

Authority Paper

Strategic delivery:	Setting standards	<input checked="" type="checkbox"/>	Increasing and informing choice	<input checked="" type="checkbox"/>	Demonstrating efficiency, economy and value	<input checked="" type="checkbox"/>
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