Draft business plan 2016/17

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	7		
Paper number	HFEA (11/11/2015) 774		
Meeting date	11 November 2015		
Author	Paula Robinson, Head of Business Planning		
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.

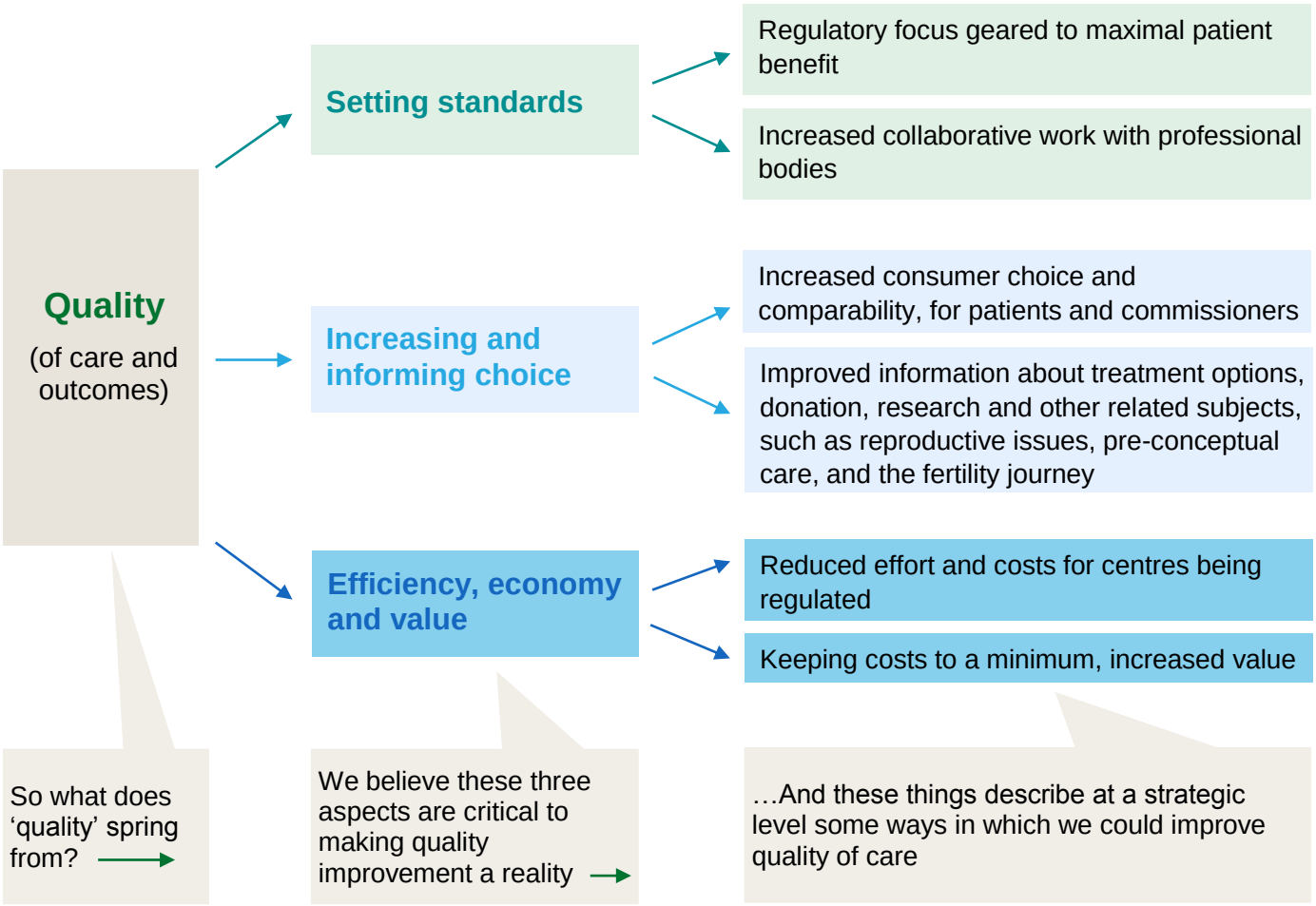
High quality care means…	• safe, ethical and effective care and treatment.
Everyone affected means…	• patients and parents • all those conceived through assisted reproduction • donor-conceived people • egg and sperm donors • clinic staff.
Assisted reproduction means…	• standard fertility treatments • 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.


Quality
(of care and outcomes)
Setting standards
Regulatory focus geared to maximal patient benefit
Increased collaborative work with professional bodies
Increasing and informing choice
Increased consumer choice and comparability, for patients and commissioners
Improved information about treatment options, donation, research and other related subjects, such as reproductive issues, pre-conceptual care, and the fertility journey
Efficiency, economy and value
Reduced effort and costs for centres being regulated
Keeping costs to a minimum, increased value
So what does 'quality' spring from?
We believe these three aspects are critical to making quality improvement a reality
…And these things describe at a strategic level some ways in which we could improve quality of 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:

Strategic Objectives

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.	Clinics are appropriately inspected and monitored against published performance indicators, and issued with licences for up to four years. Continued programme of unannounced inspections. Assurance of standards and safety for the public and other stakeholders. Positive overall impact on quality of care, outcomes, safety, support, and information clinics provide to the HFEA and publish (eg, on their websites).	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
	Processing applications for the licensing of preimplantation genetic diagnosis (PGD), human leukocyte antigen (HLA) and mitochondrial donation.	Growing area of work dealt with effectively and efficiently. 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.	Throughout year
Identifying and implementing ways of improving the quality and safety of care.	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.	Improved compliance, with a positive impact on the quality of care, outcomes and safety of patients in clinics. Clinics have reduced vulnerability to expensive adverse legal and reputational risks, and greater awareness of these risks. 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. Clinics' understanding of, and adherence to, correct consent procedures and their understanding of the importance of getting this right, is improved. Patients and donors therefore have a better experience of being asked for consent, and feel fully informed. 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.	Throughout year

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.	Publication of report on clinical incidents 2015. Sector provided with useful information about learning points from incidents and adverse events. Learning gained, to inform future inspections. Patients' negative experiences used to make improvements and prevent recurrence. Better understanding of factors contributing to particular types of adverse event. Collaborative relationship established with the recently established NHS Improvement so as to consider wider lessons learned that may have relevance.	November 2016 March 2017
	Improved Register data quality, as a result of work done under the Information for Quality (IfQ) programme.	More 'right first time' data submission from clinics into the Register. Better service quality for Opening the Register (OTR) applicants. Fewer data submission and data accuracy related non-compliances found on inspection and audit.	March 2017

Activities	Methods and channels	Benefits and outcomes	Timescale
	Working with commercial groups of clinics so as to improve quality and compliance on a group-wide basis, when relevant.	Using a clinic group's central Quality Management System (QMS) to best effect across whole group. A benefit in one clinic is shared to others without needing to wait for the next inspection date, for the ultimate benefit of patients. A more efficient, effective and quality-driven way of working for the clinics involved and the HFEA.	March 2017
	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.	More informative signposting on our website, for those who are seeking preliminary information about fertility issues and options. 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.	March 2017

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

Activities	Methods and channels	Benefits and outcomes	Timescale
Reviewing our embryo research policies and regulation.	Reviewing the consent process in collaboration with the Health Research Authority (HRA), the sector and other stakeholders. Reviewing the Code of Practice guidance and relevant licence conditions. Review the end-to-end application and approval process. Research workshop to identify the barriers to research and innovation. Collaborative work with researchers, peer reviewers and Licence Committee to ensure a common understanding. 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.	No embryos should be allowed to perish where the gamete providers would prefer them to be donated to research. 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.	March 2017
Improving the quality of commissioning decisions on fertility services.	Follow-up work with commissioners of NHS services, following road-testing in 2015/16 of the HFEA's guidance leaflet for commissioners. 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.	Improved understanding by commissioners of the key factors to consider in their decision making.	March 2017

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.			
Providing information about donor conception directly to patients and donors.	Through the Lifecyle campaign (and through the IfQ work on Choose a Fertility Clinic, CaFC), we will continue to provide information about donation and gamete availability.	Potential donors, recipients and donor conceived people have better access to clear, authoritative impartial information about a range of issues. Improved information about gamete availability. As a result they feel better informed and supported with respect to the legal aspects and obligations of donation. All involved (including clinics) understand the lifelong commitment associated with donor conception and the associated legal issues that are relevant to them.	Throughout year
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.	Through the Lifecyle campaign (and through the IfQ work on CaFC), we will continue to provide information about donation.	Clarity of role and performance for clinics in relation to donation and associated information guardianship. Improved experience for donors, donor-conceived people seeking information and patients and their families.	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
Continuing the provision of counselling support for donor-conceived people wishing to access information held on the HFEA Register.	Continuing to run the three year pilot of counselling support services for applicants to the Register. Annual evaluation to Authority.	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. Mediation services are in place for when donors and donor-conceived people meet. Basic mediation training and systems in place for dealing with identity release to donors and donor-conceived people. OTR applicants feel more supported and will be prepared to deal with the information they receive from us.	Piloting continues through to June 2018.
Implementing new EU requirements relating to the import and coding of donor eggs and sperm.	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.	Improved clarity for clinics, patients and donors. Improved internal clarity and updated procedures for our decision-making committees. Compliance with new EU directives. Robust processes in place to ensure the quality, safety and traceability of imported gametes and embryos.	April 2017 (the EU implementation date)

Activities	Methods and channels	Benefits and outcomes	Timescale
		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.	'Fertility treatment in 2015' report covering 2014–2015. - 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. - 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. - 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.	Increased information for patients and others. Information is accessible, engaging and meaningful. Patients better informed and better placed to deal with treatment issues and decisions. Patients feel safe and know they can expect certain standards in clinics. Prospective patients have clearer information and signposting. Patients more aware of the potential risks of new/different treatments as well as the possible benefits.	March 2017
	Conducting our annual horizon scanning exercise to ensure we identify relevant new scientific developments.	Policy developments and website material are informed by expert input and an understanding of scientific issues and future developments. Future work planning is improved by early identification of upcoming issues.	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.	Increased public understanding of emerging new science and future treatment possibilities. 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.	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
Enhancing the patient voice in all of our work, including information provision.	Further developing our communications with, and information provided to, patients so as to help them to make informed choices about fertility matters. Ensuring patient feedback is continuously incorporated into our core business, for example through user experience ratings of clinics.	Patient views and needs are better incorporated into our work and are reflected in the style and content of the information we provide. There are increased feedback opportunities for patients via the website, and easier interaction with us.	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).	Reduced transactional costs for clinics and increased satisfaction. 'Right first time' data quality. Reduction in unnecessary effort by clinics submitting the data.	October 2016
	Continuation of the engagement arrangements with clinics on fees charged, established in 2014/15.	Accountability and transparency in respect of the fees we charge clinics. Fees Group continues to be run effectively. Annual review of fees takes place.	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.	Continuing to share services and infrastructure with other organisations as practicable: Maximising benefit of finance resources shared with HTA. 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. Continuing to receive support services from the landlord of our office premises, via an SLA.	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).	Best overall use made of Crown Estate property. 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. Further shared services and efficiencies possible for and with other similar organisations in the health ALB family.	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 = £xxxxxk

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

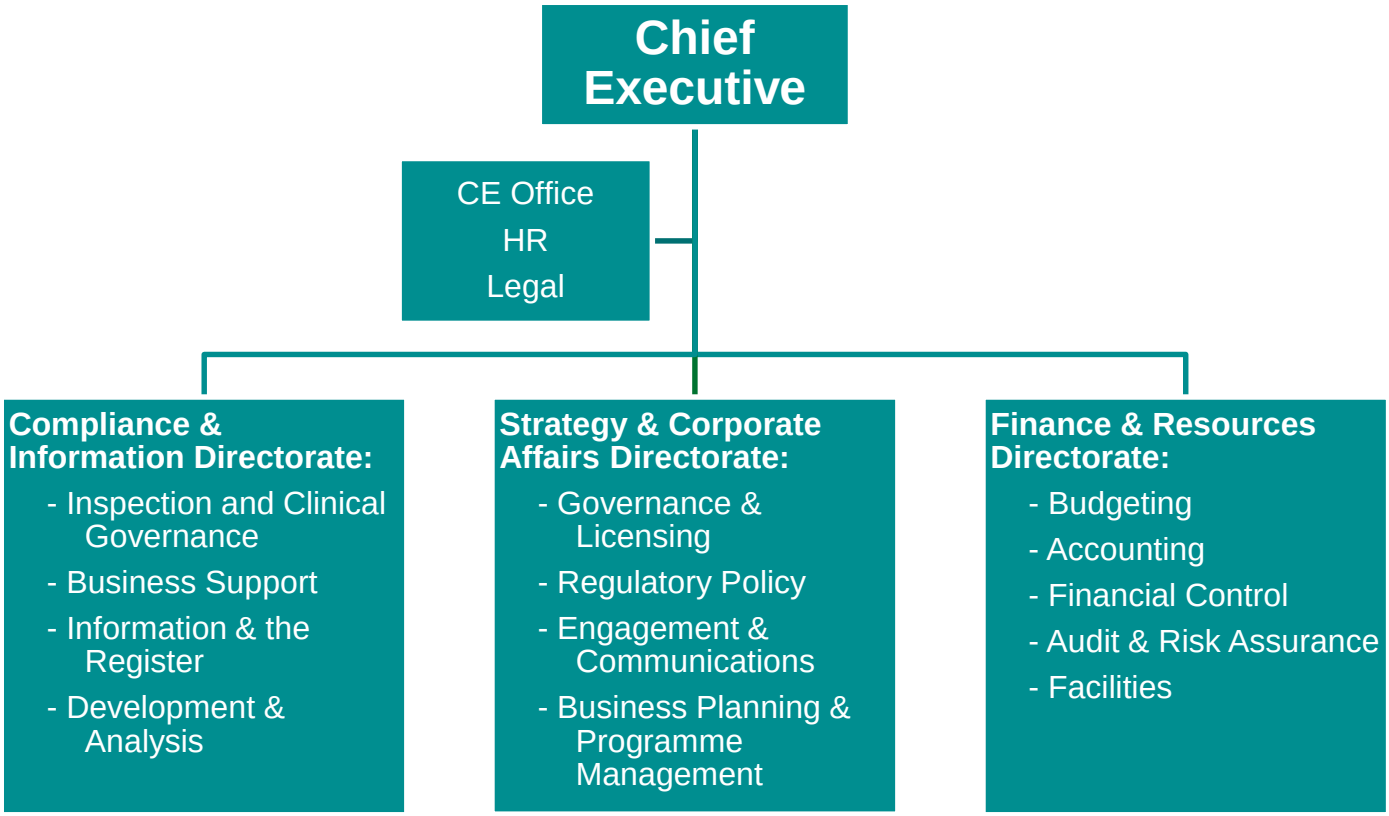
Over the past few years the HFEA has significantly reduced its staffing, in keeping with overall pressures on the public sector and Government expectations. Our staff complement has reduced from 86 in 2010/11 down to 67 2015/16. We have put in place shared services arrangements with other bodies, where 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 examplewe have worked for some years with other organisations to reduce the prevalence of multiple births in the fertilty sector and we routinely open developments to our policies and processes to a wide range of inputs and influences, including voluntary organisations.

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