaning. HFEA's suggested answer and DH's final submission both to be captured in new PQ log.	In place – Sam Hartley / Peter Thompson
Insufficient understanding of underlying system abilities and limitations, and/or of the topic or question, leading to data being misinterpreted or wrong data being elicited.	As above – expert staff with the appropriate knowledge and understanding in place.	In place – Juliet Tizzard / Nick Jones
Servicing data requests for researchers - poor quality of consents obtained by clinics for disclosure of data to researchers.	There is a recognised risk of centres reporting research consents inaccurately. Work to address consent reporting issues is being planned.	Actions to be confirmed end of September – Nick Jones

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Donor conception DC 1: OTR inaccuracy	There is a risk that an OTR applicant is given incorrect data.	Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Nick Jones
			Likelihood	Impact	Inherent risk		
			3	5	15 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			1	4	4 Low		
Tolerance threshold:			4 Low				
Causes/ sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Data accuracy in Register submissions.		Continuous work with clinics on data quality, including current verification processes, steps in the OTR process, regular audit alongside inspections, and continued emphasis on the importance of life-long support for donors, donor-conceived people and parents.	In place – Nick Jones		At tolerance (which is very low for this risk).		
		Audit programme to check information provision and accuracy.	In place – Nick Jones				
		IfQ work will identify data accuracy requirements for different fields as part of the migration process, and will establish more efficient processes.	In progress – June-September 2015 – Nick Jones				
		If subsequent work or data submissions reveal an unpreventable earlier inaccuracy (or an error), we explain this transparently to the recipient of the information, so it is clear to them what the position is and why this differs from the earlier provided data.	In place – Nick Jones				
Issuing of wrong person's data.		OTR process has an SOP that includes specific steps to check the information given and that it relates to the right person.	In place – Nick Jones				
Process error or human error.		As above.	In place – Nick Jones				

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Donor conception DC 2: Support for OTR applicants	There is a risk that inadequate support is provided for donor-conceived people or donors at the point of making an OTR request.	Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.	Inherent risk level:			↔ ↔ ↔ ↔	Nick Jones
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
3	3	9 Medium					
Tolerance threshold:			9 Medium				
Causes/ sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Lack of counselling availability for applicants.		Counselling service pilot established with external contractor in place.	In place (June 2015) – Nick Jones		At tolerance.		
Insufficient Register team resource to deal properly with OTR enquiries and associated conversations.		Additional member of staff dedicated to handling such enquiries.	In place – Nick Jones		The pilot counselling service has been in place since 1 June, and we will make further assessments based on early uptake and the delivery experience. Reporting to the Authority will occur annually during the pilot period.		
Risk of inadequate handling of a request.		Trained staff, SOPs and quality assurance in place.	In place – Nick Jones				
		SOPs reviewed by Register staff, CMG and PAC-UK, as part of the pilot set-up. Contract in place with PAC-UK for pilot delivery.	Done (May 2015) – In June the ongoing management of the Pilot transferred to Rosetta Wotton.				

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Financial viability FV 1: Income and expenditure	There is a risk that the HFEA could significantly overspend (where significantly = 5% of budget, £250k)	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Sue Gallone
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			4	3	12 High		
Tolerance threshold:			9 Medium				
Causes/ sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Fee regime makes us dependent on sector activity levels.		Activity levels are tracked and change is discussed at CMG, who would consider what work to deprioritise and reduce expenditure.	Monthly (on-going) – Sue Gallone		Above tolerance, but 2014/15 overspend was able to be met from reserves.		
		Fees Group created enabling dialogue with sector about fee levels.	In place. First meeting took place on 29-10-14; and Apr and Oct each year, ongoing – Sue Gallone				
GIA funding could be reduced due to changes in Government/policy		A good relationship with DH Sponsors, who are well informed about our work and our funding model.	Quarterly meetings (on-going) – Sue Gallone				
		Annual budget agreed with DH Finance team alongside draft business plan submission.	December annually – Sue Gallone				
		Budget confirmation for 2015/16 obtained March 2015. Capital allocation agreed as requested, in June 2015.	In place – Sue Gallone				
Budget setting process is poor due to lack of information from directorates		Quarterly meetings with directorates flags any short-fall or further funding requirements.	Quarterly meetings (on-going) – Morounke Akingbola				
Unforeseen increase in costs eg, legal, IfQ or extra in-year work required		Use of reserves, up to contingency level available. DH kept abreast of current situation and are a final source of additional funding if required.	Monthly – Sue Gallone				
		IfQ Programme Board regularly reviews the budget and costs.	Monthly – IfQ Programme Board				

Upwards scope creep during projects, or emerging during early development of projects eg, IfQ.	Finance presence at Programme Board (PB) level. Periodic review of actual and budgeted spend by PB.	Ongoing – Wilhelmina Crown
	Cash flow forecast updated.	Monthly (on-going) – Morounke Akingbola

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Capability C 1: Knowledge and capability	There is a risk that the HFEA experiences unforeseen knowledge and capability gaps, threatening delivery of the strategy.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			↓ ↔ ↔ ↔	Peter Thompson
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	3	9 Medium		
Tolerance threshold:			6 Medium				
Causes/ sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
High turnover, sick leave etc. leading to temporary knowledge loss and capability gaps.		People strategy will partially mitigate. Mixed approach of retention, staff development, and effective management of vacancies and recruitment processes.	Done – May 2015 – Rachel Hopkins		Above tolerance. This risk and the set of controls remains focused on capability, rather than capacity. There are obviously some linkages, since managing turnover and churn also means managing fluctuations in capability and ensuring knowledge and skills are successfully nurtured and/or handed over. When the period of highest turnover appeared to be ending (May 2015), CMG reduced (slightly) the likelihood of this risk, but still decided to retain it, given that high turnover could recur. In May 2015, CMG also reviewed the tolerance level for this risk, and agreed it should		
A programme of development work is planned to ensure staff have the skills needed, so as to ensure they and the organisation are equipped under any future model, maximising our resilience and flexibility as much as possible. Staff can access civil service learning (CSL); organisational standard is five working days per year of learning and development for each member of staff.		In place – Rachel Hopkins					
Organisational knowledge captured via records management (TRIM), case manager software, project records, handovers and induction notes, and manager engagement.		In place – Rachel Hopkins					

<p>The new UK government may implement further cuts across all ALBs, resulting in further staffing reductions. This would lead to the HFEA having to reduce its workload in some way.</p>	<p>The HFEA has already been proactive in reducing its headcount and other costs to minimal levels over a number of years. We have also already been reviewed extensively (including the McCracken review). Although turnover is currently reducing to more normal levels, this risk will be retained on the risk register, and will continue to receive ongoing management attention.</p>	<p>In place – Peter Thompson</p>	<p>remain at 6. Since the HFEA has become a much smaller organisation over the past few years, leaving less intrinsic resilience, it seems prudent to have a low tolerance for this risk.</p>
<p>Poor morale leading to decreased effectiveness and performance failures.</p>	<p>Engagement with the issue by managers. Ensuring managers have team meetings and one-to-one meetings to obtain feedback and identify actions to be taken.</p>	<p>In place – Peter Thompson</p>	
	<p>Staff survey and implementation of outcomes, following up on Oct 2014 all staff conference.</p>	<p>Survey done (Jan 2015) – Rachel Hopkins Follow-up communications in place (Staff Bulletin etc.) – Peter Thompson</p>	
<p>Differential impacts of IfQ-related change and other pressures for particular teams could lead to specific areas of knowledge loss and low performance.</p>	<p>Staff kept informed of likely developments and next steps, and when applicable of personal role impacts and choices.</p>	<p>In place – Nick Jones</p>	
	<p>Policies and processes to treat staff fairly and consistently, particularly if people are ‘at risk’.</p>	<p>In place – Peter Thompson</p>	
<p>Additional avenues of work open up, or reactive diversions arise, and need to be accommodated alongside the major IfQ programme.</p>	<p>Careful planning and prioritisation of both business plan work and business flow through our Committees. Regular oversight by CMG.</p>	<p>In place – Paula Robinson</p>	
	<p>Early emphasis given to team-level service delivery planning for 2015, with active involvement of team members. Delivery (and resources) in Q1 to date were also considered at monthly CMG in May, and delivery is currently on track. CMG will continue to review this.</p>	<p>In place (Jan 2015) – Paula Robinson</p>	

	Moratorium on new project work under consideration in planning for remainder of 2015/16 and for 2016/17, so as to prioritise IfQ delivery and therefore strategy delivery) within our limited resources.	Ongoing dialogue about this in place as part of business planning (August 2015 onwards) – Paula Robinson
	IfQ has some of its own dedicated resources.	In place – Nick Jones
	There is a degree of flexibility within our resources, and increasing resilience is a key consideration whenever a post becomes vacant. Staff are encouraged to identify personal development opportunities with their manager, through the PDP process, making good use of Civil Service Learning.	In place – Peter Thompson
Regarding the current work on licensing mitochondrial replacement techniques, there is a possible future risk, beyond October 2015, that we will need to increase both capability and capacity in this area, depending on uptake (this is not yet certain).	Future needs (capability and capacity) relating to mitochondrial replacement techniques and licensing applications are starting to be considered now, but will not be known for sure until later. No controls can yet be put in place, but the potential issue is on our radar.	New issue for consideration – Juliet Tizzard