Authority Agenda

Wednesday 17 September 2014
Meeting to be held at
ETC Venues, Hatton Garden, 51-53 Hatton Garden, London EC1N 8HN

Workshop Starts		**(10.00am)**
Meeting Starts		**(11:40am)**
Lunch		**(12.50pm)**
Meeting Continues		**(1.50pm)**
1.	**Welcome, Apologies and Declaration of Interests**	**(11.40am)**
2.	**Minutes of 9 July 2014** [HFEA (17/09/2014) 730] **Decision**	**(11.45am)**
3.	**Chair's Report** (verbal)	**(11.50am)**
4.	**Chief Executive's Report** (verbal)	**(12.00pm)**
5.	**Directorates Report** [HFEA (17/09/2014) 731] **Information**	**(12.10pm)**
6.	**Committee Chairs Update** (Verbal) **Information**	**(12.25pm)**
7.	**McCracken** [HFEA (17/09/2014) 732] **Information**	**(12.35pm)**
	~ Lunch ~	***(12.50pm)***
8.	**Strategy Implementation** [HFEA (17/09/2014) 733] **Decision**	**(1.50pm)**
9.	**Update on People Strategy** Verbal Presentation **Information**	**(2.10pm)**

10.	**National Information Board** Verbal Presentation **Information**	**(2.25pm)**
11.	**Information For Quality** [HFEA (17/09/2014) 734] **Decision**	**(2.40pm)**
12.	**Any Other Business**	**(3.10pm)**

Close **3.15pm**

Next meeting: **Wednesday 12 November, 2014.**

Authority Paper

Strategic delivery:	**Setting standards**	☑	**Increasing and informing choice**	☑	**Demonstrating efficiency, economy and value**	☑
Paper title	**Minutes of Authority meeting 9 July 2014**					
Agenda item	2					
Paper number	[HFEA (17/09/2014) 730]					
Meeting date	17 September 2014					
Author	Charlotte Keen, Information Access and Policy Manager					
For information or decision?	Decision					
Recommendation	Members are asked to confirm the minutes as a true and accurate record of the meeting.					

Minutes of the Authority meeting on 9 July 2014 held at
ETC Venues, Bonhill House, 1-3, Bonhill Street, London, EC2A 4BX.

Members

There were 7 members at the meeting, 5 lay members and 2 professional members.

Members present

Sally Cheshire (Chair)
Gemma Hobcraft
Professor David Archard
Sam Abdalla FRCOG
Dr Susan Price
Dr Andy Greenfield
Rebekah Dundas

Apologies

Dr Alan Thornhill
Debbie Barber
Jane Dibblin
Bishop Lee Rayfield

Observers

Kim Hayes (DH)

Staff in attendance

Peter Thompson
Nick Jones
Juliet Tizzard
Sue Gallone
Catherine Drennan
Paula Robinson
Debra Bloor
Matthew Watts
Joanne Anton
Joanne McAlpine
Charlotte Keen

1. Welcome, Apologies and Declaration of Interests

1.1. The Chair opened the meeting by welcoming Authority members and members of the public. This was the fourth meeting of 2014 and it was being audio-recorded for the second time. The recording would be made available on the HFEA website to enable interested members of the public who were not able to attend the meeting to listen to the HFEA's deliberations. This was part of the HFEA's drive to increase transparency about how the Authority goes about its business.

1.2. Apologies were received from Dr Alan Thornhill, Debbie Barber, Jane Dibblin and Bishop Lee Rayfield.

1.3. Declarations of interest were made by:

- Sam Abdalla (Person Responsible at a licensed centre).

2. Minutes of Authority meeting held on 14 May 2014

2.1. Members agreed the minutes of the meeting held on 14 May 2014 as a true record, for signature by the Chair.

3. Chair's Report

3.1. The Chair advised members that she had given an interview in Health Service Journal (HSJ) in June. The main focus of the piece was on commissioning IVF in the context of the new health care system. It seemed to have been well received, and one of the HFEA's key stakeholder groups, the National Infertility Awareness Campaign (NIAC), recently issued a statement in support of the Chair's comments on Clinical Commissioning Groups (CCGs). Improving the position on commissioning was a priority for the HFEA and featured in its new strategy.

3.2. The Chair, together with the Chief Executive, the Director of Strategy and Corporate Affairs and the Chair of the Expert Panel, had met the Minister for Public Health, Jane Ellison, on 11 June, to brief her on mitochondrial replacement following the Expert Panel's third scientific review. Also on 11 June, the Chair advised members that she had chaired the Multiple Births Stakeholder Group, which was a very productive meeting.

3.3. The Chair and the Chief Executive had also met Felicity Harvey, Director General at the Department of Health, on 17 June for the Annual Accountability meeting, which was very encouraging. The Chair thanked Authority members and HFEA staff for their contributions.

3.4. The Chair advised members that on 24 June she had attended a meeting of health ALB Chairs to hear from the Secretary of State for Health what his priorities were over the next 12 months.

3.5. In her role as Chair of the Authority, the Chair advised members that she had started meeting key stakeholders and, over the next few months, she intended to meet with clinicians, professional groups such as the British Fertility Society (BFS), and with other regulators including the Human Tissue Authority (HTA) and the Medicines and Healthcare Products Regulatory Agency (MHRA). Where possible, the Chair would be looking to build further alliances and to seek system wide co-operation on particular issues.

3.6. Finally, the Chair advised members that the HFEA was looking to recruit two new Authority members (one lay and one professional) and the advert had recently gone out via the Cabinet Office with a closing date of 14 July.

4. Chief Executive's Report

4.1. The Chief Executive began by welcoming Juliet Tizzard in her new capacity as the Director of Strategy and Corporate Affairs.

4.2. The Chief Executive advised members that he had attended an event organised by the Association of Chief Executives on 20 June on the sponsorship of public bodies.

4.3. On 25 June, the Chief Executive attended the opening by the Secretary of State for Business, Innovation and Skills (BIS), Vince Cable, of the Stem Cell Catapult at Guy's Hospital. This was part of the Government's initiative to find ways of priming key sectors of the economy, of which the life sciences sector was one.

4.4. Press Coverage: the Chief Executive summarised press coverage since the last Authority meeting, details of which had been circulated to members.

4.5. Mitochondria: the biggest media event organised by the HFEA since the last Authority meeting was the publication of the third scientific review into mitochondrial replacement, which was launched at a press conference at the Science Media Centre. The launch went very well, with mostly accurate and supportive reporting both in the UK and abroad.

4.6. The Chief Executive advised members that the decision whether to lay regulations now rested with the Government, although media attention remained. Professor Robin Lovell-Badge, an expert panel member, together with the interim Head of Policy and Communications, had given a long interview to the Japanese newspaper, Asahi Shimbun, which planned to run a piece on mitochondrial replacement in the coming weeks.

4.7. The HFEA had also been contacted by BBC Radio 4, who were planning a one-off half-hour programme on mitochondrial replacement for an evening slot on 30 July, and had requested interviews with members of the expert panel and the Executive at some point over the next few weeks.

4.8. Other BBC programmes: since the last meeting, the HFEA had provided data and interviews for a number of radio programmes including:

- Radio 4 Face the Facts – data on complaints and incidents
- Radio 4 Woman's Hour – the Director of Strategy and Corporate Affairs went live on air to discuss issues around PGD as part of a panel
- BBC Scotland drive time – mitochondria
- Radio 4 PM – donor sperm
- A one-off Radio 4 programme on the importation of Danish sperm, in which the Director of Strategy and Corporate Affairs also featured as the HFEA representative.

4.9. European Society of Human Reproduction and Embryology's (ESHRE) Annual Conference in Munich: whilst a number of stories featured in the press as a result of studies launched during the conference, the HFEA had not been contacted in relation to any of them, although as the source data for a story regarding success rates of older sperm donors (over 40 years old) came from the organisation, the HFEA was referenced widely as a result, although not always accurately.

4.10. One story did develop from the ESHRE press conference, where it was asserted that there was a shortage in donor sperm and that, as a consequence, clinics could potentially accept lesser quality sperm. When approached, the HFEA was keen to reinforce the fact that donations were generally on the increase, and

although it was true that foreign imports accounted for a reasonably substantial percentage of sperm donations, the actual numbers involved were quite small.

4.11. Incidents: the Chief Executive advised members that the HFEA had released its Incidents Report on 8 July, which outlined and explained the Grade A, B and C incidents which had occurred at licensed clinics between 2010 and 2012.

5. Directorates' Report

5.1. The Director of Compliance and Information provided members with a general review of the key performance indicators. Members noted that performance had been good overall for all the key performance indicators including licensing, the administration and processing of PGD applications and corporate performance.

5.2. The Director of Compliance and Information advised members of the publication of the HFEA Incidents Report which the Chief Executive had touched upon and would be discussed later in more detail. The report highlighted trends and incidents over the last three years and the publication had been part of the HFEA's wider openness and transparency agenda.

5.3. The Director of Compliance and Information advised members that the Head of Inspection had taken on a wider role including incidents and clinical governance, and the Directorate had taken the opportunity with staff changes to strengthen the work relating to complaints and incidents and whistleblowing.

5.4. The Director of Compliance and Information advised members that one area the Directorate had been reflecting on was poor performance in clinics and this would be taken to Ethics and Standards Committee in September to give its members a flavour of the findings from the inspections in the 2013/14 financial year.

5.5. The Director of Compliance and Information reminded members of the research regulation which the HFEA undertook, with inspection of around 30 research licences at any given time. It was important that the HFEA's inspection and regulatory practices were consistent with the direction of travel in the research field. The HFEA worked closely with the Health Research Authority (HRA), the MHRA and the HTA in order to avoid duplication and conflict of work and processes within this field.

5.6. The Director of Strategy and Corporate Affairs advised members that, since she had been made a permanent Director, there were now two vacancies within her Directorate at Head of Department level (Head of Engagement and Head of Regulatory Policy) which had recently been advertised.

5.7. The Annual Report was almost ready to be laid in Parliament and would be published shortly thereafter.

5.8. The Director of Strategy and Corporate Affairs reminded members of the paper brought to Authority on the provision of support and intermediary services for people who were seeking information from the HFEA Register about donor conception. Authority members had subsequently approved a three year pilot and the Executive had been working with stakeholders, who had helped in developing the proposals, to consider how they would be rolled out in practice. The HFEA was planning to issue an invitation to tender after the summer to potential suppliers. Thought would be given as to how to measure the quality of the service and the performance of the supplier in order to ensure the provision of a good service to those people who needed support when thinking about getting further information on donor conception.

5.9. The Director of Strategy and Corporate Affairs advised members that the HFEA had received the findings from user research carried out under the Information for Quality (IfQ) programme. The HFEA had hired a company to understand more about all the different audiences that used the HFEA's public facing and clinic facing communications tools, such as the public website, Choose a Fertility Clinic (CaFC) and the clinic portal. The Executive also wanted to explore the potential for a donation specific website under the Lifecycle banner, with a slightly different tone and audience from that of a regulator.

5.10. The Director of Finance and Resources advised members that the Executive was planning to expand on the financial information provided in the current Directorates' Report summary. Budgets have been set for this financial year and there were currently no significant financial issues. Treatment fee income was very much as expected.

5.11. The developments to the financial information within the Directorates' Report would be to draw out more detail in relation to income and also to identify any particular issues with costs.

5.12. The Director of Finance and Resources advised members that, at year-end, the audit from the National Audit Office (NAO) had been quite protracted. A lessons learned meeting had been planned with the NAO to see what both the HFEA and the NAO could do differently next time around to make the process easier. The Comptroller General had signed off the Accounts as planned.

5.13. The Director of Finance and Resources advised members that the Finance team was settling down well following recent changes. Both the Finance Director and the Head of Finance were shared with the HTA. Progress had been made on understanding the costs of various activities and how that related to fees and this work would allow the Executive to have meaningful discussions with the Fees Group – one of the recommendations in the McCracken Report - to be set up in the autumn. Consideration had also been given to the HFEA's cash flow and the need for reserves, and discussions would take place with the Department for Health about the reserves policy and the HFEA's performance indicator in that area.

5.14. The Chair expressed her thanks to the Finance team and everyone across the organisation who had contributed to the HFEA Annual Report.

5.15. Members noted the verbal updates and the summarised Directorates Report.

6. Committee Chairs' Update

6.1. The Chair of the Licence Committee reported that the Committee had met on 26 June and had considered and made determinations on two research licence renewals, together with a treatment and storage licence renewal, a variation to a research licence and a variation to remove a condition for a treatment and storage licence. The Licence Committee would meet again on 10 July to consider eight items.

6.2. The Chair of the Statutory Approvals Committee (SAC) reported that the Committee had met on 29 May. There were two PGD applications, one of which was deferred as there was insufficient information about the severity of the symptoms.

6.3. The Chair of the Scientific and Clinical Advances Advisory Committee (SCAAC) advised members that the Committee had met on 4 June, where an agenda was set for the next twelve months. The Chair of SCAAC advised that the Committee was hoping to invite speakers for the next three meetings. There were four major

topics at the meeting: an overview of the IfQ Programme, the review of the Getting Started guide, an HFEA publication aimed at people approaching fertility services for the first time, a discussion about reproductive immunology and, finally, the annual look at the science around using embryonic stem cells for research.

6.4. The Chair of the Audit and Governance Committee (AGC) advised members that the Committee met on 11 June with the NAO in attendance, feeding back on the audit work which had been completed. The internal auditors had also attended the meeting and had fed back to the Committee on recent internal audits and the various associated management recommendations, although all areas audited had been given a 'satisfactory' rating. The High Level Risk Register and the HFEA risk management policy were also considered by the Committee.

6.5. A member of the Ethics and Standards Committee (ESC) provided an update of the meeting on 18 June. There were five items on the agenda, including a number of updates to the Code of Practice coming into force in October, most notably additional guidance on surgical procedures; an outline forward work plan, with the Committee agreeing to meet quarterly; and a paper on ethical issues broached by developments in new technologies in embryo testing. The Committee also considered the new Regulators' Code from BIS, which came into statutory effect on 6 April, and the extent to which the HFEA was compliant. There was general agreement that the organisation complied well. Finally, the Committee agreed to revise General Directions to relax the register data submission deadlines, so as to reduce unnecessary regulatory burden.

7. HFEA Strategy

7.1. The Head of Business Planning provided an overview of the background and the work that had been carried out so far in relation to the HFEA strategy. The Authority and HFEA staff had worked together with stakeholders over the past six months to develop a new strategy for the next three years. The process had included a survey-based consultation, meetings with stakeholder groups, focus groups with patients and members of the public, and a particular focus on strategic issues at the annual conference in February 2014.

7.2. Members were advised that the most recent phase of work had been an engagement document which had proposed that patients (including donors and donor conceived people) and the quality of care they received should be at the centre of the HFEA's concern. The engagement exercise had set out some key areas of focus (the patient, donor conception, and quality), with some potential future activities under each heading. The consultation survey had asked respondents to identify in each case the three potential activities they thought were most important and the three they thought least important. From the responses received, it was clear that the key message was a strong endorsement for the broad thrust of the HFEA's proposed strategy, with the strongest message being about focusing on the basics – the quality and outcomes of the care people received in clinics.

7.3. The Head of Business Planning advised members that this approach had engaged people well, and had provoked responses and useful comments. The feedback obtained was brought to the Authority at its May meeting when members then considered the vision and main aspirations for the HFEA over the next few years, the broad ways in which these aspirations could be met and the benefits to be achieved.

7.4. The Head of Business Planning advised members that the new strategy for 2014-17 had now been drafted, in line with all previous discussions and the feedback received through the consultation. The strategy articulated the HFEA vision for the next three years, and set out how the organisation would achieve it through various strategic objectives and ways of working. The proposed draft vision statement, as set out in the paper and taking into account members' feedback to date, was to deliver "a high quality experience for everyone affected by assisted reproduction".

7.5. Once the strategy had been agreed and published as a short, accessible document, it would then be possible to complete other linked pieces of work which would assist the HFEA in delivery and monitoring. These were:

- Completion of the People Strategy and associated work with staff
- Review of the current business plan (2014-15)
- Revision of the Directorates' Report structure, for performance and delivery monitoring purposes
- Revision of the High Level Risk Register to ensure that it reflected risks to delivering the HFEA vision and strategic objectives
- Consideration of objectives and main activities for the 2015/16 and 2016/17 business plans.

7.6. The intention was to finalise and publish the Strategy on the HFEA website by the end of July with, in time, the People Strategy alongside. The other work set out above, and in paragraph 1.9 of the paper, would be completed between August and December 2014. Both the Chair and the Chief Executive expressed their thanks to the Head of Business Planning for the work involved in bringing the strategy to fruition.

7.7. A member raised the issue of the Executive's ability to deliver the strategy within the limited resources available. This point was well made, and the Corporate Management Group (CMG) would explicitly bear this mind in planning discussions.

Decision

7.8. Following a discussion, particularly around the vision statement, Authority members noted and approved:

- The HFEA Strategy for 2014-17 for publication, subject to design and minor changes and amendments in content agreed at the meeting – including potential minor changes to the wording of the vision statement to incorporate the word 'care'.[1]
- The range of related work described in paragraph 1.9 of the paper for completion by the end of the calendar year.

8. Lifecycle next phase: (from September 2014 to 2017)

8.1. The Policy Manager presented this item, reminding members that the National Donation Strategy Group had been set up in September 2012 and was made up of key stakeholders from donation and related fields. The Group was supported by the HFEA although it was independent. The Group had developed the

[1] Further to this, the vision statement was subsequently revised to read 'high quality care for everyone affected by assisted reproduction'.

campaign ‘Lifecycle, working together for donor conception’. The Group would come to the end of its initial two-year phase in September 2014.

8.2. Lifecycle’s objectives were to:

- Increase awareness of donation
- Improve the ‘customer service’ that donors received when they contacted clinics
- Encourage donors to provide helpful and appropriate information about themselves
- Improve information provision to all those affected by donation.

8.3. Since its inception, Lifecycle had achieved many of its original aims, including:

- Forming key partnerships
- Attending patient and clinic events
- Receiving positive feedback from the sector
- Developing a range of leaflets.

8.4. Before Lifecycle came to the end of its two year phase in September 2014, it would also have achieved the following:

- Finalising some best practice guidelines for clinics treating donors
- Developing a leaflet for donors to help them tell their own children that they had donated
- Developing a leaflet on donor family history for parents and donor-conceived people.

8.5. The Policy Manager asked members to consider whether they felt there was a sufficient role for Lifecycle to merit it continuing for a further period of time. That consideration should note that there remained important work to do, that the resources required were affordable and that this work had begun to make a difference to what had been a fragmented and confused area of health provision. Future proposed work for Lifecycle included:

- From September 2014, to focus on addressing the current information gaps for those affected by donation
- To develop a dedicated donor conception website (dependent on receiving the relevant government approvals) that would provide information for all people involved in donation from the earliest stages of interest and treatment
- Like ‘One at a Time’, Lifecycle would be stakeholder led but with the national reach of the HFEA and would also be able to reach audiences at the earliest stage of their treatment or donation journey.

8.6. The aim of the Lifecycle website would be to create:

- Greater awareness of different types of donation, treatments and their implications
- Greater awareness of the need for more egg and sperm donors
- Dedicated space for factual, non-judgmental information on donation
- An all-inclusive view of donation, including the acknowledgement and options on treatment outside of the UK.

8.7. Members noted that the website was supported by user research and had wide stakeholder support. The Policy Manager thanked Lifecycle members for their work and support over the last 2 years.

Decision

8.8. Following a discussion, Authority members agreed:

- To continue to support Lifecycle for a further three years in the next phase of its work, mapping the HFEA Strategy with the work of Lifecycle.

9. Information for Quality

9.1. The Director of Compliance and Information provided members with a brief summary of progress in relation to Information for Quality (IfQ), which was a large programme of work to transform the way in which the HFEA defined the data requirements collected primarily from clinics, the way in which clinics presented and provided that information to the HFEA and the uses to which the organisation put it, both in terms of the products and the medium by which that information was accessed. This encompassed everything from the dataset to the website and every point in between.

9.2. The Director of Compliance and Information provided members with a summary of issues emerging from the IfQ Advisory Group, chaired by Dr Alan Thornhill and its Expert Groups, which included:

- Some membership changes within the Groups
- Discussions and debates about the purpose of the Register
- A real potential for data item reduction without impacting on the quality of the data
- Early changes to data submission deadlines for introduction in October
- Potential for ‘flash’ collection capability
- Expert groups merging interests and boundaries between them, driving greater collaboration
- Mapping the patient journey and what patients wanted to see in ‘information about clinics’.

9.3. The Director of Strategy and Corporate Affairs advised members that, in order to make the discussion wider on a number of more significant changes, the HFEA planned to launch a consultation, with the following structure:

- Informing people about firm plans, giving them a public airing before any action was taken (for example, replacing EDI with a web-based data submission system)
- Creating a dialogue with key audiences to solicit their views on proposals (for example, patient experience information on Choose a Fertility Clinic (CaFC))
- Providing a few options for key stakeholders, asking for opinions/preference on each option (for example, how should success rates be presented on CaFC).

9.4. The Director of Strategy and Corporate Affairs advised members that the plan was to launch a short consultation at the beginning of October to run through until mid-November, comprising a short document, a web-based questionnaire and also a couple of workshops primarily focused on the sector. Once the Expert

Groups had considered the findings of the consultation and the Advisory Group had considered their recommendations, the outcome would be brought to the Authority at its meeting in March 2015.

9.5. The Director of Compliance and Information advised members that the IfQ programme of work was on track and user research was now underway, as was the technical proof of concept stage, with ongoing stakeholder engagement throughout.

9.6. The Director of Compliance and Information advised members that he would bring developments and, where appropriate, proposals to subsequent meetings of the Authority.

9.7. Following a discussion, Authority members noted the presentation and the proposed timescale for implementation.

10. Handling Incidents in Clinics

10.1. The Head of Inspection presented this item, updating Authority members on a range of issues in relation to incident reporting by clinics, associated transparency and information sharing and the inspection of clinics' procedures for incident reporting and investigation.

10.2. The Head of Inspection informed members that the Person Responsible (PR) for an HFEA licensed clinic had a statutory duty to report and analyse the causes of incidents. Similarly, the Authority had a duty to investigate and had a significant role to play in taking appropriate control measures in relation to reported incidents. The primary reason for the reporting and investigating of adverse events was to improve safety for patients, embryos and clinic staff. Reporting an incident was not enough on its own: there should be learning from incidents to minimise the risk of recurrence.

10.3. The Head of Inspection advised members that, since 2009, Grade A incident related Licence Committee minutes and incident investigation reports were published on the HFEA's CaFC website on the page of the particular clinic where the incident occurred. Going forward, in order to be more open and transparent it was proposed that this information, and learning from all incidents, should be accessible on a dedicated clinical governance web page and the Executive therefore wanted to explore this further in order to share such information with other regulators and professional bodies.

10.4. On 8 July 2014, the HFEA had published a review of incidents reported to the HFEA between 2010 and 2012. The report outlined the key features of the incidents reported by clinics and made recommendations for all clinics in order for them to avoid having similar incidents.

10.5. The next phase would be to monitor the impact of this report and, in the future, the Executive intended to publish a similar report at least annually on the proposed dedicated clinical governance web page and accessible to all.

10.6. The Head of Inspection advised members that it was important for patients to be informed when incidents happened. However, it remained the case that clinics sometimes elected not to inform patients who might have been affected in case, for example, this caused unnecessary alarm. Clinics were always strongly encouraged to be open with patients about incidents but it was not clear what action was proportionate where clinics declined to disclose this information. The HFEA, therefore, proposed to work with the British Fertility Society (BFS) and other relevant expert groups to develop a policy on what, if any, action should be taken where clinics chose not to inform patients following an incident.

10.7. The Head of Inspection informed members that the HFEA received reports of between 500-600 incidents each year. There were approximately 60,000 cycles of fertility treatment carried out in the UK each year and it was estimated that 1% of those cycles were affected by some sort of adverse incident, with three Grade A incidents in the 3 years covered by the recently published report. The HFEA had a robust process in place for grading and investigating adverse incidents, and the incident grading matrix was considered flexible enough to ensure that the right degree of scrutiny was applied when incidents happen and that regulatory action was taken when warranted.

10.8. However, the Head of Inspection felt that the HFEA could add more value if it evolved its current approach to focus on how clinics investigated and learned from incidents in the course of future inspections. The HFEA was therefore in the process of undertaking a review of renewal inspection methodology and proposed to run workshops for clinics to help them get the best from incident investigation and learning. Inspectors would be trained on what a good root cause analysis investigation looked like so that they could advise where local investigations were not sufficiently robust and, where clinics reported no adverse incidents, the focus on inspection would relate to wider learning based on the recommendations of the HFEA's summary report of incidents.

10.9. Since the majority of clinical incidents reported to the HFEA were related to ovarian hyper-stimulation syndrome (OHSS), the Executive wanted to give further consideration to collecting additional data when an incident involving OHSS was reported, to give the HFEA an improved picture of the overall incidence of OHSS and common factors that could contribute to its development. In the context of the IfQ programme, the HFEA proposed to take expert scientific and medical advice on whether such data collection would be of value and the feasibility of collecting reliable information.

Decision

10.10. Following a discussion, Authority members agreed to:

- The HFEA giving greater prominence to Grade A adverse incident reports and minutes on the HFEA website by creating a clinical governance page
- The HFEA working with the British Fertility Society and others to develop a policy on what, if any, action should be taken where clinics chose not to inform patients following an incident
- Consideration of the collection of additional data relating to OHSS.

11. Surgical Procedures Guidance: Recommendations for Inspections

11.1. The Regulatory Policy Manager presented this item and reminded members the surgical procedures guidance had been produced as part of work to reduce regulatory overlap where HFEA licensed clinics in England were also registered with the CQC. In October 2013, the HFEA had extended its remit to include the inspection of activities associated with the provision of surgical procedures. This had enabled independent (non-NHS) IVF clinics in England to cancel their registration with the CQC. To ensure there were no regulatory gaps as a result of de-registration with CQC, new guidance was developed with respect to four additional areas of practice, and on suitable premises.

11.2. The Regulatory Policy Manager advised members that, in order to refine the guidance and methodology, the Executive had sought feedback from all those

clinics inspected and, more widely, through Clinic Focus, the Licensed Centres Panel and the Professional Bodies Stakeholder Group.

11.3. Clinics had provided positive feedback, reporting that the new methodology used by the HFEA was appropriate and that the guidance was relevant in their setting. Some of the feedback had been to request clarification about the paperwork required to support the inspection of the new guidance but this was being addressed by the Inspection team. Both the Licensed Centres Panel and the Professional Bodies Stakeholder Group were satisfied with the progress of the work and had provided positive comments.

11.4. In January 2014, members had agreed in principle to making the new guidance applicable to all HFEA licensed clinics across the UK, subject to the Executive consulting affected clinics and regulators in the devolved nations and trialling the guidance on relevant clinics due for inspection between January and June 2014 to understand its impact.

11.5. In considering how this guidance might apply to IUI and Storage clinics (whether in England or the devolved nations), the Executive had to be conscious of the fact that activities in IUI and Storage clinics were markedly different to an IVF clinic. As a result of that, amended tools had been developed to support these inspections and inspection of compliance against the new guidance had been trialled at two of these facilities. Feedback following these inspections was positive. Clinics noted that inspectors considered the guidance in the context of the activities they carried out.

11.6. To consider how this guidance could apply to the devolved nations of Scotland, Wales and Northern Ireland, meetings had been held with the regulatory bodies in the devolved nations, given that each of the regulators had a distinct regulatory regime and all were required by statute to have regulatory oversight of minor aspects of the work of HFEA licensed clinics. None of the regulators expressed reservations or concerns about the guidance being applicable to clinics under their regulatory scrutiny. Similarly, feedback from clinics suggested that inspectors were proportionate and clinics were supportive of new guidance being applicable to clinics in the devolved nations.

11.7. Since there was a risk that the inspection against this guidance by the HFEA in clinics subject to the scrutiny of another regulator could introduce overlap, the Executive proposed tailoring the inspection to the individual circumstances of each clinic. The devolved nations all agreed that it would also be beneficial to establish formal agreements to allow relevant information to be shared by, and with, the HFEA to ensure effective and proportionate regulation. The Regulatory Policy Manager informed members that work was being initiated to establish such agreements.

Decision

11.8. Authority members agreed to:

- New guidance applying equally to all HFEA licensed clinics from 1 October 2014
- Where clinics in the devolved nations were subject to the scrutiny of another regulator, the HFEA should adopt a flexible inspection approach tailored to the circumstances of the individual clinic and influenced by learning from observations of other regulators' activities
- Information sharing agreements should be established with Healthcare Improvement Scotland (HIS), Healthcare Inspectorate Wales (HIW), and

the Regulation and Quality Improvement Authority (RQIA) in Northern Ireland.

12. Interpreting 'suffers from' in HLA testing

12.1. The Director of Strategy and Corporate Affairs introduced this item, providing members with some background to the subject. The HFE Act 1990 (as amended) set out the circumstances in which embryo testing could legally be performed. One such circumstance was to select for a child who could be a tissue match for an existing sibling suffering from a serious medical condition. This form of testing was sometimes known as 'saviour sibling' treatment or human leukocyte antigen (HLA) testing.

12.2. The diseases which could be treated with cells from an HLA-matched sibling donor were disorders of the blood. Some of these diseases were inherited. HLA testing could be used in conjunction with genetic testing (PGD) for couples at risk of having a child with an inherited disease by testing their embryos for both the disease and the HLA type. This enabled couples to have a child who was both free from the disease and also a potential tissue-matching donor for an existing, affected sibling.

12.3. The Director of Strategy and Corporate Affairs informed members that what had come to light over the last few months was the possibility that the child to be treated with a serious medical condition was not necessarily suffering from symptoms at the time that the application was made for HLA testing. This raised the question of how to interpret the term "suffers from" in the legislation, which was not defined in the statute.

12.4. The legislation states "1ZA (1) A licence….cannot authorise the testing of an embryo, except for one or more of the following purposes….(d) in a case where a person ("the sibling") who is the child of the persons whose gametes are used to bring about the creation of the embryo (or of either of those persons) *suffers from* a serious medical condition which could be treated by umbilical cord blood stem cells, bone marrow or other tissue of any resulting child, establishing whether the tissue of any resulting child would be compatible with that of the sibling."

12.5. This terminology ('suffers from') could imply that the child with a serious condition needed to be actively suffering from symptoms. This therefore raised the question of how to deal with cases where, for example, a child was being treated for a particular disease but they were in remission, or where there was a genetic disease in the family which meant that it was known that a child would develop symptoms of the disease, most likely during childhood, but wasn't necessarily actively suffering from those symptoms at the time of the application. The Executive had received one such application in which the sibling was non-symptomatic. The Executive was therefore seeking guidance from the Authority on how the relevant Committee, either the Statutory Approvals Committee (SAC) or the Executive Licensing Panel (ELP) should consider these cases in the future.

12.6. At its meeting on 23 April the Ethics and Standards Committee (ESC) had considered three possible interpretations of 'suffers from':

- **Option A:** 'suffers from' should only apply to cases where the existing sibling is manifesting symptoms of the medical condition in question and would benefit from a donation as soon as possible
- **Option B:** In addition to Option A, 'suffers from' should also apply to cases where the sibling has received successful treatment, but may relapse in

future. In these cases, the existing sibling would not need immediate treatment, but might be expected to need it in the future

- **Option C:** In addition to Option B, 'suffers from' should also apply to cases where the existing sibling does not yet have the symptoms of the condition but is likely to develop them in the future.

12.7. The Director of Strategy and Corporate Affairs advised members that external legal advice had been received and informed the ESC discussion, whose members felt that the child to be treated did not necessarily need to have active symptoms of the disease at the time of application.

12.8. ESC had debated the three options and was minded not to adopt Option A. However the Committee had not come to a firm conclusion, recommending that the Authority consider the issue alongside further information about possible scenarios. Following the ESC discussion, the Department of Health (DH) had advised the HFEA that 'suffers from', when the Act was drafted, was not intended to carry any meaning other than an individual being 'affected by' or 'subject to a medical condition'. In DH's view, the key point was not the interpretation of 'suffers from' but rather how the seriousness of the medical condition was assessed.

12.9. Another question which the ESC considered was how the regulation of HLA testing compared with that of PGD, where there was a similar requirement for the disease in question to be serious, but the wording in the statute contemplated using embryo testing to avoid the birth of a child who would have developed a particular disease later in life. Given that both PGD and HLA testing could be used together to create a child who was both free from a particular inherited genetic disease and also a compatible tissue donor for an existing sibling, choosing Option B as set out above would be inconsistent.

12.10. The Director of Strategy and Corporate affairs advised members that, taking all these issues into consideration, the Executive recommended that the Authority adopted the more ordinary-language meaning of 'suffers from', which would mean adopting Option C as set out above.

12.11. In order to provide clarity as to the matters that may be taken into account by the relevant committee and to provide guidance on certain key considerations, the Executive had produced draft guidance set out in Annex A of the paper.

Decision

12.12. Following a discussion, Authority members agreed to Option C, subject to further consideration by the Executive of the wording. Members also suggested that the guidance should be revisited whenever specific issues arose that had not been anticipated. The Authority agreed:

- It should adopt the more ordinary-language meaning of 'suffers from': 'that HLA testing can be used in cases where the child in question has or is likely to develop a serious medical condition'
- the relevant approvals committee uses guidance to consider cases of non-symptomatic HLA.

13. Any Other Business

13.1. The Chair confirmed that the next meeting would be held on Wednesday, 17 September 2014 at ETC Venues, Hatton Garden, 51-53 Hatton Garden, London, EC1N 8HN.

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

Chair _____

Date

Authority paper

Strategic delivery:	**Setting standards**	☐	**Increasing and informing choice**	☐	**Demonstrating efficiency, economy and value**	☑
Paper title	**Directorates Report**					
Agenda item	5					
Paper number	[HFEA (17/09/2014) 731]					
Meeting date	17 September 2014					
Author	Paula Robinson					
For information or decision?	Information					
Annexes	A: Directorates Report Summary – July data					

1. Introduction

1.1 Directorates Report Summary

The attached paper summarises the main performance indicators up to and including July 2014, following discussion by CMG at its August performance meeting.

1.2 Recommendation

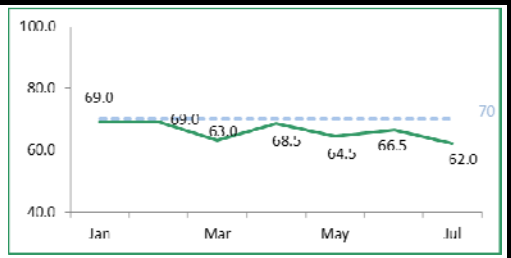
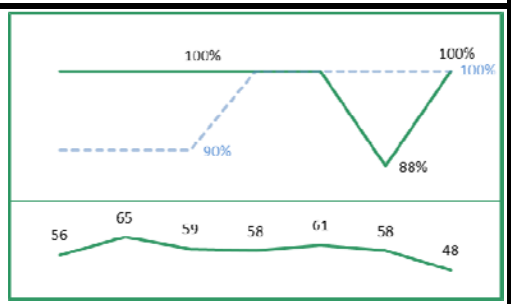
The Authority is invited to note the summarised Directorates Report.

Paula Robinson
Head of Business Planning
September 2014

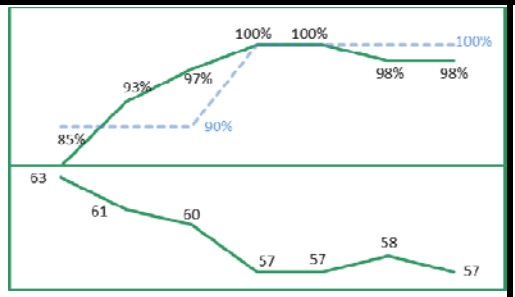
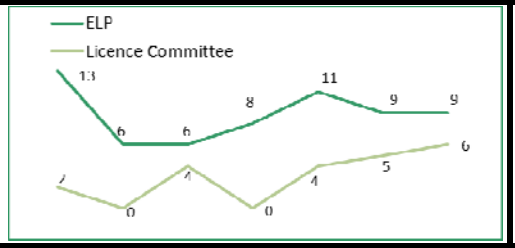
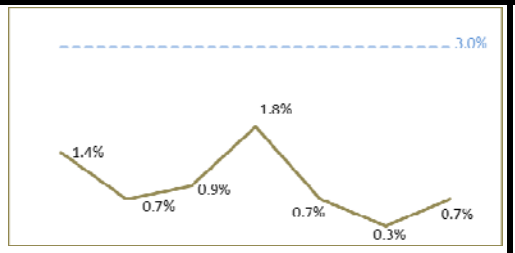
Annex A

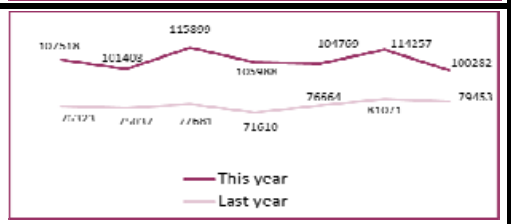
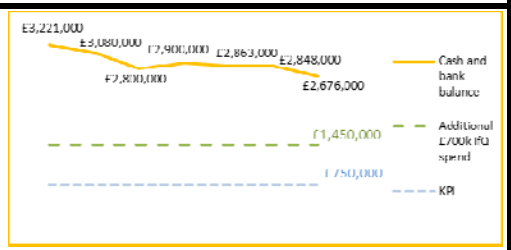
HFEA Performance Scorecard

Key Performance and Volume Indicators: July Performance Data

Indicator	Performance	RAG	Recent Trend[1]	Aim[2]	Notes
Average number of working days taken for the whole licensing process, from the day of inspection to the decision being communicated to the centre.	62 working days	★		 Maintain 70wd or less	KPI: Less than or equal to 70 working days. Note: this KPI can be adversely affected if there are a large number of non-compliances found on multiple inspections in the same period.
Monthly percentage of PGD applications processed within 3 months (66 working days). **Average number of working days taken.**	100% 48 working days	★		Reach and maintain 100% 	New KPI: 100% processed (i.e. considered by LC/ELP) within 3 months (66 working days) of receipt of completed application. [KPI Updated in April 2014 from 90% in 88 working days]

[1] Blue dashed line in graphs = KPI target level. This line may be invisible when performance and target are identical (e.g. 100%).
[2] Direction in which we are trying to drive performance. (Are we aiming to exceed, equal, or stay beneath this particular KPI target?)

Indicator	Performance	RAG	Recent Trend[1]	Aim[2]	Notes
Annualised (rolling year) percentage of PGD applications processed within 3 months (66 working days) **Average number of working days taken.**	98% 57 working days	⇔		Reach and maintain 100%	KPI: As above. (Annualised score). Performance has reached target, bar one very complex 10-type PGD application in June, which took longer to process. [KPI Updated in April 2014 from 90% in 88 days]
Licensing decisions made: - **By ELP** - **By Licence Committee**	9 6	⇧		No KPI – tracked for workload monitoring purposes	Volume indicator (no KPI target).
Staff sickness absence rate (%) per month.	0.7%	★		Maintain 3% or less	KPI: Absence rate of ≤ 3%. Public sector sickness absence rate average is 8 days lost per person per year (3.5%).

Indicator	Performance	RAG	Recent Trend[1]	Aim[2]	Notes
Percentage of Opening the Register requests responded to within 20 working days	100%	★		Maintain at 100% 	KPI: 100% of complete OTR requests to be responded to within 20 working days (excluding counselling time)
Number of visits to the HFEA website (cw previous year)	100,282 (79,453)	⇩		No KPI – tracked for general monitoring purposes.	Volume indicator showing general website traffic compared to the same period in previous year. Measured on the basis of 'unique visitors'.
Cash & Bank Balance	£2,676k	⇩		 Reduce	KPI: To move closer to DH recommended £750k cash reserves. (KPI for review at end of Q2).

Indicator	Performance	RAG	Recent Trend[1]	Aim[2]	Notes
Management Accounts					

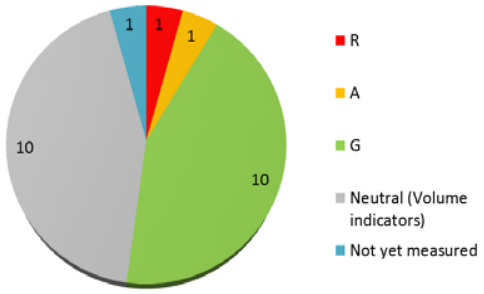
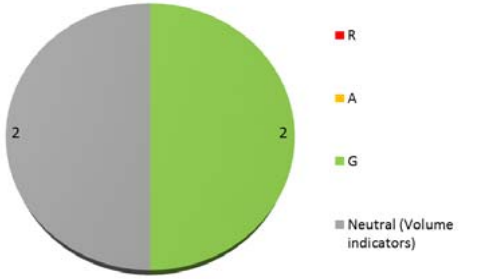
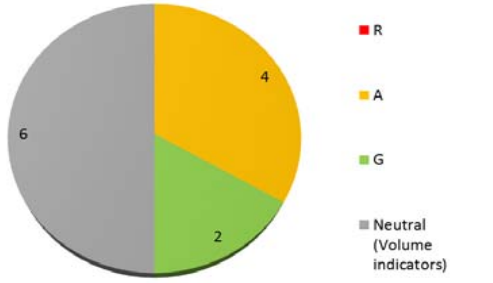
Income & Expenditure Account — Jul-2014

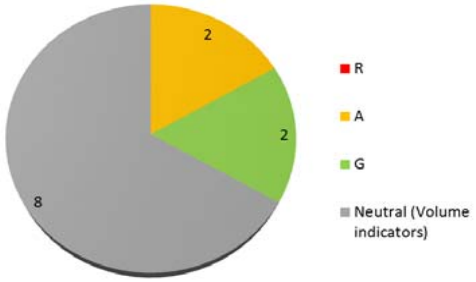
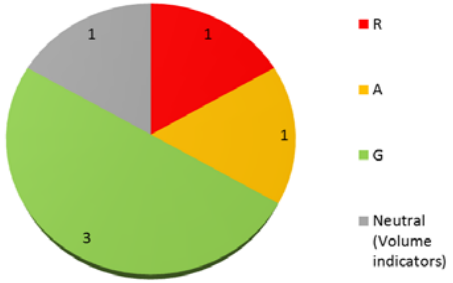
Cost Centre Name All Cost Centres
Department Name All Departments

SUMMARY (Operational Activity)	Year to Date Actual YTD £	Year to Date Budget YTD £	Variance YTD £	Full Year Forecast £	Full Year Budget £	Variance £
Income						
Grant-in-aid	250	225	(25)	900	900	-
Licence Fees	1,407	1,415	8	4,193	4,193	-
Other Income	2	2	(1)	6	6	-
Total Income	1,659	1,641	(18)	5,099	5,099	-
Revenue Costs - Charged to Expenditure						
Salaries	1,117	1,163	45	3,478	3,478	-
Other Staff Costs	80	81	2	241	286	(45)
Authority/Committee costs	79	98	19	298	298	-
Other Compliance Costs	11	11	0	37	37	-
Other Strategy Costs	37	53	16	175	175	-
Facilities Costs incl non-cash	112	118	6	356	356	-
IT costs Costs	36	32	(3)	102	102	-
Legal Costs	77	58	(19)	231	231	-
Professional Fees	22	35	12	172	127	45
Total Revenue Costs	1,571	1,650	79	5,089	5,089	-
Total (Surplus)/Deficit before Capital & Project costs	88	(8)	(97)	10	10	-
Less Capital & Project Costs - Reserves funded	199	302	(103)	1,220	1,220	-
Other Capital Costs	-	3	3	10	10	-
TOTAL NET ACTIVITY	**287**	**297**	**(197)**	**1,240**	**1,240**	**-**

Indicator	Performance	RAG	Recent Trend[1]	Aim[2]	Notes
Notes:	As at month four (July 2014), we have a year-to-date surplus of £97k before the IFQ Project. No major issues to report. Income is less than 1% up on budget. This is due to receipt of more GIA than budgeted for the month of June. This will even out over the year with the full GIA being drawn down. Licence and Treatment fees are slightly down on budget (0.5%) Total costs are down on budget by 4.8%, before capital spend. Areas that are currently under particular review are salaries costs, which are less than expected at this stage, and the overspend on legal costs. Forecasts are being reviewed, in particular for salaries and legal costs, with a more detailed review in all areas at the mid year point. The adjustment to the other staff costs forecast made this month reflects the need for less spend on recruitment than budgeted.				

Summary Table:

Scorecard area	KPIs / RAG Status	Red Indicators and Management Comments on Controls
Regulatory Operational Performance		The single red indicator is for the percentage of applications for HLA, the target for which is processing within 6 weeks of receipt. Two items were due in June, but completed in July. However these were held back deliberately (rather than delayed through slow processing), pending a decision about the processing of items where the affected individual was current asymptomatic. This meant that both items missed the six week processing deadline, but were considered by ELP as soon as the handling of the items had been clarified. The delay and the reasons for it were communicated to the applicants at the time, and patients were not adversely affected.
Capacity		No red indicators. It is worth noting that we have had three staff resignations in August (i.e. after the July figures were collected for this report). This will increase our establishment turnover figure (which has been stable at around 10-15% for the past year), which may therefore be rated amber or red next month.
Corporate Governance		No red indicators. The amber indicators are all projects that are being monitored and managed. The project risks relate to various resource pressures and (in one case) timeline slippages. There is a higher than usual number of neutral indicators, since 3 projects have ended in July (and will be removed from the report next time).

Scorecard area	KPIs / RAG Status	Red Indicators and Management Comments on Controls
Information Provision		No red indicators.
Financial Performance		The single red indicator relates to the collection of debts, the target for which is 85% within 60 days. In general, performance on debt collection is improving. In July, there were some payments of old debts. However, this led to an apparent decrease in performance (to 79%), since the old debts collected were beyond the 60 days required by the performance indicator. In other words, this apparent negative result is actually an artefact of good performance, rather than anything of concern. We are looking at ways to have a generally more robust debt chasing process all year round, which should help to avoid anomalous performance outcomes such as this.

CMG commentary on July data:

Performance remains largely positive, with few red indicators.

CMG discussed that there have been a number of clinics recently with a high number of non-compliances on inspection. The Compliance and Information Directorate has been reflecting on some recent poor performance in clinics and an item about this will be taken to Ethics and Standards Committee in September to give its members a flavour of the findings from the inspections in the 2013/14 financial year.

Regarding PGD processing, although the indicator is currently on amber, as explained above this is entirely because of a particularly large 10-type PGD application in June, which took longer to process owing to its complexity. This does not reflect any performance issues. It should be noted, however, that we are currently also seeing a large rise in the number of PGD applications (13 were received in July). This sudden spike in the volume of business may also lead to a dip in overall processing times, despite our best efforts. For instance, the items may need to be spread across several Committee meetings, extending the end-to-end decision-making process for some items.

The current version of the Directorates report will shortly be adapted to align with the new Strategy, now that it has been published. This work will be done mainly in September and October.

Authority paper

Strategic delivery:	**Setting standards**	☑	**Increasing and informing choice**	☑	**Demonstrating efficiency, economy and value**	☑
Paper title	McCracken review: an update					
Agenda item	7					
Paper number	[HFEA (17/09/2014) 732]					
Meeting date	17 September 2014					
Author	Peter Thompson, Chief Executive					
For information or decision?	Information					
Recommendation	To note the progress made over the past six months: of the ten recommendations in the McCracken review we have completed seven and the remainder are partially complete or well underway. And that this report will be the final standalone update on McCracken.					
Resource Implications	Different recommendations have different resource implications. Recommendation 6 will incur significant capital expenditure.					
Implementation	See Annex 1					
Communication	Different recommendations require different communications mechanisms.					
Organisational Risk	Different recommendations incur different levels of organisational risk. The programme as a whole will require careful oversight alongside the day-to-day business of the HFEA.					
Evaluation	Different recommendations will require different evaluation – to be developed over time.					
Annexes	Annex 1					

1. Introduction

1.1. Justin McCracken's review of the HFEA and the HTA (Human Tissue Authority) was accepted by the Government in July 2013.[1] The Authority agreed its response to the recommendations in the McCracken review at its meeting last September.[2] Part of that response was a commitment to regular updates on progress. The first six monthly update was presented to the Authority in March 2014[3]; this paper provides the second, and final, six month update.

2. The McCracken review

2.1. The McCracken review made 18 recommendations in total, 10 of which required action by the HFEA. The 10 recommendations and the agreed actions are set out in full at Annex 1.

2.2. In summary, we have made good progress: **we have completed seven recommendations and the remainder are partially complete or well underway**.

2.3. As in previous updates, the 10 recommendations can usefully be brigaded into five themes. The remainder of this paper provides an overview of the progress made over the last six months against those themes.

Shared services (Recommendation 2)

2.4. The McCracken review recommended the 'Finance and Resource functions' of the HFEA and the HTA should be merged under a single Director reporting to two Chief Executives.

2.5. We reported this recommendation as being **complete** at the March 2014 update. The new shared Director, Sue Gallone, has been in post for six months now and it is clear that the new arrangements are working well: the NAO approved this year's accounts with no significant issues. We will, of course, look to see what further efficiencies can be found over time and keep staffing levels under review.

Stakeholder engagement (Recommendations 4, 5 and 13)

2.6. The McCracken review recommended we should take action to improve the way in which we engage, listen and feed back to the sector we regulate (Recommendations 4 and 13). At its meeting in September 2013, the Authority agreed a range of actions on stakeholder engagement, including the commissioning of a survey on stakeholder perceptions.[4] Our annual conference in February 2014 (our first for some years) was a great success and indicated a significant improvement in our relations with stakeholders. The conference was part of a consultation on our new strategy for 2014-17 (see also paragraph 2.16 below). And a new stakeholder engagement plan was agreed at the May 2014 Authority

[1] https://www.gov.uk/government/publications/review-of-human-fertilisation-embryology-authority-and-human-tissue-authority
[2] *Authority response to the McCracken review* (11/09/2013) 691
[3] *Progress on the McCracken Review* (05/03/2014) 715
[4] *Stakeholder engagement* (11/09/2013) 692

meeting[5].

2.7. The Authority has recently appointed a Head of Engagement (to start in October 2014), who will lead on implementing our stakeholder engagement plan, as well as our wider work around patient engagement. Our new engagement approach commits us to:

- more face-to-face meetings with stakeholders, including a regular conference;
- making Authority decisions more widely known, with for example audio recordings of meetings on our website (now complete); and
- updated patient information, including new version of the Getting Started booklet.

2.8. A further survey of our stakeholders in spring 2015 will tell us whether such initiatives are having the desired effect. Stakeholder engagement is, by definition, a process, but, taken together, we view the range of actions taken so far as meaning that Recommendations 4 and 13 are now **complete**.

2.9. In addition, the McCracken review suggested the establishment of a separate fees review group to 'improve accountability and facilitate dialogue' with fee payers (Recommendation 5). We have started our preparations to establish such a group with a planned first meeting in October 2014.

Better use of Information (Recommendations 6 and 7)

2.10. McCracken recommended that we review the information we collect and how we validate and verify that information and that this work should proceed with stakeholder involvement (Recommendation 6). To that end we have established a significant programme of work which we have titled: 'Information for Quality' (IfQ). The Authority agreed this approach at its September 2013 meeting.[6]

2.11. Since then, we have reported progress on IfQ to every Authority meeting. Engagement with stakeholders has been extensive with the establishment of an Advisory Group and several Expert Groups. A paper to this meeting will seek approval for a consultation exercise, commencing on 1 October 2014, on the main areas where we are proposing change and invite further comment: from the information we collect and the frequency of collection; the systems in place to send it to the HFEA; and the means by which we make that information public, notably our websites including changes to 'choose a fertility clinic'.

2.12. The McCracken report also proposed (Recommendation 7) that we develop in time two additional information projects: one on making available better aggregated data for research and another on identifying the best means of providing support to donor conceived individuals when they access information from our Register. At its meeting in March 2014 the Authority agreed to set up three-year pilot which will provide

[5] *Stakeholder engagement* (14/05/2014) 721
[6] *Information for quality* (11/09/2013) 693

counselling and intermediary support for Opening the Register applicants.[7] The proposal envisages entering into a contract with an external provider (likely a post-adoption agency) to supply this service and a formal procurement exercise will begin shortly. We are of the view that Recommendation 7 is now **partially complete**.

Working with other regulators (Recommendations 8, 11 and 12)

2.13. The McCracken review made three related recommendations in this area: that the Authority eliminates any regulatory overlap with the CQC (recommendation 12); that the HFEA and the HRA work more closely together to ensure a single, seamless application process for research applicants (Recommendation 8); and that the HFEA and the MHRA clarify their roles to achieve effective joint working (Recommendation 11).

2.14. Like all relationships between organisations, these three recommendations can be viewed as work in progress. That said, in March 2014 we reported that the formal aspects of these recommendations should be regarded as **complete**. Since then, we have maintained good working relations with all three organisations.

Regulatory focus (Recommendation 10)

2.15. Arguably the most challenging recommendation in the McCracken review concerned the recommendation to conduct a review of the balance of our regulatory activity 'to ensure that it reflects the relative risks of the different activities that it oversees.' The Authority agreed in September 2013 that our new Strategy was the most appropriate vehicle to locate such a review.

2.16. Following an extensive public consultation in the first few months of 2014,[8] the Authority agreed at its July meeting a new strategy for 2014-17 which puts quality of care and outcomes at the centre of what we do[9]. As we set out in the strategy consultation document, we believe that, as the regulator, we can improve the quality of care in three different, but linked ways:

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

2.17. The next stage is ensure that the new Strategy drives our priorities and business planning processes and a paper to this meeting will set out how we plan to do this.[10] We will deliver the strategy through various activities – and through our ways of working – across the next three business years.

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[7] *Improving the sharing, quality and disclosure of donor information* (05/03/2014) 714
[8] *Our future strategy* http://www.hfea.gov.uk/8572.html
[9] *HFEA Strategy 2014-2017* (09/07/2014) 725
[10] Strategy Implementation (17/09/2014) 733

2.18. The Authority has already incorporated more input from patients into inspections, successfully introducing unannounced inspections, where there is greater focus on speaking to the patients who are present in the clinic, rather than only (or mainly) to clinic staff. Much of the work described in our Strategy is about providing better information and support, in various ways, for patients, donors and donor-conceived people. We will also explicitly be focusing on the quality and safety of care, through the way in which we conduct our regulatory activities. Throughout the Strategy the change in stance is evident – we have moved from simply considering patients' (and others') views, to consciously positioning their perspective so it is at the absolute front and centre of our decision-making and our purpose. We have also signalled a move towards even greater collaborative working with professional stakeholders and other regulators, for the benefit of patients and others affected by assisted reproduction.

2.19. The true test of the effectiveness of the Authority's new regulatory focus will only be seen in the decisions it takes over the coming months and years, but we are of the view our new Strategy meets the formal requirements set out in the McCracken review and that recommendation 10 should therefore be regarded as **complete**.

3. Recommendations

3.1. The Authority is invited to note the progress made over the past six months in meeting the McCracken recommendations in section 2 above and at Annex 1. In summary: **we have completed seven recommendations and the remainder are partially complete or well underway**. In view of the progress made the Authority is also invited to agree that progress on the remaining outstanding recommendations (5, 6 and 7 – in part) should be undertaken in other formats. If accepted, this progress report on McCracken will be the last.

Agenda item 7 **Paper number [HFEA (17/09/2014) 732]**

Annex 1

McCracken Review Action Plan

Recommendation	Response	Lead Officer
Theme: Shared services		
Recommendation 2 **The support services of the two bodies [the HFEA and HTA] should be combined and managed by a single Director of Finance and Resources supporting both Chief Executives. This will facilitate the achievement of significant further efficiency savings, estimated at £2.8M over 10 years.**	**Complete:** the new shared Director of Finance and Resources started in March 2014.	**Peter Thompson** CEO
Theme: Stakeholder engagement		
Recommendation 4 **In order to improve transparency, both the HFEA and the HTA should review and strengthen their arrangements for consulting with stakeholders on their approach to regulatory activities, and should ensure that issues raised with them and their responses are publicly available and discussed regularly in open Authority meetings.**	**Complete:** stakeholder survey commissioned in January 2014 to understand better perceptions of the HFEA, its work, and to gather views about possible improvements. The findings of the survey informed a stakeholder engagement plan which was agreed by the Authority in May 2014. Stakeholder survey will be rerun in Spring 2015 to assess progress.	**Juliet Tizzard** Director of Strategy and Corporate Affairs

Recommendation 13 **The HFEA should review its approach to engagement with its stakeholders and should publish an action plan within 6 months. In 12-18 months' time the HFEA should undertake a structured and anonymous stakeholder attitude and satisfaction survey, and publish the results and associated action plan.**	See recommendation 4.	
Recommendation 5 **Both the HFEA and the HTA should establish and operate a (permanent) fees review group to improve accountability and facilitate dialogue with licence fee payers.**	**In progress:** fees review group expected to be in place in October 2014.	**Sue Gallone** Director Finance and Resources
Theme: Better use of Information		
Recommendation 6 **To reduce unnecessary regulatory burden the HFEA should proceed without delay with its planned fundamental review of information requirements, using the BFS/ACE paper as the basis for discussion, and adopting for the project an inclusive approach similar to that used successfully in the "One at a Time" project. The HFEA should publish the Project Initiation Document for this work by July 2013 and**	**In progress:** work programme entitled 'Information for Quality: modernising how we collect, use and publish information' set out in scoping paper August 2013. Programme overseen by an Advisory Group established in October 2013 and progress reported to each Authority meeting. The group has established four expert sub-groups to advise on: the data dictionary; data submission; data reporting; and website/public information. Options appraisal and user research review completed in May 2014. It is expected that the Programme will be completed in the 2015-16 business	**Nick Jones** Director Compliance and Information

then make quarterly progress reports available to open meetings of the Authority. It is estimated that this will yield savings of approximately £1M.	year.	
Recommendation 7 **On completion of the review of information requirements the HFEA should establish inclusive projects (a) to review whether further use could be made of the information in its statutory Register to promote public understanding and facilitate more research into issues pertaining to ART; and (b) to identify the best means of providing information from the register, together with appropriate support, to people born as a result of ART.**	**Partially complete:** on (a), the McCracken recommendation assumes completion of Recommendation 6 before beginning work. On (b), HFEA staff met a range of external stakeholders in June 2013 to discuss information and support for people seeking information from the Register. Options presented to the Authority in March 2014 and agreement reached on three year pilot project to provide counselling and intermediary services for Opening the Register applicants. Formal procurement exercise to begin in Autumn 2014.	Tba (a) **Juliet Tizzard** Director of Strategy and Corporate Affairs (b)
Theme: Working with other regulators		
Recommendation 8 **In order to improve the approval process for research projects involving gametes and embryos the HFEA should commit to participating fully in the new IRAaS system from its launch in 2014 (and to cooperating fully with the other bodies involved), and should make adequate resources available now to prepare for it.**	**Complete:** agreement reached in November 2013 with the HRA that HFEA will participate in the new IRAaS system when it launches (tbc 2015).	**Debra Bloor** Chief Inspector

Recommendation 11 **The HFEA should clarify to all concerned how it cooperates with the MHRA to achieve effective joint working on matters falling within the latter's regulatory oversight but which take place within premises regulated by the HFEA.**	**Complete:** an information sharing agreement between the HFEA and the MHRA was agreed. It covers: • The exchange of information on medical devices used in ART • MHRA Field Safety Notices and other information sent to users by the manufacturer • HFEA Grade A incidents which involve medical devices MHRA / HFEA collaboration has already resulted in CE Marking Guidance being issues to licensed clinics. The work has established effective lines of communication between HFEA and MHRA and liaison where there are areas of common concerns is now embedded.	**Debra Bloor** Chief Inspector
Recommendation 12 **The HFEA should implement their agreement with the CQC, which was approved by the HFEA during my review, to eliminate duplication of regulatory activity between them.**	**Complete:** HFEA / CQC agreement effective from 1 April 2013. Feedback on additional inspection activities undertaken by HFEA as a result of this work has been very positive.	**Debra Bloor** Chief Inspector
Theme: Regulatory focus		
Recommendation 10 **The HFEA should conduct a review of the balance of its regulatory focus to ensure that it reflects the relative risks of the different**	**Complete:** New Strategy 2014-17 will address directly the issues of regulatory focus. Consultation on aspects of the strategy issued online on 10 February 2014 and	**Peter Thompson** CEO

activities that it overseas. Its approach should reflect the relative maturity of the sector it regulates now, the need to ensure appropriate oversight of technical developments in the field of ART, the need to ensure that appropriate standards of practice are implemented consistently throughout the sector, and the continuing need for a high degree of public assurance regarding the sensitive activities that it oversees. This should not lead to any overall increase in regulatory activity or cost, but a rebalancing of activity.	closed on 28 March 2014. Finalised Strategy agreed by Authority and subsequently published in July 2014. New Business Plan underway.	**Paula Robinson** Head of Business Planning

Authority paper

Strategic delivery:	**Setting standards**	☑	**Increasing and informing choice**	☑	**Demonstrating efficiency, economy and value**	☑
Paper title	Strategy Implementation					
Agenda item	**8**					
Paper number	[HFEA (17/09/2014) 733]					
Meeting date	17 September 2014					
Author	Paula Robinson, Head of Business Planning					
For information or decision?	Decision					
Recommendation	The Authority is asked to approve the outline of Business Plan activities for the three year strategic period.					
Resource implications	In budget.					
Implementation	Across three business years (2014/15; 2015/16; 2016/17)					
Communication	The HFEA's Business Plans, once approved by the Department of Health, are published on our website.					
Organisational risk	Low-medium.					
Annexes	A: Three year outline of activities to implement the HFEA Strategy 2014-2017.					

1. Strategic Planning

1.1. Now that we have published our new three-year strategy, it is possible, for the first time in several years, for us to take a longer term view in our planning. This is a welcome position to be in.

1.2. It is also now possible for us to take a more cohesive approach to strategic risk management and the monitoring of delivery.

1.3. This paper therefore sets out how we will plan, manage and monitor the delivery of the strategy.

2. Business Planning

2.1. Through recent discussions at the Corporate Management Group (CMG), the executive has reviewed the current business plan (for 2014/15) in light of the strategy. The revised document, realigned to correspond to the areas of our strategy, has been circulated to members separately, and will be republished shortly.

2.2. CMG has also begun to consider the range and timing of the work that will be required in order to address the whole strategy across the next three years.

2.3. Annex A summarises CMG's deliberations to date, setting out at a high level which activities will occur in each of the three years (2014/15 through to 2016/17). Future planning will be needed, and more detail will emerge as we go through the process of working up the business plan for 2015/16 over the next two months.

2.4. A draft of the 2015/16 business plan will be brought to the Authority for approval in November, prior to submission to the Department of Health at the end of the calendar year, in the usual way.

3. Strategic Risk Management and Assurance

3.1. Alongside the development of future business plans, we will be redeveloping other, related, documentation and processes, so that we can manage our strategic risks effectively and monitor our performance and progress.

3.2. The first step will be a review of the high level risk register, to ensure it appropriately reflects the real risks to delivering our vision (high quality care for everyone affected by assisted reproduction) and strategic objectives. This will be progressed in the next two months, through CMG.

3.3. As well as reviewing the content of the high level risk register, we will also take this opportunity to address several of the recent internal audit recommendations for improving our risk register and our wider risk system, including developing a risk assurance mapping methodology and reviewing the way in which we record and monitor our operational risks.

3.4. The new high level risk register will be taken to the Audit and Governance Committee (AGC) when it is complete, and will then also be scheduled for a future Authority meeting.

3.5. The Directorates Report will also need to be redeveloped, although much of the current content will continue to be relevant. A detailed, operational, version of this report is reviewed regularly by CMG in order to create the summary version that is presented to the Authority at each meeting. The longer version lists many operational indicators, currently split into various sections: regulatory operational performance, capacity, corporate governance, information provision and financial performance.

3.6. A revised version, with new sections giving a better correlation with our strategic objectives, will be presented for initial discussion at a CMG meeting in October. Between October and December, CMG will then focus on developing an additional new dashboard of overall strategic indicators, which would then be included in the summary received by the Authority, equipping us with an ongoing picture of strategic progress and performance. The informal morning workshop on the day of the Authority meeting will also enable members to have input into this new development.

4. Recommendations

4.1. The Authority is asked to:

4.1.1. Note and approve the broad three year plan set out in Annex A. If the Authority is content with this, the draft business plan for 2015/16 will then be prepared along these lines, for consideration at the November meeting.

4.1.2. Note the other developments planned to refresh and improve our strategic risk management and assurance mechanisms, as set out in section 3 above.

Annex A

Planning for 2014-2017 – Strategic Implementation Across Three Business Plans

Vision: High quality care for everyone affected by assisted reproduction

Activities	Business Year		
	2014/15	2015/16	2016/17
Setting Standards			
Improving the quality and safety of care through our regulatory activities			
Full compliance cycle of inspection, audit and licensing.	CORE (ongoing work)		
Identifying and implementing ways of improving the quality and safety of care:			
• Making patient experience integral to assessment of clinic performance.			
• Increasing focus on learning from incidents and adverse events and complaints from patients.			
• Continuing to evaluate areas of regulatory concern, and identifying performance levers.	CORE (ongoing work)		
• Working with professional groups to identify the best ways to optimise success rates.			
• Publishing more of our data to drive improvements in clinic performance (following on from IfQ improvements to website and CAFC).			
• External review of the inspection regime, to evaluate the impact of our work.			
Acknowledging that treatment is often unsuccessful, and exploring with professional stakeholders how the HFEA and clinics could better address this issue.			

Activities	Business Year		
	2014/15	2015/16	2016/17
Reviewing and advising on issues relating to mitochondrial replacement, as and when requested by Ministers.	Scientific review; briefings; advice on regulations	Implemen-tation (subject to Parliamen-tary approval)	CORE (ongoing work)
Reviewing issues with the current storage consent regime; consideration of future actions.	Review	Implemen-tation	
Maintaining our role as UK's Competent Authority for ART in the European Union.	CORE (ongoing work)		
Coordinating with other relevant bodies in the HFEA's approach to research regulation:			
• Research regulation and regenerative medicine developments.			
• Working with HRA, HTA, MHRA to ensure streamlined regulation of stem cell therapies.			
• Working with HRA to ensure an integrated research application process through IRAS (the Integrated Research Application Service).			
Improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families			
Supporting and informing the work of the Lifecycle campaign:			
• Establishing Lifecycle website to provide information about donation and related issues.			
• Ensuring clinics prepare patients adequately for donation and that clinics understand their important lifelong role as a provider of accurate information about past treatments.			

Activities	Business Year		
	2014/15	2015/16	2016/17
Collecting and publishing information about availability of donor gametes in the UK.	Consul-tation	Implemen-tation	
Implementing access to support services for applicants to the Register.	Piloting period		
Facilitating timely access to information from the Register for those who are entitled to it.	CORE (ongoing work)		
Evaluating donation policies introduced in 2012.			
Projects to: • Implement new EU requirements on the import of donor gametes • Implement new EU coding requirements for human tissue and cells.	Start-up once EU has passed the relevant Directive	Completion	
Increasing and informing choice			
Using the data in the HFEA register of treatments to improve outcomes and research			
Publishing and supplying the information we hold, for the benefit of stakeholders:	CORE (ongoing work)		
• Regularly updated 'Choose a Fertility Clinic' (CAFC) information to assist patient choice.	CORE (ongoing work)		
• Through the IfQ Programme, improve the presentation of CAFC.	Consul-tation	Implemen-tation	
• Work with commissioners of NHS services to improve quality of commissioning decisions.			
• Information provision for researchers requesting access to Register data.	CORE (ongoing work)		
Maintaining the Register of treatments and outcomes and supporting clinics in reporting the data.	CORE (ongoing work)		

Activities	Business Year		
	2014/15	2015/16	2016/17
Publishing reports on the information we hold, for the benefit of stakeholders.	CORE (ongoing work)		
Ensuring patients have access to high quality meaningful information			
Identifying quality factors through user research, and then using our data to drive up standards in clinics.	Start-up	Delivery	
Enhancing CAFC further by including user experience scores.	Consider-ation of method-ology	Delivery	CORE (ongoing work)
Ensuring clinics prepare and support patients and donors through the information they give them (e.g. through their websites and publications).			
Ensuring patient views and needs are better incorporated into the HFEA's work and the information it provides, by: • Enhancing the patient voice in all of the HFEA's work • More effectively seeking patients' views.	Exploration and consul-tation	Piloting/ Implemen-tation	CORE (ongoing work)
Redeveloping the HFEA website to make better use of feedback mechanisms, video and integration with social media platforms.	Plan	Build / complete	
Improving HFEA information about treatment options, research and other subjects.			CORE (ongoing work)
Working with clinics and experts to publish information about new treatments.			CORE (ongoing work)

Activities	Business Year		
	2014/15	2015/16	2016/17
Collaborating with professional stakeholders to put patients in touch with better information and services when they first realise they may have a fertility issue.	Ground-work	Delivery	
Demonstrating efficiency, economy and value			
Ensuring the HFEA remains demonstrably good value for the public, the sector and Government			
Building our establishment staff capacity and skills to ensure good quality delivery of our strategy and our core work, so that the HFEA is professional, capable, easy to deal with, agile and responsive, as well as effective.			
Modernising the HFEA's Register function and processes:	Exploration	Implemen-tation	
• Data Dictionary Project reviewing and simplifying register forms and fields collected.	Exploration	Implemen-tation	
• Data Submissions Project transforming current electronic data interchange (EDI) system and recalibrating current data validation and correction regime.	Exploration	Implemen-tation	
• Reviewing verification processes for clinic outcomes on Choose a Fertility Clinic (CAFC).	Exploration	Implemen-tation	
Working collaboratively with other organisations for the benefit of stakeholders: • Working effectively with the MHRA and UKAS (the body that accredits laboratories), as relevant • Working as a partner in the Department of Health National Information Board, and in particular with the Health and Social Care Information Centre, in developing a collective vision for maximising the use of data and technology across the health and care system – to work to the best advantage for patients, professionals, citizens and taxpayers.	CORE (ongoing work)		

Activities	Business Year		
	2014/15	2015/16	2016/17
Establishing a mechanism for increasing accountability and transparency in respect of the fees the HFEA charges clinics.	Start-up	CORE (ongoing work)	
Ensuring internal Compliance processes and systems assist regulatory efficiency and quality.	CORE (ongoing work)		
Ensuring governance tools underpinning licensing and other decisions are in place and effective.	CORE (ongoing work)		
Maintaining an overview of emerging developments and supporting evidence-based decision-making.	CORE (ongoing work)		
Facilitating access to information under various regimes and fulfilling Government requests.	CORE (ongoing work)		
Continued delivery of core internal finance and facilities work so that services are provided in the most efficient way.	CORE (ongoing work)		
Continue to seek opportunities for shared services and efficiency savings with the Human Tissue Authority (HTA), the Care Quality Commission (CQC) or other organisations:	CORE (ongoing work)		
• Maximising benefit of finance resources shared with HTA.	CORE (ongoing work)		
• 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.	CORE (ongoing work)		
• Continuing to receive support services from the CQC (or other landlord when there is a change of office premises), via an SLA.		**Office move**	
• Upgrading Finance systems to enable further efficiencies and shared services.			

Authority Paper

Strategic Delivery:	**Setting standards**	☐	**Increasing and informing choice**	☑	**Demonstrating efficiency, economy and value**	☐
Paper title	Information for Quality: consultation plans					
Agenda item	**11**					
Paper number	HFEA (17/09/2014) 734					
Meeting date	17 September 2014					
Author	Juliet Tizzard, Director of Strategy and Corporate Affairs					
For information or decision?	Decision					
Recommendation	• Endorse the proposed approach to consulting on proposals from the IfQ Advisory Group • Endorse the contents of the IfQ consultation materials, subject to drafting and layout changes					
Resource implications	The consultation and analysis itself will require staff resources from the Policy and Communications departments. Implementing the findings through the Information for Quality (IfQ) programme will have significant costs associated which are tracked through that programme.					
Implementation	Decisions made following the consultation will be implemented through the IfQ programme in the 2015/16 business year.					
Communication	Consultation to be launched in 1 October with communications work to promote it and the workshops.					
Organisational risk	Medium					
Annexes	Draft consultation document (restricted distribution)					

1. Information for Quality

1.1. Information for Quality (IfQ) is an ambitious programme to transform the way we collect, use and publish information to benefit patients, the public and clinics. Through the programme, we will redevelop our data submission, analysis and publication systems and modernise how we provide information for patients, donors and donor-conceived people.

2. Stakeholder engagement to date

2.1. As members will know, the IfQ programme is being guided by a dedicated Advisory Group, as well as a set of subject-specific Expert Groups, which are made up of a varied group of professionals and patients. The Expert Groups have focussed on the following areas:

- What data we collect and how it is defined
- How clinics submit data to us
- Data reporting and success rate presentation
- Publishing information for patients

2.2. The Expert Groups have spent the past six months developing proposals for change in their respective areas. Those proposals have been discussed by the Advisory Group and the consultation materials (attached) represent proposals from the Advisory Group as a whole.

3. User research

3.1. During the same period, we have commissioned a research project to understand our different users' needs. Carried out by a specialist user research agency, Fluent Interaction, the research focussed on our data submission tool (EDI), the password-protected website for clinic transactions (Clinic Portal), the HFEA website including Choose a Fertility Clinic and our general communications with clinics.

3.2. The findings from the user research have been incorporated into the consultation document.

4. The consultation process

4.1. The consultation will launch on 1 October and will consist of an online survey, supplemented by explanatory materials setting out our plans, proposals and questions. The materials and questions fall into three main areas:

- the information we collect – what the dataset should include and why
- how clinics submit data to us – the system for submitting data and how we check data for publication
- how we publish information – how success rates should be published on our website and what additional information – such as patient experience information – should be presented.

4.2. Although we expect professional audiences to be most interested in the consultation, we have tried to make the materials as accessible to lay audiences as possible.

4.3. Because of the focussed nature of the consultation, we will keep the survey open for six weeks, ending on 12 November. We will also supplement the online survey with two workshops (in London and Manchester) to allow more detailed discussions about the proposals.

5. Recommendations

5.1. The Authority is asked to:

- Endorse the proposed approach to consulting on proposals from the IfQ Advisory Group
- Endorse the contents of the IfQ consultation materials, subject to drafting and layout changes

5.2. The Executive will return to the Authority in January 2015 with recommendations about the questions asked during the consultation.