Audit and Governance Committee meeting - agenda

15 June 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

	Agenda item	Time
1.	AGC Members - Training Session – Reviewing the Annual Accounts	10:00am
2.	Welcome, apologies and declaration of interests	11:00am
3.	Minutes of 16 March 2016 **[AGC (15/06/2016) 494]**	
4.	Matters Arising **[AGC (15/06/2016) 495 SG]**	
5.	People Strategy & HR Risks a) Staff survey results **[AGC (15/06/2016) 496 PT]**	
6.	Information for Quality (IfQ) Programme – Register Data Migration **[AGC (15/06/2016) 497 PR]**	
7.	Internal Audit a) Annual Assurance Statement – 2015/16 **[AGC (15/06/2016) 498 DH Internal Audit]** b) 2016/17 plan **[AGC (15/06/2016) 499 DH Internal Audit]**	
8.	Implementation of Recommendations – Progress Report **[AGC (15/06/2016) Oral WEC]**	
9.	Information Assurance & Security **[AGC (15/06/2016) 500 SG]**	
10.	Lunch (Refreshments & Lunch provided)	12:30pm

11.	Strategic Risks **[AGC (15/06/2016) 501 PR]**	1:00pm
12.	Annual Report & Accounts (including Annual Governance Statement) – Approval **[AGC (15/06/2016) 502 MA]**	
13.	External Audit a) Audit completion report **[AGC (15/06/2016) 503 NAO]**	
14.	AGC Forward Plan **[AGC (15/06/2016) 504 SG]**	
15.	Any other business	
16.	Close	2:00pm
17.	Session for members and auditors only	2:00pm
18.	Next Meeting 10am Wednesday, 21 September 2016, London	

Minutes of Audit and Governance Committee meeting 16 March 2016

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☐ Demonstrating efficiency economy and value
Details:			
Meeting	Audit and Governance Committee		
Agenda item	3		
Paper number	AGC (15/06/2016) 494		
Meeting date	15 June 2016		
Author	Dee Knoyle, Committee Secretary		
Output:			
For information or decision?	For decision		
Recommendation	Members are asked to confirm the minutes as a true and accurate record of the meeting		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☐ Low	☐ Medium	☐ High
Annexes			

Minutes of Audit and Governance Committee meeting on 16 March 2016 held at etc.venues, Tenter House, 45 Moorfields, London EC2Y 9AE

Members present	Rebekah Dundas (Chair) Gill Laver Jerry Page Margaret Gilmore
Apologies	Anita Bharucha
External advisers	Internal Audit Karen Finlayson, Price Waterhouse Coopers (PWC) George Smiles, National Audit Office (NAO)
Observers	Kim Hayes (Department of Health)
Staff in attendance	Peter Thompson, Chief Executive Sue Gallone, Director of Finance & Resources Wilhelmina Crown, Finance & Accounting Manager Nick Jones, Director of Compliance & Information Paula Robinson, Head of Business Planning Catherine Drennan, Head of Legal Dee Knoyle, Committee Secretary

1. Welcome, apologies and declarations of interests

1.1 The Chair welcomed attendees to the meeting, including Karen Finlayson who was attending for the first time as head of Internal Audit for the HFEA.

1.2 There were apologies from Anita Bharucha.

1.3 There were no declarations of interest.

2. Minutes of the meeting held on 9 December 2015

2.1 The minutes of the meeting held on 9 December 2015 were agreed as a true record of the meeting and approved for signature by the Chair.

2.2 Clarification of the conclusions of the review of Audit and Governance Committee (AGC) effectiveness was requested. This will be circulated again and was reported to the Authority on 9 March.

Action

2.3 Director of Finance & Facilities to recirculate to the committee the clarification of the conclusions of the review of Audit and Governance Committee (AGC) effectiveness.

3. Matters arising

3.1 The committee noted the progress on actions from previous meetings. Some items were ongoing and others were dependent on availability or were planned for the future.

3.2 Action (f) was now complete. Gill Laver and Jerry Page had both observed an inspection. They reported that the inspections they observed were conducted professionally by the HFEA inspection team and were most informative.

3.3 Progress on information governance actions (Action 9.6) was slow due to other priorities but should be complete by December 2016.

4. Finance and Resources – Risks

4.1 The Director of Finance and Resources presented the risks in this area with details of how they are being managed.

4.2 Finance processes are running smoothly. However, pressure on resource available at times is an ongoing issue. Planning ahead and prioritising is essential and it is necessary for others to remember to consult finance as necessary as staff cannot attend all meetings. The shared resource with the Human Tissue Authority is working to the satisfaction of both organisations.

4.3 Financial management risks arise from the uncertainty of treatment numbers (the majority of the HFEA's income comes from treatment fees) and legal costs. These areas are monitored and forecast. There was a surplus from treatment fees this year, which is retained in reserves. The numbers seeking treatment do not seem to be constrained by the economic climate.

4.4 The HFEA will be moving to share office space with The National Institute for Health and Care Excellence (NICE) in April 2016. This will provide better facilities services for the HFEA. There will be less space in the new office, including for storage and office based staff will hot desk, rather than have their own allocated desks. However, the new office is an airy, fresh space and staff will have new IT equipment. There has been a lot of communication with staff to ensure this culture change is managed and additional travel costs will be paid for a period of time. Additional resource has been brought in to manage the office move.

4.5 The Business Continuity Plan will be refreshed after the office move. Although the HFEA is now using some cloud services, the HFEA's servers will move to the new office.

4.6 The Committee expressed their appreciation for the work on the office move and the effort that will be put into year end accounts and reports.

Action

4.7 Director of Finance and Resources to circulate presentation slides to Audit and Governance Committee members.

5. Information for Quality (IfQ)

5.1 The Director of Compliance and Information reminded the Committee of the purpose and outcomes from IfQ and presented progress to date.

5.2 The IfQ programme is currently in the Beta phase. The team are working on the HFEA Website and Clinic Portal, which will be subject to assessment by the Department of Health (DH), and Government Digital Service (GDS), to ensure they meet the required standards before they are released in the 'Public Beta' stage. The products exist now and user testing is underway. These digital services will be previewed at the HFEA annual conference on 24 March 2016. There is a risk of delay in securing GDS approval, but relationships are now in place to minimise this.

5.3 The programme plan was revised in January 2016 and the programme is operating within budget, although some spend takes place in 2016/17. Contracts with suppliers are capped which contains costs. Some IfQ related work has been absorbed into business as usual resources.

5.4 The HFEA will be working with clinics to cleanse data before it is migrated to the new Register.

5.5 The key risks in the programme are quality and resources and the Programme Board reviews these risks regularly. The pressures are on human rather than financial resources.

5.6 The committee found the presentation more reassuring than the paper, which was written in the midst of the work and risks. They explored whether the update was overly optimistic and were satisfied that the products are developing well and risks are at an acceptable level.

5.7 The committee requested that the IfQ update at the June meeting focusses on the new Register and the plan to gain assurance that data will be migrated properly.

Action

5.8 Director of Finance and Resources to commission Register Data Migration as the focus of the IfQ update at the Audit and Governance Committee Meeting scheduled in June 2016.

6. Strategic risks

6.1 The Head of Business Planning presented the strategic risk register, which had been discussed with the Authority last week.

6.2 Six risks were above tolerance when the register was last updated, relating to capability, IfQ programme risks, incorrect data released, the forthcoming office move and legal challenge.

6.3 Some of the strategic risks were discussed in depth during the review of other Agenda items. The committee was assured that the levels of risk were appropriate and that actions are being taken to mitigate the risks

6.4 The mitigation of providing more detailed responses separately to Parliamentary Questions for the risk of releasing incorrect data was queried. This happens rarely and only when it is appropriate to do so.

7. Legal Risks

7.1 The Head of Legal issued a document that was subject to legal privilege, summarising three recent cases.

7.2 There is a risk that costs could be awarded against the HFEA if cases brought against the HFEA were not successful. Some of the cases carry a low financial risk, but there is a risk that HFEA processes need to be reviewed or guidance written as a result of judgements. There are reputational risks too.

7.3 The committee noted that these cases are unusual and were assured that risks are controlled as far as possible.

7.4 The committee requested that legal risks should be brought to Audit and Governance Committee annually at the March meeting.

Action

7.5 Director of Finance and Resources to add Legal Risks to the Forward Plan for future Audit and Governance Committee meetings in March.

8. Internal Audit

8.1 The Head of Internal Audit reported progress against the internal audit plan. All planned audits have now been delivered. Assurance mapping was added to the plan and took place in February.

8.2 High priority actions outstanding from 2014/15 have been implemented – there were none in 2015/16. The annual opinion for 2015/16 is expected to be satisfactory.

8.3 A planning meeting with the Senior Management Team has been arranged for 19 April, to prepare the 2016/17 audit plan.

8.4 The report from the workshop to assurance map capacity and resilience was reviewed. Controls were in place and accord to the discussions at AGC today. Management are aware of the pressure points. Recommendations were made, which aim to be as pragmatic as possible.

8.5 The committee commented that assurance mapping needs to be proportionate for the HFEA and believe this exercise was. The recommendations can be addressed over time, in conjunction with other priorities.

8.6 The culture of support for staff was discussed, which is measured in part by the staff survey. The last survey showed that staff sometimes feel under pressure but they are supported. The committee asked to review the outcome of the staff survey.

8.7 The committee noted that resourcing is a live issue and were assured that there are good systems and processes in place to manage resources.

Action

8.8 Head of Human Resources to brief members on the HFEA Staff Survey results at the Audit and Governance Committee meeting in June 2016.

9. External audit

9.1 The National Audit Office provided an oral update.

9.2 All of the necessary information had been submitted to the auditors and some interim work had been completed. The main interim audit will take place next week.

9.3 The auditors will be reviewing the accounting treatment for IfQ.

9.4 The office move is a risk but will be past when the final audit takes place in May.

9.5 The system for reporting annual accounts has changed and the finance team has received some guidance from the NAO. The Director of Finance and Resources reported that there were no concerns with the timing of submitting the accounts to the NAO and is confident that they will lay the accounts in time before recess. There will be careful planning in place to ensure that the deadlines are met.

10. Implementations of recommendations progress report

10.1 The Finance Manager provided the committee with an update.

10.2 The committee was very pleased to hear that all recommendations had been implemented.

11. Training Programme

11.1 The committee discussed training that might be delivered after AGC meetings. The training arranged by the HTA is open to HFEA members, although there can be benefits in more tailored training and discussion. Members agreed to submit ideas for training that would be of benefit to them by email.

Action

11.2 The Director of Finance and Resources to circulate details of HTA training and ask Audit and Governance Committee members to propose HFEA training topics by email.

12. Forward plan

12.1 The committee was satisfied with the content of the Forward Plan of agenda items for meetings, with the additions discussed at this meeting.

12.2 It was agreed that four meetings per year are needed at present. This will be considered again in September.

13. Any other business

13.1 The Director of Finance and Resources confirmed the following:

- There were no whistleblowing or suspected fraud incidents reported since the last meeting.
- There were no contracts awarded since the last meeting, however some services associated with the office move were commissioned.

13.2 Members and auditors retired for their confidential session.

13.3 The next meeting will be held on Wednesday, 15 June 2016 at 10am.

14. Chair's signature

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

Signature

Name

Rebekah Dundas

Date

15 June 2016

Audit and Governance Committee Paper

Paper Title:	**Matters arising from previous AGC meetings**
Paper Number:	**[AGC (15/06/2016) 495]**
Meeting Date:	15 June 2016
Agenda Item:	**4**
Author:	Sue Gallone
For information or decision?	Information
Recommendation to the Committee:	To note and comment on the updates shown for each item.
Evaluation	To be updated and reviewed at each AGC.

Numerically:

- 6 items added from March 2016 meeting, 6 completed.
- 4 items carried over from earlier meetings, 0 completed.
- 3 items carried over from AGC self–assessment of performance, 0 completed.

Matters Arising from Audit and Governance Committee – actions from 11 June 2014 meeting			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
3.2 HFEA to monitor Authority members' completion of online information governance training	Executive Assistant to Chair and Chief Executive	20 September 2014	**Ongoing** – two new members to be asked to complete
Matters Arising from Audit and Governance Committee review of performance December 2014			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
e) Arrange for external members to attend Authority meeting as observers	Head of Governance & Licensing	September 2015	**Ongoing** – members invited to meetings, suitable dates to be agreed.
f) Arrange for external members to observe an inspection	Head of Governance & Licensing	September 2015	**Ongoing** – Inspectorate's business support team in contact with external members and attempting to find suitable dates.
i) Institute formal annual report to Authority board	Head of Governance & Licensing	July 2015	**Ongoing** – To be introduced for July 2016.
Matters Arising from Audit and Governance Committee – actions from 10 June 2015 meeting			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
9.6 Report progress on actions from the information governance group to AGC	Director of Finance and Resources	December 2016	**Ongoing**
Matters Arising from Audit and Governance Committee – actions from 9 December 2015 meeting			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
12.6 The Executive to add a review of the procedures for representations to the Business Plan for 2016/17 and report back	Head of Business Planning	April 2016	**Ongoing** – added to business plan, work to start in October 2016

Matters Arising from Audit and Governance Committee – actions from 11 June 2014 meeting			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
to the Authority with recommendations, in due course.			
14.5 The Triennial review report is to be sent to committee members.	Director of Finance	When published	**Ongoing** – Review report not yet published
Matters Arising from Audit and Governance Committee – actions from 16 March 2016 meeting			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
2.3 Recirculate conclusions of review of AGC effectiveness	Director of Finance	April 2016	**Completed**
4.7 Circulate Finance and Resources risk slides	Director of Finance	April 2016	**Completed**
5.8 Commission Register migration at the focus of the IfQ update at June meeting	Director of Finance	June 2016	**Completed**
7.5 Add legal risk item to forward plan for March meeting	Director of Finance	June 2016	**Completed**
8.8 Brief members on staff survey results at June meeting	Head of HR	June 2016	**Completed**
11.2 Circulate details of HTA training and ask members for future training topics	Director of Finance	April 2016	**Completed**

Staff survey 2015 results

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☐ Demonstrating efficiency economy and value
Details:			
Meeting	AGC		
Agenda item	5		
Paper number	[AGC (15/06/2016) 496 RH/PT]		
Meeting date	15 June 2016		
Author	Rachel Hopkins, Head of Human Resources Peter Thompson, Chief Executive		
Output:			
For information or decision?	For information		
Recommendation	AGC are asked to note the report		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☐ Low	☐ Medium	☐ High
Annexes	Annex A: Staff survey 2015 results		

1. Background

1.1. At its on 16 March 2016, Audit and Governance Committee asked to review the outcome of the HFEA's staff survey at its next meeting.

1.2. Our staff survey is undertaken annually, and in October/November 2015 the questions replicated the Civil Service People Survey for the first time. The results of the survey were shared with all staff and discussed at the all staff conference in December 2015.

1.3. Our staff survey results are set out in Annex A and are reported in the same format as the Civil Service survey results, where questions are grouped into key areas. Comparator details for the Department of Health and overall Civil Service are provided to aid benchmarking.

1.4. Overall the results are very encouraging in that in all but two of the ten key areas our results were more positive than the DH and the wider Civil Service. There were some mixed (albeit not extreme) results in the 'wellbeing questions' which we believe reflected the heavy workloads faced by some teams during the period of the staff survey.

1.5. Our response rate was slightly lower than previous years, and below our target of 75% (and lower than DH and the Civil Service) and we will seek to focus on increasing this with this year's survey.

1.6. A verbal summary will be provided at the meeting.

2. Recommendation

2.1. AGC are asked to note the report.

Annex A: Staff survey 2015 results

					HFEA %	DH %	CS %
Response rate:					**68**	80	75
Theme		**Question**			**HFEA %**	**DH %**	**CS %**
My work	B01	I am interested in my work	92	% strongly agree or agree	**82**	75	74
	B02	I am sufficiently challenged by my work	80	% strongly agree or agree			
	B03	My work gives me a sense of personal accomplishment	86	% strongly agree or agree			
	B04	I feel involved in the decisions that affect my work	66	% strongly agree or agree			
	B05	I have a choice in deciding how I do my work	84	% strongly agree or agree			
Organisational objectives and purpose	B06	I have a clear understanding of The HFEA's purpose	98	% strongly agree or agree	**95**	76	83
	B07	I have a clear understanding of the HFEA's objectives	96	% strongly agree or agree			
	B08	I understand how my work contributes to the HFEA's objectives	92	% strongly agree or agree			

Theme		Question			HFEA %	DH %	CS %
My manager	B09	My manager motivates me to be more effective in my job	76	% strongly agree or agree	75	70	68
	B10	My manager is considerate of my life outside work	92	% strongly agree or agree			
	B11	My manager is open to my ideas	88	% strongly agree or agree			
	B12	My manager helps me to understand how I contribute to the HFEA's objectives	74	% strongly agree or agree			
	B13	Overall, I have confidence in the decisions made by my manager	86	% strongly agree or agree			
	B14	My manager recognises when I have done my job well	84	% strongly agree or agree			
	B15	I receive regular feedback on my performance	68	% strongly agree or agree			
	B16	The feedback I receive helps me to improve my performance	66	% strongly agree or agree			
	B17	I think that my performance is evaluated fairly	74	% strongly agree or agree			
	B18	Poor performance is dealt with effectively in my team	42	% strongly agree or agree			
My team	B19	The people in my team can be relied upon to help when things get difficult in my job	78	% strongly agree or agree	75	80	80
	B20	The people in my team work together to find ways to improve the service we provide	76	% strongly agree or agree			
	B21	The people in my team are encouraged to come up with new and better ways of doing things	72	% strongly agree or agree			

Theme		Question			HFEA %	DH %	CS %
Learning and development	B22	I am able to access the right learning and development opportunities when I need to	62	% strongly agree or agree	**44**	53	49
	B23	Learning and development activities I have completed in the past 12 months have helped to improve my performance	44	% strongly agree or agree			
	B24	There are opportunities for me to develop my career in the HFEA	20	% strongly agree or agree			
	B25	Learning and development activities I have completed while working for the HFEA are helping me to develop my career	48	% strongly agree or agree			
Inclusion and fair treatment	B26	I am treated fairly at work	84	% strongly agree or agree	**81**	77	74
	B27	I am treated with respect by the people I work with	84	% strongly agree or agree			
	B28	I feel valued for the work I do	72	% strongly agree or agree			
	B29	I think that the HFEA respects individual differences (e.g. cultures, working styles, backgrounds, ideas, etc)	82	% strongly agree or agree			
Resources and workload	B30	In my job, I am clear what is expected of me	90	% strongly agree or agree	**75**	72	73
	B31	I get the information I need to do my job well	68	% strongly agree or agree			
	B32	I have clear work objectives	82	% strongly agree or agree			
	B33	I have the skills I need to do my job effectively	92	% strongly agree or agree			
	B34	I have the tools I need to do my job effectively	72	% strongly agree or agree			
	B35	I have an acceptable workload	56	% strongly agree or agree			
	B36	I achieve a good balance between my work life and my private life	66	% strongly agree or agree			

Theme		Question			HFEA %	DH %	CS %
Pay and benefits	B37	I feel that my pay adequately reflects my performance	32	% strongly agree or agree	**33**	32	30
	B38	I am satisfied with the total benefits package	44	% strongly agree or agree			
	B39	Compared to people doing a similar job in other organisations I feel my pay is reasonable	24	% strongly agree or agree			
Leadership and managing change	B40	I feel that the HFEA as a whole is managed well	72	% strongly agree or agree	**66**	38	43
	B41	SMT in the HFEA are sufficiently visible	82	% strongly agree or agree			
	B42	I believe the actions of SMT are consistent with HFEA's values	72	% strongly agree or agree			
	B43	I believe that the Authority has a clear vision for the future of the HFEA	70	% strongly agree or agree			
	B44	Overall, I have confidence in the decisions made by the HFEA's SMT	70	% strongly agree or agree			
	B45	I feel that change is managed well in the HFEA	42	% strongly agree or agree			
	B46	When changes are made in the HFEA they are usually for the better	52	% strongly agree or agree			
	B47	The HFEA keeps me informed about matters that affect me	76	% strongly agree or agree			
	B48	I have the opportunity to contribute my views before decisions are made that affect me	60	% strongly agree or agree			
	B49	I think it is safe to challenge the way things are done in the HFEA	66	% strongly agree or agree			

Theme		Question			HFEA %	DH %	CS %
Employee Engagement	B50	I am proud when I tell others I am part of the HFEA	76	% strongly agree or agree	67	56	57
	B51	I would recommend the HFEA as a great place to work	80	% strongly agree or agree			
	B52	I feel a strong personal attachment to the HFEA	60	% strongly agree or agree			
	B53	The HFEA inspires me to do the best in my job	50	% strongly agree or agree			
	B54	The HFEA motivates me to help it achieve its objectives	50	% strongly agree or agree			
Taking action	B55	I believe that SMT in the HFEA will take action on the results from this survey	48	% strongly agree or agree			
	B56	I believe that managers where I work will take action on the results from this survey	58	% strongly agree or agree			
	B57	Where I work, I think effective action has been taken on the results of the last survey	32	% strongly agree or agree			
Organisational culture	B58	I am trusted to carry out my job effectively	90	% strongly agree or agree			
	B59	I believe I would be supported if I try a new idea, even if it may not work	76	% strongly agree or agree			
	B60	My performance is evaluated based on whether I get things done, rather than solely follow process	82	% strongly agree or agree			
	B61	When I talk about the HFEA I say "we" rather than "they"	84	% strongly agree or agree			
	B62	I have some really good friendships at work	80	% strongly agree or agree			

Theme		Question			HFEA %	DH %	CS %
Discrimination, bullying and harassment	E01	During the past 12 months have you personally experienced discrimination at work?	4	% yes	**4**	11	11
	E03	During the past 12 months have you personally experienced bullying or harassment at work?	8	% yes	**8**	11	10
Subjective wellbeing	W01	Overall, how satisfied are you with your life nowadays? (0=Not at all, 10=Completely satisfied)	63	% 7-10	**63**	64	65
	W02	Overall, to what extent do you feel the things you do in your life are worthwhile? (0=Not at all, 10=Completely worthwhile)	77	% 7-10	**77**	72	71
	W03	Overall, how happy did you feel yesterday? (0=Not at all, 10=Completely happy)	48	% 7-10	**48**	62	62
	W04	Overall, how anxious did you feel yesterday? (0=Not at all, 10=Completely anxious)	40	% 0-3	**40**	49	50
Future intentions	*C01*	*I want to leave the HFEA as soon as possible*	*6*	*%*	***6***		
	C02	*I want to leave the HFEA within the next 12 months*	*38*	*%*	***38***		
	C03	*I want to stay working for the HFEA for at least the next year*	*35*	*%*	***35***		
	C04	*I want to stay working for the HFEA for at least the next 3 years*	*21*	*%*	***21***		

Information for Quality (IfQ) Programme – Data Migration

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	AGC		
Agenda item	6		
Paper number	HFEA (15/06/2016) 497		
Meeting date	15 June 2016		
Author	Nick Jones, Director of Compliance & Information		
Output:			
For information or decision?	For information		
Recommendation	The Committee is asked to note this report.		
Resource implications	As outlined		
Implementation date	Ongoing		
Communication(s)	Ongoing		
Organisational risk	☐ Low	☐ Medium	☒ High
Annexes Annex A – programme timeline Annex B – Digital service Assessment			

1. Introduction and summary

1.1. The purpose of this report is to provide the Committee with a progress report on the IfQ programme. The Programme has now reached the closing stages of the Beta phase and we are preparing to launch both the new Website and Clinic Portal to 'public beta'.

1.2. After successfully passing the May assessment against the Government Digital Service (GDS) standards by the Department of Health (DH), the team is focused on addressing the resulting recommendations prior to completing 'public beta' and subsequently putting release 1 of the services to full 'live'.

1.3. Annex A sets out the timeline for the remaining IfQ Beta phase, leading both to 'live' and to the next DH/GDS assessment.

2. IfQ projects update

2.1. IfQ DH/GDS assessment

- Since the last report, the IfQ team has achieved a significant milestone on our journey to releasing the HFEA's new Website and Clinic Portal to 'public beta'.
- On 11 and 12 May, the Department of Health conducted a full review of the new Website and Clinic Portal against the 18 Government Digital Service Standards, to assess the readiness of both services to proceed to 'public beta'.
- We are pleased to report that both products passed this assessment, which serves as a welcome endorsement of the work of the IfQ Programme team to date.
- As with any useful review process, our pass came with some recommendations, and activity to address those will now be incorporated alongside our other priorities during each 'sprint' (see annex B). The associated GDS spend control approval process to release planned budget to be spent on preparing for full release 1 'live' and release 2 development is now underway.

2.2. IfQ private and public beta – website and clinic portal

- Having been granted permission to do so, the next important step for the programme team is to now go ahead and transition the service from development to 'public beta', which is to make the website and portal available to real end users.
    - **For both the new HFEA website and the new Clinic Portal, the services will be put to public beta on 29 June 2016**.

      For the first two weeks, only clinics will have access to the new HFEA website, in order to provide them with some time to view the new content and statistics that relate to them on their CaFC Profiles. After this two-week period, the new HFEA website will then be made available to the broader public.
- We are currently anticipating that public beta for both the portal and the website will run for a period of approximately 10 weeks.
- This may change, subject to what we learn during public beta. For example, if users indicate that there are significant changes required, we can extend the length of public beta. Alternatively, if there are limited changes required, or approvals are received quickly, we may require less time.

- After public beta, release 1 of IfQ will then be transitioned to a full 'live' service. This step requires both the website and clinic portal services to pass another full gateway assessment by the Department of Health against the 18 Government digital standards.

2.3. Planning for 'Release 2'

- The IfQ Programme team is now finalising all planning activity for the next significant milestone in the programme – 'release 2' that is the replacement for EDI and the new Register. This follows a review and refinement of all requirements. This detail is being utilised to inform the order of priority for building the key features of release 2, which will be incorporated in IfQ's overall delivery plan.
- In line with the programme's delivery plan, foundational work on the internal infrastructure and architecture required to support release 2 has commenced.

2.4. IfQ data cleansing

- The Register Information team is working with centres currently on 'severity 1 errors' - initially by way of a 'pilot.' There were only 63 errors being addressed in the first tranche of eight centres. We are now following up with a further 18 centres. The process is being managed carefully so as to ensure that our staff are available to field queries from the centres and to assist them where necessary.
- There are currently a total of 3500 severity 1 errors to be reviewed prior to the data migration. 1240 errors have been fixed across all centres during the last period of cleansing – demonstrating reasonable progress.
- Centres who have fixed all their severity 1 errors will be sent additional severity 2 errors to keep the momentum, and cleanse as much as possible data prior the data migration. Also note that severity 2 cleansing is not an impediment for the data migration process.
- The differences between the draft data dictionary and the proposed new Register structure are being discussed by the project team. These discussions will ensure that the final published data dictionary will properly match the underlying new data structure.

3. Update on data migration process

3.1. Background on the revised Register of treatments

- As AGC members are aware, IfQ involves important changes to the way we collect, use and publish information. Critically, this work will involve significant changes to the HFEA's 'Register of Treatments' (the Register).

- The Register holds information about people receiving fertility treatment, egg and sperm donors, and children conceived following treatment. Keeping the Register is one of the HFEA's statutory obligations and the information currently held in the Register is likely the largest database of assisted reproductive treatments in the world. The Register is critically important for a number of reasons:

    - As a comprehensive record of all treatments, it provides crucial information on the safety and effectiveness of treatments
    - It enables donor conceived people to have knowledge of their genetic inheritance
    - It enables parents to access information about the donor used in their treatment
    - It enables donors to understand the outcome of their donation
    - It enables patients to make more informed choices about their treatment options
    - It supports intelligent regulation and makes possible important research and analysis.

- A key outcome of IfQ will be changing what information is kept in the Register, how that data is recorded and how it is collected or obtained. To achieve this, we have carried out a review to ensure each item of data collected from clinics is fully justified, and subsequently determined a new draft dataset that should be collected from clinics.

- Based on this new dataset, we are creating a revised Register, which will use modern database practices and technology. Improvements to the way that data is recorded and stored in the revised Register will result in higher quality data, which is more accessible to us and to other key stakeholders and interest groups – such as researchers.

- In addition, the revised Register will work hand in hand with the replacement for EDI to meet key investment objectives for IfQ by reducing the administrative burden for clinic users.

3.2. Data migration process and strategy

- The revised Register must be populated with data, requiring the transfer of historic information from the existing Register database in to the new Register database structure. This is referred to as the IfQ 'data migration' process. This process is related, though different to, the 'data cleansing' process, which seeks to improve the quality of historical data being transferred to the revised Register.

- Due to the importance of the Register and the highly sensitive nature of the data contained within it, a well-managed and successful data migration process is central to realising many of the anticipated benefits of the IfQ Programme. At its last meeting AGC requested a more in-depth report on progress to date.

- In recognition of the importance of the data migration process, external suppliers 'Avoca' were engaged to provide their expertise and work with us to develop a strategy for completing the data migration process appropriately. That strategy was reviewed and accepted by the HFEA in March 2015, and has been used to inform each key step of the migration process since.

- The strategy required a foundational ‘health check’ of the data to be conducted, which identifies data quality issues at the outset of the project, to guide realistic project planning and risk mitigation activities. This Health Check was completed in late 2015, with the results presented to the IfQ Programme Board.

- Following the health check of the data, the strategy requires five separate data migration ‘loads’ of all of the historical data in to the new Register structure. The first four are ‘trial loads’ in preparation for the fifth and final load. To ensure that an appropriate level of testing, quality control and assurance has been carried out before the fifth and final load, the following key processes are undertaken within each prior load:

    - **Interim File Format (IFF) mapping report:** provides an overview of how well Register data will ‘fit’ into the new Register database, including visibility of a variety of scenarios that require further attention.

    - **Code set mapping report:** indicates how well the new Register can be populated using the actual data values present in the current Register, again including various scenarios requiring further attention.

    - **Mapping and rules document:** contains detailed but plain-English descriptions of how each and every field in the new Register will be populated, including all cleansing (corrective) rules to be applied as well as data transformations to suit the new Register’s different structure.

    - **Reconciliation report:** audits the quantities of data in the current Register against what was migrated to the new Register during a trial load, to prove that no data has been lost unless this has been agreed by all stakeholders.

    - **Migration exceptions report:** gives management visibility of errors or problems encountered with a trial data load, so issue resolutions can be tracked over time.

    - **Approval to proceed document:** summarises outstanding tasks for data quality improvement, to be carried forward into subsequent stages of the migration.

- In reality, there are many more than only five loads, with each trial load phase including a series of data loads to evaluate errors and problems as they are addressed incrementally.

3.3. Timeline for data migration

- Currently, the Programme is progressing through trial load 1, having now produced each of the above reports and documents and having conducted several incremental trial loads. The team is currently finalising the reconciliation and migration exceptions reports in the lead up to commencing trial load 2.

- Trial load 1 was scheduled to be completed by 17 May 2016. Due to pressures on the internal systems team associated with completing the beta phase of the new website and clinic portal, we anticipate trial load 1 will be fully completed by 28 June 2016. Notwithstanding this delay, the team still anticipates being ready to complete trial load 5 by the end of September, in line with the current delivery plan for IfQ.

- This confidence is based on trial load 1 requiring each process to be conducted for the first time. The process will become significantly less burdensome as we progress through each subsequent trial load phase. Further, to account for this risk there was a large contingency built in to the timeframe for trial load 5, which will be partially consumed.

- Current timelines for the Data Migration process:

Programme milestone	Planned completion date	Anticipated completion date
Trial load 1	17 May 2016	28 June 2016
Trial load 2	28 June 2016	13 July 2016
Trial load 3	13 July 2016	28 July 2016
Trial load 4	28 July 2016	12 August 2016
Trial load 5	21 September 2016	21 September 2016

3.4. Data migration strategy assurance

- Regrettably, 'Avoca', the external supplier who produced the data migration strategy, has since gone out of business. This leaves unmet an important assurance role that we were anticipating Avoca would provide.

- Accordingly, we are currently in discussion with service providers and recruitment agencies, and we expect to finalise a procurement round before the end of June 2016, securing assurance services from another adequately qualified service provider. This will provide external assurance that we are completing the steps required in the data migration strategy, to the appropriate level of quality.

- In addition, the data migration activity has been subject to a number of internal audit reviews. The finding of each internal audit review have been considered by the IfQ Programme Board, and incorporated in to our ongoing assurance management log. Primarily, the key recommendations from those reviews have focused on adherence to the data migration strategy outlined above and managing the risk of balancing timely delivery of data migration against maintaining an adequate level of data quality as a result of data cleansing activity.

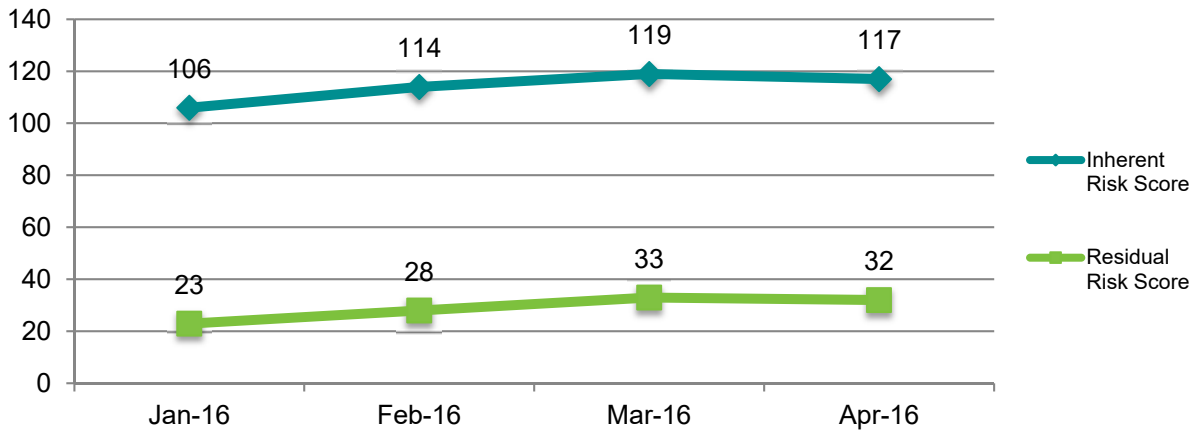
3.5. Safeguards

- Throughout the entire data migration process and when the new Register structure is operational, the existing Register database will be retained as a reference. This will ensure that there is no risk that the data migration activity compromises the actual data held in the current Register structure.

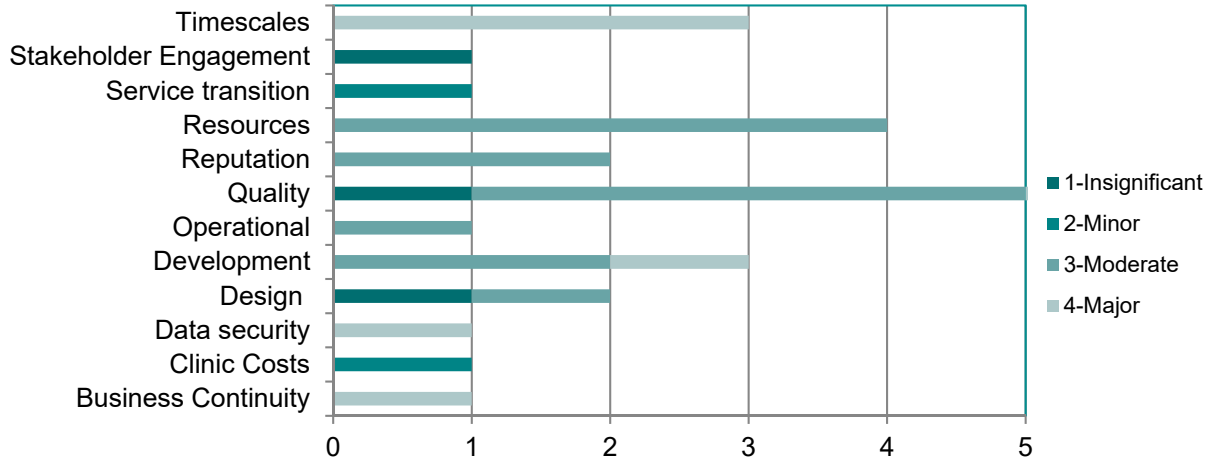
- As defined above, a reconciliation report will be produced during each trial load to identify where data has not been transferred in a usable way, according to the quality standards and technical structure of the new Register. This will ensure the HFEA knows exactly what data has been transferred successfully. In addition, data that doesn't meet these quality metrics will be 'flagged' in the new structure, to ensure it will be addressed, and as stated above, retained in the reference copy of the current Register for information.

4. IfQ risks and issues

- The below line graph represents the overall IfQ risk score, which combines the perceived impact and likelihood of the current risks each month. The overall risk score for the IfQ programme has slightly decreased since March 2016.



- The below bar graph shows the number of risks in the top 12 risk categories, coloured according to severity of risk. It shows that the greatest number of risks are contained in the quality, resources, timescales and development risk categories. The most severe risks are associated with timescales, development, data security and business continuity.



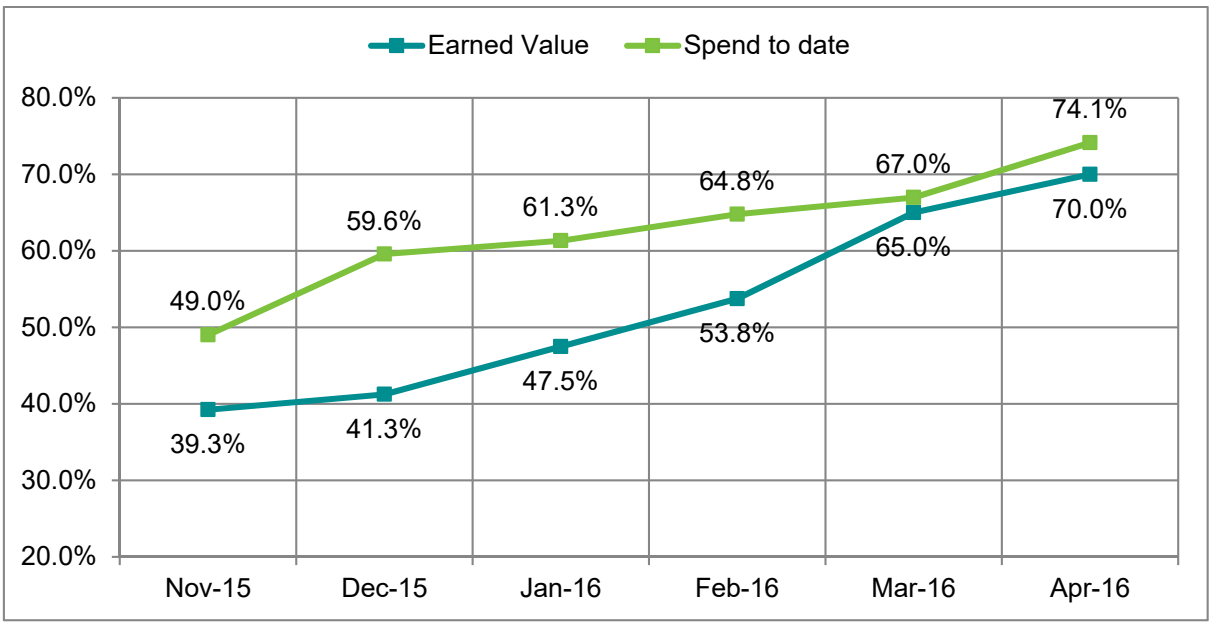
5. IfQ budget

- At the end of the 2015/16 financial year it was necessary to carry over £467k to the new financial year.
- Despite the underspend the total programme budget remains broadly on track across the 2015/16 and 2016/17 financial years.
- On 24 May 2016, SMT decided to allocate an additional (and new) £90k to the overall Programme budget to ensure that critical staff are retained on the team as the transition from delivering release 1 to release 2 is made. This modest additional investment essentially means we can continue working at pace but sharing the load so as not to burden key staff disproportionately.

6. Earned value

- The earned value and spend to date are converging. We are expecting the spending figures to increase in the upcoming month, due to receiving the beta invoices from Reading Room and also payment of external contractors who have started the work on security/CLAS needed for the internal systems project.
- There is a slight caveat to this, in that the percentage increase in the earned value measures the work under way for delivery of the project, rather than against the Agile 'definition of done' assessment. For April the main focus was on fixing bugs in existing work so as to ensure readiness for the GDS assessment. This was important work, but it meant that the proportionate level of new delivery underway was actually less than in previous months.

Period	Nov-15	Dec-15	Jan-16	Feb-16	Mar-16	Apr-16
Earned Value	39.3%	41.3%	47.5%	53.8%	65.5%	70.0%
Spend to date	49.0%	59.6%	61.3%	64.8%	67.0%	74.1%



7. Recommendation:

7.1. The Audit and Governance Committee is asked to:

- Note progress, risks and the budget position on IfQ
- Note in particular the update on the data migration process.

8. Annexes:

- Annex A: Timeline for the remaining IfQ Beta phase
- Annex B: Health digital service assessment Website and Clinic Portal

Programme Plan

15/6: Data shared with clinics in excel via CF and CE letter

29/6: Live CaFC site shared with clinics/stakeholders

10/8: Website User testing

17/8: Portal User testing

7/9: Website & Portal assessment

5/10: Website & Portal (R1) LIVE

	Sprint 11	Sprint 12	Sprint 13	Sprint 14	Sprint 15	Sprint 16	Sprint 17	Sprint 18	Sprint 19	Sprint 20
	18/5 – 31/5	1/6 – 14/6	15/6 – 28/6	29/6 – 12/7	13/7 – 26/7	27/7-9/8	10/8 – 23/8	24/8 – 6/9	7/9 – 20/9	21/9 – 4/10
Website	PREPARE FOR PUBLIC BETA (6 WEEKS)			CLINIC PUBLIC BETA (2 WEEKS)	PUBLIC BETA (8 WEEKS)				GDS APPROVAL & FURTHER TWEAKS (4 WEEKS)	
Clinic Portal	PREPARE FOR PUBLIC BETA (6 WEEKS)	EARLY ADOPTERS BETA		ALL CLINICS PUBLIC BETA (2 WEEKS)	PUBLIC BETA (8 WEEKS)				GDS APPROVAL & FURTHER TWEAKS (4 WEEKS)	

Health digital service assessment

HFEA website and clinic finder tool

The HFEA website provides information for patients, donors, donor-conceived people, professionals working in clinics, researchers and the media. The redesign project aims to better meet user needs and upgrade an outdated infrastructure.

The clinic finder is a tool for patients and clinics to get impartial, unbiased information about clinics, the treatments they offer and how successful they are. The redesign project aims to give users a greater understanding of treatments and data.

Department / Agency	Human Embryology and Fertility Authority (HFEA)
Date of assessment	11th May 2016
Assessment stage	Beta
Lead assessor	Matt Harrington (DH)
Result of assessment	Pass
Assessors	Dan Sheldon, Olga Passet , Lauren McAllister
Service manager	Trisram Dawahoo
Digital leader	Adam Bye

Assessment report

The HFEA website and clinic finder has been reviewed against the 18 points of the Service Standard at the end of beta development.

Outcome of service assessment

After consideration, the assessment panel has concluded that the HFEA website and find a clinic tool is on track to meet the Digital by Default Service Standard at this stage of development.

The panel would like to thank the service team for their time, the amount of effort which clearly went into the assessment and congratulate them on passing.

There are however, a number of recommendations which the team are now expected to address. Similarly, there is concern that an 8 week public beta may be too ambitious a time frame to truly learn about users and validate the decisions that have been made. The team should look to do the maximum amount of user research they can.

Reasons

User needs and assisted digital:
The assessment panel were pleased with the approach to user research by the team and the work they have done since alpha. It is clear that user needs are core to the development work and it was good to see how the team have taken steps to understand user groups and personas.

The team have taken steps to engage with assisted digital users as part of their research which is positive and this should be continued through beta to continue to develop this understanding.

It was good to hear the service manager and team talk passionately about working with users and give examples of learnings from user research. There is a plan for testing during beta and it puts the team in a good place where they will be able to learn even more with quantitative data.

The team:
The team appears to be working well and there are clearly defined roles for most positions you would expect within an agile team. As per the recommendations from Alpha, the team have brought in more content support in the form of a copywriter. It would be good to build relationships with the cross-government content design community and for the copywriter to avail themselves of any training and development opportunities provided in that network.

The team are continuing to work in agile, running two week sprints with sprint artefacts. The team use show and tells to communicate their work to the wider organisation and are using a backlog to manage the work and prioritise development. The team have also set up a physical wall to better communicate the team's priorities and what everyone is working on.

Certain roles in the team are currently filled by a supplier, this seems to be working well and it is positive that the team is co-located. There is skill transfer happening and this will be particularly important in the future when the supplier contract ends.

Improving the service and design:
It was positive to see that the team have changed the service significantly since the Alpha assessment based on their user research. At the assessment we discussed further opportunities for testing and the team were keen to try these out.

The team still have challenges ahead, particularly in relation to displaying complex data. The work gone into this so far has been positive and the team understand the real user need. However, the team may benefit from stepping back and working with colleagues to see how else they could display complex data.

Security, privacy, tools and standards:

There is only one part of the service that captures data from users - the proposed comment facility at the bottom of some pages. Although this facility is subject to pre-moderation, the team should consider how to capture and store data that could be personal or sensitive. The

team should review whether this feature is necessary, or whether there are alternative ways to meet the same objective.

The team have chosen a technology stack aligned to their in-house skills. The team were aware of the risks of lock-in, and are confident their choice of technology will give them enough flexibility to iterate the service. The team should be wary of doing too much closely coupled customisation to Umbraco, as this will make future upgrades and changes harder.

The team are planning to open source their code when the service is live. The team should start to code in the open rather than waiting to the end to release code, ensuring any sensitive text (e.g. passwords) are kept in separate files and not shared in public repositories.

Although the team have an aspiration to open up clinic data, the plans are not clear. The team have not yet engaged with GDS to discuss registers.

Analysis and benchmarking:
The team already get data from an existing live service and have recently got a net promoter score to help act as a baseline for the future service. In addition to this, the team are going to add analytics ready for beta so that data can be collected from the outset. Retesting the new site to see change in net promoter score will provide some insight but shouldn't be the only measure.

The team are expecting to use the in-page rating and commenting tool to enable them to iterate based on user feedback. It is positive to see they are keen to do this, but should consider all options available to get direct user feedback.

It was particularly pleasing to hear that the team are already considering KPIs for public beta to measure hypotheses, these will be good to show at the live assessment.

Testing with the Minister

The team have engaged their Chief Executive who has seen the service which is positive, they should however put a plan in place to test with the minister to showcase their work.

Recommendations:

Before public beta:

- Resolve Javascript issues prior to public beta launch to ensure the website works fully without Javascript capability.

User needs and assisted digital:

- Develop a plan, and conduct user research to integrate qualitative research with the incoming google analytics data.
- Run a heuristic analysis of the interface design elements with focus on usability, interactive elements and design language consistency.

- Have a way to measure the success of the assisted digital support through the beta period.

The team:

- The work doesn't stop after public beta. The team need to establish a plan for the continued development of the service once the current delivery partner leaves.

Improving the service and design:

- Take time to review against the service manual and design patterns. Some of this has been done, but there are more opportunities to improve the service. (Additional design comments sent via email)
- Review the possibilities of integrating iconographic elements to increase the recognisability of information fields and improve the overall UX (something that could be tested with A/B tests).
- Test different designs of the clinic search to see whether efficiency could be improved, e.g. one line of information per clinic to make comparison easier, advanced filtering appearing later in the journey etc.
- Review and improve the user journey for donors.
- Review search functionality as it is currently confusing and consider/test a universal search function.
- Review the need for a published comment facility at the bottom of content pages. Investigate alternatives (e.g. a GOV.UK style simple feedback mechanism)

Security, privacy, tools and standards:

- Provide the list of clinics as a public register via an API and variety of different standard representations.
- Engage with Paul Downey at GDS to discuss the cross-government registers work, and reuse the code or build their register to the standards GDS are setting.
- Work closely with NHS Choices to provide the clinic data to their service finder.
- Review privacy impacts of comment facility.
- Start to code in the open.

Summary:

The team have made great progress and done well continuing to iterate the website and clinic finder since the alpha assessment. The team have it within their ability to build a user focused service and a public beta will provide them with qualitative data to go alongside their user research to continue to build and iterate.

Digital by Default Service Standard criteria

Criteria	Passed	Criteria	Passed
1	Yes	2	Yes
3	Yes	4	Yes
5	Yes	6	Yes

7	Yes	8	Yes
9	Yes	10	Yes
11	Yes	12	Yes
13	Yes	14	Yes
15	Yes	16	Yes
17	Yes	18	Yes

Health Digital Service Assessment

HFEA clinic portal

The clinic portal allows clinics to submit, obtain and manage clinic information and allows HFEA to give clinics performance data. Clinics will access alerts, guidance and news via the portal. Inspection reports and other compliance activities will be published here.

HFEA are redesigning the clinic portal to combine existing and enhanced functionality and make it easier to use by: improve the quality of data submitted to HFEA; reduce the “burden” associated with data submission; provide added utility; provide an improved user experience of accessing information and submitting data.

Department / Agency:□	Human Embryology and Fertility Authority (HFEA)
Date of Assessment:	12 May 2016
Date of Original Assessment:	N/A
Assessment Stage:□	Public Beta
Lead Assessor:□	L. Scott
Result of Assessment:	Pass
Assessors:	A. Davidson, O. Passet
Service Manager:□	Chris Hall
Digital Leader:	Adam Bye

Assessment report

The HFEA clinic portal has been reviewed against the 18 points of the Service Standard at the end of the beta development.

Outcome of service assessment

After careful consideration the assessment panel has concluded that on balance, the clinic portal service is on track to meet the Digital by Default Service Standard at this mid stage of development, and can proceed into public beta.

The panel would like to thank the service team for their time, the amount of effort which clearly went into the assessment and congratulate them on passing.

There are however, a number of recommendations which the team are now expected to

address. Similarly, there is concern that an 8 week public beta may be too ambitious a time frame to address these recommendations and remain on track to progress to a live service.

Reasons

The service was assessed against all 18 points of the Digital by Default Service Standard. We asked questions from the prompts and evidence for assessors, supplied by GDS. This document has questions and the evidence sought for alpha, beta and live phases. We asked questions from the beta section.

On balance, the service currently meets the requirements of the standard for an beta service. The comments below reflect some of the observations we made during the discussion. Recommendations are listed later in this report.

The service team must address the recommendations made, course-correcting development where necessary, to ensure that the project remains on track and adheres to the service standard as it moves through the next phase.

User needs and assisted digital

The team have carried out 1:1 research sessions with a regional spread. These were recorded and the service manager observed some. The development team works closely with the user researcher to gain insights. The usability sessions were task-led, prompted by user needs uncovered in earlier research. Although the information architecture has been iterated following research, it wasn't a user-led design from the start.

The service manager also meets regularly with stakeholder and expert groups, demonstrating the prototype and gathering feedback.

The team have amassed learnings about users during development, and could demonstrate knowledge about the types of users they had, and contextual information about them. They pointed to where their assumptions has been challenged, eg around the 'person responsible' being the sole user.

Although the team get updates from the user researcher and have access to the reports, they should be taking the opportunity to accompany the researcher and get exposure to users in the field. The public beta is a perfect opportunity for the whole team to visit clinics and observe users trying out the service. Developers and designers will benefit from seeing research first hand, being able to use their knowledge of the software to suggest better functionality to meet needs.

We spent some time discussing the Knowledge Base part of the service. This is a core user need - finding guidance from HFEA. Expert view (backed up by the service team's research) shows that this needs significant iteration to meet user needs. The important information takes a lot of scrolling to get there. It looked like this part of the service was being used to broadcast corporate messages as well as meeting user needs, with the former taking priority.

The To Do List also addresses a big problem users experience now re: tracking outstanding actions with HFEA. It's tested well, though the panel found the interplay of 'status' and 'priority' confusing.

The design of the performance dashboard may look like data visualisation rather than formatting. We discussed ways of mitigating this.

The team have not found any users with any assisted digital needs. They plan to ensure this is the case during public beta. There is a support centre in place, accessed via telephone, if people need help accessing the digital service.

The team plan to carry further rounds of lab testing in public beta.

The team

Most of the deep digital roles are provided by the supplier. Some skills transfer is taking place. Independent contractors are also skilling up the in-house IT team to ensure they can support the service. Great to see the service manager taking an active role in user research - although professional skills should still be sought to ensure that methodologies, best practice etc is being applied. Service manager, content and delivery manager skills are in-house. This set up will continue during public beta. The team should make plans now for continuous improvement of the live service, factoring in costs for buying in expert skills, as that looks likely to still be necessary.

The team are using agile techniques to plan work and seem content and comfortable with agile artefacts. Great to hear examples of agile being applied at a more strategic level - eg the roadmap has completely changed from a year ago, due to learnings from research and experimentation.

Security, privacy, tools and standards

The team are planning to open source their code when the service is live. The team should start to code in the open now rather than waiting to the end to release code, ensuring any sensitive text (e.g. passwords) are kept separately and not shared in public repositories (for instance, in an associated private repository, or a secrets-management service).

The team currently have a commendably agile approach to deployment, with code being automatically deployed as soon as tests have been successfully performed. However, the panel is concerned that they are planning to be less agile in future, by "bundling up" changes to be released in the middle of the night or potentially at the end of a sprint. We recommend that they instead maintain their current process and focus their effort on minimising the user impact of a release through, for instance, parallel-stack/dns-switching deployment.

The technical architecture of the service appears rather over-engineered for the current stage and expected load on the service, even once fully rolled-out. Whilst the panel recognise that future storage of patient-identifying data may result in some data-separation requirements, we

believe that a simpler architecture may have allowed the team to deliver user benefits earlier, and would encourage an 'emergent architecture' approach.

The team have clearly done some thinking around security threats and potential for fraud, and are engaging with appropriate risk owners. We recommend that for future assessments the team provide evidence of this thinking in a short document, listing potential threats alongside their likelihood and potential impact, and actions they have taken to mitigate each threat.

Design

Although the service is exempt from the visual look and feel of GOV.UK, the GDS design patterns still stand as an accepted starting point for evidenced best practice in service design and user interaction standards.

Again, the GDS content style guide should be used as starting point for patterns (even if the service is exempt from technical style guide adherence) as to how users will successfully engage with a government service.

We couldn't see evidence that the team have adopted the design patterns or the content style guide as a starting point, despite a recommendation after alpha development. We did discuss the issue of accordions, which the team had considered, and we reiterate the point that the patterns are a starting base and the adoption should be 'consistent not uniform'.

Analysis and benchmarking

The team continue to mostly rely on user research to gather evidence for user needs and test concepts. Service teams should be making more use of data and analytics at this stage of development. There was still no evidence that the team had considered service metrics in any depth. Google Analytics will be instrumented during public beta. The team need a plan to make sure they are gathering meaningful data, analysing it and using this evidence to inform improvements.

There is no offline competing channel. Digital take-up targets are therefore 100%.

The team cited evidence from research that their users expect and desire to use a fully digital service.

Testing with the Minister

The team have engaged their Chief Executive who has seen the service. They have no plans as yet with the current minister with portfolio for this area, and do not know who this is.

Recommendations

User needs and assisted digital

1. The whole team needs to be involved in ongoing user research, including the development team at the supplier. Take the opportunity to go and observe users in context using the service in public beta.
2. Put thought into finding ways to make the navigational paths for your everyday power users more efficient.
3. Collect feedback on how personalisation (saving favourite documents, put together your own dashboard, etc.) can support your users.
4. Ensure the icons and the labelling in the ToDo list are understood by the users - gather evidence to demonstrate this.
5. Data and numbers are needed to justify design decisions made - ensure you use this kind of evidence to back up user research observations.
6. Ensure you have a way of collecting feedback (a banner could be an option) from users who view the beta service.
7. Don't forget to make use of the personas and update them if necessary.

The team

1. Establish a plan for continued development and a managed service once the current delivery partner leaves.
2. Ensure you have funding for and access to specialist roles in future. For example, user research. Whilst it's great the team is learning some of the principles and practices, expert help will be needed when using research to make service design decisions.

Technology, security and standards

1. Keep the current deployment automation in place.
2. Increase test coverage - 50% is acceptable for the current stage - it will not be for a live service.
3. Introduce explicit regression testing and smoke-testing for releases.
4. Keep in mind the danger of over-engineering for requirements which do not need to be accounted for yet.
5. Produce a document of risks considered, likelihood and impact of threat, and what mitigation is in place
6. Make code open now, and code in the open from now on.
7. Get analytics data on browsers and devices and design accordingly.
8. Produce an explicit plan for disaster recovery.
9. Consider a fallback offsite backup facility. Regularly test both local and offsite backups.

Design and content

1. Test and measure whether users understand the meaning of certain words and acronyms (red, green status...)
2. Plan for how to improve the interaction design as you gather more evidence during beta when you'll get a higher volume of users.
3. Review the order of the navigational elements against evidenced user needs.
4. Obtain data and evidence on what browsers and devices your users are using, and design accordingly. Analytics from the existing service may help here.
5. Run a heuristic analysis of the interface design elements with focus on usability, interactive elements and design language consistency against the GDS design patterns.
6. Resolve Javascript issues prior to public beta launch. Currently the service requires Javascript for some critical things - e.g. viewing what's required on a to-do list.
7. Check that the capitalisation is in sentence case style consistently across the site and avoid using full caps for anything apart from acronyms.
8. Ensure that the responsive design actually works on mobile devices: eg the burger menu doesn't work in Chrome on a smaller screen without a refresh.
9. Consider testing a more appropriate way of visualising percentages and other data on the dashboard.

Analysis and benchmarking

1. Work out a plan for measuring the service against the 4 mandated KPIs (where these are relevant). Communicate this.
2. Plan to collect, analyse and act on any other meaningful metrics that will whether the service is making things better.

Testing with the Minister

1. Identify the Minister with portfolio for this area and make plans to demonstrate the service.

Summary

The cross-government panel really appreciated the honesty and clarity of the responses - this helped us assess the service against the standard. Great to see significant progress made since the alpha assessment. It's excellent to see a multidisciplinary team working together to deliver this service. By taking the steers outline above, the service team will be making sure that the standard is adhered to throughout the next stage of development, resulting in a service that is user led, safe and secure, and easily improved.

Digital by Default Service Standard criteria

Criteria	Passed	Criteria	Passed
1	Yes	2	Yes

3	Yes	4	Yes
5	Yes	6	Yes
7	Yes	8	No
9	Yes	10	No
11	Yes	12	Yes
13	Yes	14	Yes
15	No	16	No
17	Yes	18	No

ANNUAL ASSURANCE REPORT 2015/16

Human Fertilisation and Embryology Authority

Health Group Internal Audit Service

Background

In order to be able to provide an annual opinion for 2015/16 to the Human Fertilisation and Embryology Authority's (HFEA) Accounting Officer, it is necessary to consider the work undertaken by Internal Audit over the course of the year, the outcomes of that work and feedback from management on improvements to their areas of responsibility as a result of that work. This together with wider intelligence gathered from all sources of assurance (including the NAO) and performance reporting, inform the Head of Internal Audit's view of controls, governance and risk management. This report provides an overall summary of Internal Audit work delivered in 2015/16 as well as including the formal annual opinion of the Head of Internal Audit.

Executive Summary

Over the last few years, the Human Fertilisation and Embryology Authority has developed its regulatory model and its status within the NHS and beyond. To achieve its objectives, both executive and non-executive management have undertaken significant work to ensure that the organisation's governance structures including internal control and risk management arrangements are fit for purpose. Internal Audit has continuously provided assurance and advice where appropriate to support management's efforts.

Our opinion is based solely on our assessment of whether the controls in place support the achievement of management's objectives as set out in our 2015/16 Internal Audit Plan and Individual Assignment Reports.

We used the following levels of rating (in line with the agreed definitions across all government departments) when providing our internal audit report opinions:

Rating	Definition
Substantial	In my opinion, the framework of governance, risk management and control is adequate and effective.
Moderate	In my opinion, some improvements are required to enhance the adequacy and effectiveness of the framework of governance, risk management and control.
Limited	In my opinion, there are significant weaknesses in the framework of governance, risk management and control such that it could be or could become inadequate and ineffective.
Unsatisfactory	In my opinion, there are fundamental weaknesses in the framework of governance, risk management and control such that it is inadequate and ineffective or is likely to fail.

2015/16 Performance Summary

2015/16 Agreed programme	**3**
Total reviews deferred to complete in 2016/17	**0**
Total reviews added to programme in 2015/16	**1**
Total to deliver 2015/16	**4**
Total reviews completed in 2015/16	**3**
Review to support the data migration within the Register of Treatments project abandoned, as this work is now to be undertaken by a third party	**1**
% of programme completed	**75%**

Total Number of Audits completed by rating (excludes follow up of recs)

Total no reviews completed 2015/16	Substantial	Moderate	Limited	Unsatisfactory	Advisory	Total Rated Work	Advisory Work
3	0	2	0	0	1	**2**	**1**
						66%	**34%**

Resources 2015/16

Period	Full year Budget (man days)	Year to Date			Full year Forecast (man days)
		Budget	Actual	Variance	
April 2015 to March 2016	**42.9**	**42.9**	**41**	**1.9**	**41**

In 2015/16 our programme included two elements of advisory work. One of these involved assurance mapping of capacity and resilience arrangements within HFEA. This work was not rated but the findings are taken into account where relevant in forming our overall opinion for the year. The other element of advisory work was providing support to management in relation to the data migration for the Register of Treatments. This work has now been concluded as management has engaged a third party in this process and so further support from internal audit is not required.

Internal Audit Plan Delivery 2015/16 - Assurance and Advisory Work Summary

#	Audit Title	Status	Outcome	Recommendations agreed by priority		
				High	Medium	Low
1	Requests for Information	Complete	Moderate	0	2	2
2	Incident handling	Complete	Moderate	0	0	6
3	Capacity and Resilience	Complete	No rating – assurance mapping exercise	N/A – No ratings provided		
4	Data Migration - Register of Treatments	Abandoned	No rating – advisory support to management	N/A – No ratings provided		
			Total	**0**	**2**	**8**

Compliance with Public Sector Internal Audit Standards and Quality Assurance

Health Group Internal Audit Services (HGIAS) was subject to an external quality assessment of its services in March 2016, a requirement of HM Treasury which should be undertaken at least every 5 years. Touchstone Renard Limited were commissioned to perform the EQA which is based on a quality assessment framework (The IAQAF). The IAQAF has been designed to help evidence effective internal auditing in line with the Public Sector Internal Audit Standards (PSIAS), with a focus on outcomes that help meet public service delivery commitments. The conclusion can be one of three assessment opinions – Fully Conforms (FC), Generally Conforms (GC) and Partially Conforms (PC) to the above standards. HM Treasury standard requirements are "Generally Conforms".

I am very pleased to advise that, in line with our own internal annual assessments, HGIAS has been rated as Generally Conforms. This is a good result, especially so because of the complex internal audit shared service HGIAS provides.

The report details that in 7 of the 17 IAQAF subsections HGIAS Fully Conforms and in the other 10 sections, Generally Conforms. The following is a high level summary of the report findings:

- **Purpose and positioning** – HGIAS has the appropriate status, clarity of role and independence to fulfil its professional remit.
- **Structure and resources** – HGIAS has the appropriate structure and resources to deliver the expected service.
- **Audit execution** – HGIAS has the processes to deliver an effective and efficient internal audit service.
- **Impact** – HGIAS has had a positive impact on the governance, risk and control environment within the organisation.

The report highlights a number of improvements which can be made to strengthen the service and an action plan has been agreed to address the recommendations made, a number of these have already been actioned. We will ensure that the action plan and progress made is formally reported to the Audit and Governance Committee in due course.

We are particularly pleased that the external assessment acknowledged the complex shared service provided across the health group and the efforts made by all members of the HGIAS team to provide a quality and meaningful service which our customers have acknowledged in their feedback.

Head of Internal Audit Opinion 2015/16

"In accordance with the requirements of the UK Public Sector Internal Audit Standards, I am required to provide the Accounting Officer with my annual opinion of the overall adequacy and effectiveness of the organisation's risk management, control and governance processes.

My opinion is based on the outcomes of the work that Internal Audit has conducted throughout the course of the reporting year and on the follow up action from audits conducted in the previous reporting year. There have been no undue limitations on the scope of Internal Audit work and the appropriate level of resource has been in place to enable the function to satisfactorily complete the work planned. Internal Audit is fully independent and remains free from interference in determining the scope of internal auditing, performing work and communicating results.

For the three areas on which I must report, I have concluded the following:

- In the case of **risk management:** Moderate
- In the case of **governance:** Moderate
- In the case of **control:** Moderate

Therefore, in summary, my overall opinion is that I can give **MODERATE assurance** to the Accounting Officer that the Human Fertilisation and Embryology Authority has had adequate and effective systems of control, governance and risk management in place for the reporting year 2015/16.

Karen Finlayson

Head of Internal Audit

ANNUAL INTERNAL AUDIT PLAN FOR 2016/17

Human Fertilisation and Embryology Authority

Health Group Internal Audit Service

Introduction

This document sets out the internal audit risk assessment and plan for the Human Fertilisation and Embryology Authority (HFEA) for 2016/17.

The HFEA is the regulator of fertility treatment and human embryo research in the UK. The role of the organisation includes licencing of clinics, setting standards and checking compliance with them through inspections. HFEA also plays a public education role by providing information about treatments and services for the public, people seeking treatment, donor-conceived people and donors. HFEA's role is defined in law by the Human Fertilisation and Embryology Act 1990 and the Human Fertilisation and Embryology Act 2008.

HFEA has identified its overall strategic goals as follows:

- **Setting standards – quality and safety**: improving the quality and safety of care through our regulatory activities.
- **Setting standards – donor conception**: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.
- **Increasing and informing choice – register data**: using the data in the register of treatments to improve outcomes and research.
- **Increasing and informing choice – information**: ensuring that patients have access to high quality meaningful information.
- **Efficiency, economy and value:** ensuring the HFEA remains demonstrably good value for the public, the sector and Government.

(These themes are further developed in the HFEA Business Plan, published in March 2016.

The internal audit work that we are planned to undertake during 2016/17 will be focused on governance, internal control, risk management, as well as key strategic and tactical risks faced by the HFEA. Where there are gaps in assurance, audit work will also cover critical activities and their commensurate risks. For this reason, the plan will be subject to review and change, as required during the year, as part of ongoing consultation with management and the Audit and Governance Committee as to the key risk areas.

Internal Audit Policy, Purpose and Responsibilities

Our professional responsibilities as Internal Auditors are set out in the UK Public Sector Internal Audit Standards (UK PSIAS). In line with these requirements, we perform our Internal Audit work with a view to reviewing and evaluating the risk management, control and governance arrangements that the HFEA has in place to:

- Establish and monitor the achievement of the HFEA's objectives.
- Identify, assess and manage the risks to achieving the HFEA's objectives.
- Ensure the economical, effective and efficient use of resources.
- Ensure compliance with established policies, procedures, laws and regulations, including the HFEA's own governance arrangements.
- Safeguard the HFEA's assets and interests from losses of all kinds, including those arising from fraud, irregularity or corruption.
- Ensure the integrity and reliability of information, accounts and data.

Internal Audit Planning 2016/2017

To ensure that internal audit resources are used efficiently, we plan on a risk basis. Therefore, the HFEA's Internal Audit plan is aligned (as closely as possible) to the key strategic risks facing the organisation. Internal audit reviews were selected using the actions below:

- Review of the HFEA's Risk Register to identify key risks, their assurance sources and mitigating actions with a view to providing added assurance where required.
- Consulting with the senior management team.
- Our knowledge of other emerging sector issues.
- Drawing on outcomes from recent internal audit work that remains relevant.

The budget for Internal Audit provision for 2016/17 equates to approximately 40 days of audit work. This document takes into account the budget allocation and has been prepared in consultation with senior management. Internal Audit considers that the programme is sufficient to ensure that HFEA meets its obligations in respect of internal audit.

Risk assessment

Below we consider the current strategic risks facing HFEA before setting out our Internal Audit Plan for 2016/17.

The table below summarises the current high risks according to the HFEA Strategic Risk Register for March 2016, which takes into account its 2016/17 strategic objectives:

Risk area	Description of risk / strategic objective	Residual Risk	April 2016
(1) Legal challenge: Resource diversion	There is a risk that the HFEA is legally challenged in such a way that resources are diverted from strategic delivery. **(Efficiency, economy and value)**	**15 – High**	• Complex and controversial area. • Lack of clarity in HFE Act and regulations, leading to the possibility of there being differing legal opinions from different legal advisers, that then have to be decided by a court. (e.g. one current case challenging the long-held policy position on storage regulations may need to be decided by a court). • Decisions and actions of the HFEA and its committees may be contested. • Subjectivity of judgements means the HFEA often cannot know in advance which way a ruling will go, and the extent to which costs and other resource demands may result from a case. • HFEA could face unexpected high legal costs or damages which it could not fund. • Legal proceedings can be lengthy and resource draining. • Adverse judgements requiring us to alter or intensify our processes, sometimes more than once.
(2) Information for Quality: Improved information access	If the information for Quality (IfQ) programme does not enable us to provide better information and data, and improved engagement channels, patients will not be able to access the improved information they need to assist them in making important choices.	**12 – High**	• Inability to extract reliable data from the Register. • Unable to work out how best to improve CaFC, and/or failure to find out what data/information patients really need. • Stakeholders not on board with the changes. • Cost of delivering better Information becomes too prohibitive, either because the work needed is larger than anticipated, or as a result of the protracted approval periods associated with required DH/GDS gateway reviews.

Risk area	Description of risk / strategic objective	Residual Risk	April 2016
	(Increasing and informing choice – information)		• Redeveloped website does not meet the needs and expectations of our various user types. • Government and DH permissions structures are complex, lengthy, multi-stranded, and sometimes change mid-process. • Resource conflicts between delivery of website and business as usual (BAU). • Delivery quality is very supplier dependent. Contractor management could become very resource-intensive for staff, or the work delivered by one or more suppliers could be poor quality and/or overrun, causing knock-on problems. • New CMS (content management software) is ineffective or unreliable. • Communications infrastructure incapable of supporting the planned changes. • Benefits not maximised and internalised into ways of working. • Potential risks associated with the HFEA's office move in April 2016, in that this will coincide with the delivery period for some IfQ milestones.
(3) Information for Quality: Delivery of promised efficiencies	There is a risk that the HFEA's promises of efficiency improvements in Register data collection and submission are not ultimately delivered. **(Efficiency, economy and value)**	**12 – High**	• Poor user acceptance of changes, or expectations not managed. • Clinics not consulted/involved enough. • Scoping and specification are insufficient for realistic resourcing and on-time delivery of changes. • Efficiencies cannot, in the end, be delivered. • Cost of improvements becomes too prohibitive. • Required GDS gateway approvals are delayed or approval is not given. • Benefits not maximised and internalised into ways of working. • Potential risks associated with the HFEA's likely office move in April 2016, in that this will coincide with the delivery period for some IfQ milestones.
(4) Data: Incorrect data released	There is a risk that incorrect data is released in response to a Parliamentary question (PQ), or a Freedom of	**12 – High**	• Poor record keeping. • Excessive demand on systems and overreliance on a few key expert individuals – request overload – leading to errors.

Risk area	Description of risk / strategic objective	Residual Risk	April 2016
	Information (FOI) or data protection request. **(Efficiency, economy and value)**		• Answers in Hansard may not always reflect advice from HFEA. • Insufficient understanding of underlying system abilities and limitations, and/or of the topic or question, leading to data being misinterpreted or wrong data being elicited. • Servicing data requests for researchers - poor quality of consents obtained by clinics for disclosure of data to researchers.

Risk assessment mapping

The following table details, by directorate, our risk assessment, the internal audit work completed in 2014/15 and 2015/16, and the internal audit work that it is planned we complete during 2016/17. The total level of coverage to be provided is considered sufficient to ensure Internal Audit undertakes a satisfactory level of assurance work.

Directorate	Key activities	Strategic risks	IA work 2014/15	IA work 2015/16	IA plan 2016/17
Compliance & Information Directorate	• Inspection and Clinical Governance • Business Support - Information and the Register • Development and Analysis	(1) Legal challenge: Resource diversion (2) Information for Quality: Improved information access (3) Information for Quality: Delivery of promised efficiencies (4) Data: Incorrect data released	• Information for Quality (IfQ) • Register of Treatments	• Requests for Information • Data Migration - Register of Treatments	• Cyber penetration testing • Information standards
Strategy & Corporate Affairs Directorate	• Governance and Licensing • Regulatory Policy • Engagement and Communications • Business Planning and Programme Management	(1) Legal challenge: Resource diversion (4) Data: Incorrect data released	• Internal Policies	• Incident Handling • Capacity & Resilience	• Board effectiveness • Assurance mapping
Finance & Resources Directorate	• Budgeting • Accounting • Financial Control • Audit and Risk Assurance • Facilities		• Standing Financial Instructions		• Quality and efficiency of revenue data • Income generation process

Audit reviews included in the 2016/17 plan

Based on review of the strategic risks as above and discussions with HFEA senior management, the table below sets out the proposed reviews within the draft 2016/17 internal audit plan. The table summarises the internal audit plan 2016/17 including indicative timing and estimated audit day allocation, which are both subject to agreement following detailed planning.

Suggested review	Rationale for inclusion	Proposed Scope	Indicative timing and audit day allocation
Income generation process	HFEA receives the majority of its funding from the regulated clinics in form of fee income generated from individual IVF treatments. Those fees, together with licence fees, cover the cost of regulation. Remaining funding is received in the form of grant-in-aid from the sponsors and Department of Health.	This review will evaluate the process and controls within the end to end income generation process, considering how data is used to generate billing.	Q1; 5 days
Quality and efficiency of revenue data		This subsequent review will consider the control of data quality relevant to the billing process and its overall efficiency.	Q2; 4 days
Information standards	Two strategic high risks were identified for information sharing and access to data (3) and (5).	In June/July 2016 HFEA is launching a policy concerning the publication of information on the HFEA's website. This review will consider the information governance arrangements supporting application of the new policy and evaluate the controls in place to ensure published information is up to date and accurate.	Q3; 5 days
Board effectiveness	The evaluation of Board performance is central to good corporate governance. The main goal of Board evaluation is to enable the Board to identify and address any barriers that	This review will assess the Board effectiveness via surveys and interviews, and review of Board papers. We may also agree to observe a board meeting to inform our conclusions.	Q2; 6 days

Suggested review	Rationale for inclusion	Proposed Scope	Indicative timing and audit day allocation
	may impede its effectiveness. Governance contributes to management of all risks and to achievement of corporate objectives.		
Management of Cyber Penetration threat	Cyber threats are of increasing concern to government, public sector and private sector organisations. There are reputational risks should HFEA's network and data be accessed or interrupted, particularly if access was gained to sensitive data.	We will review the cyber security controls put in place by management in relation to HFEA's network, IT and data and the penetration testing performed, and assess whether the arrangements appear to reflect good practice in mitigating the risks which HFEA faces in this area.	Q2, 5 days
Assurance mapping	Following the assurance mapping of capacity and resilience in 2015/16, HFEA management has requested further assurance mapping be included as part of the 2016/17 audit plan.	We will deliver an assurance mapping workshop, having prepared a controls assessment framework for the area under review and agreed that with management. The area to be mapped will be agreed in consultation with management and the Audit and Governance Committee.	Q3; 3 days
Audit management		All aspects of audit management to include: • Drafting the Audit Plan; • Attendance at liaison meetings and HFEA Audit and Governance Committee meetings; • Drafting committee papers/progress reports;	Ongoing; 7 days

Suggested review	Rationale for inclusion	Proposed Scope	Indicative timing and audit day allocation
		• Follow-up work on prior recommendations; • Resourcing and risk management activities; and • Contingency.	
Contingency			5 days
		Total	**40 days**

Action Required

The Audit and Governance Committee is invited to consider:

- whether it agrees with our proposed priorities for reviews;
- the scheduling of proposed reviews over the year; and
- suggest any other key areas for inclusion on the audit plan.

Audit and Governance Committee Paper

Paper Title:	**Information Assurance**
Paper Number:	[AGC (15/06/2016) 500]
Meeting Date:	15 June 2016
Agenda Item:	**9**
Author:	Sue Gallone
For information or decision?	Information
Resource Implications:	None
Implementation	N/A
Communication	N/A
Organisational Risk	Not to have an assessment would undermine the I Governance Statement and improvement required may not be identified and acted upon.
Recommendation to the Committee:	The Committee is asked to note the SIRO's assessment of information governance and discuss.
Evaluation	Annually, to inform the consideration of the annual report and accounts
Annexes	

Information Assurance

Background

1. It is a Cabinet Office (CO) requirement that boards receive assurance about information risk management. This provides for good governance in its own right, ensures that the board is involved in information assurance and informs the Audit and Governance Committee's consideration of the Governance Statement. The Senior Information Risk Officer (SIRO) makes an annual report to the Accounting Officer to inform the Governance Statement and this paper provides that report for the Committee's purposes too. The report is also reviewed by the Senior Management Team (SMT).

2. The Department of Health (DH) usually requires arms length bodies (ALBs) to make a similar report to them, to inform their departmental reporting to CO.

3. My assessment is based on the requirements of the Security Policy Framework (SPF) Security policy framework - Publications - GOV.UK. and the 10 Steps to Cyber Security, the guidance issued as part of the Government's cyber security strategy. We are not reporting using the Information Governance Toolkit, which organisations who deal with patient data are required to use. The HFEA's patient data is not of the same nature or subject to the same processes as in the NHS institutions who report using the more detailed Information Governance Toolkit.

Recommendation

4. Members are asked to note the assessment set out in this paper.

Report

5. The HFEA has a sound culture of protecting information and staff have a good understanding of the need and protocols. There have been no incidents of data loss in 2015/16 and there is a good track record of properly protecting information and systems. Satisfactory penetration testing last took place in March 2012 and the Head of IT performs monthly vulnerability assessments. Further external penetration testing is planned for 2016/17 after the next server upgrade. Policies were updated in 2015/16 and need to be communicated further to staff.

6. The high level assessment of the 10 areas relating to cyber security is:

i. Information risk management – action required to formally risk assess information assets

ii. Secure configuration – considered satisfactory, based on assurances from IT team

iii. Network security - considered satisfactory, based on assurances from IT team

iv. Managing user privileges – satisfactory

v. User education and awareness – policies need to be communicated and assurance sought that these are understood

vi. Incident management – satisfactory

vii. Malware prevention – considered satisfactory, based on assurances from IT team

viii. Monitoring – considered satisfactory, based on assurances from IT team

ix. Removable media controls - satisfactory

x. Home and mobile working – satisfactory.

Assessment of HFEA compliance with the Security Policy Framework 2014
As at May 2016

	Mandatory Requirement	Compliance	Further actions required
1	Departments and Agencies must establish an appropriate security organisation (suitably staffed and trained) with clear lines of responsibility and accountability at all levels of the organisation. This must include a Board-level lead with authority to influence investment decisions and agree the organisation's overall approach to security.	Director of Finance and Resources is SIRO, Head of Information Technology has day to day responsibility. Both are appropriately trained and experienced.	Better communication of any issues to SIRO
2	Departments and Agencies must: * Adopt a holistic risk management approach covering all areas of protective security across their organisation. * Develop their own security policies, tailoring the standards and guidelines set out in this framework to the particular business needs, threat profile and risk appetite of their organisation and its delivery partners.	Risks identified escalated to operational and strategic risk registers as necessary. Policies in place.	Keep policies up to date
3	Departments and Agencies must ensure that all staff are aware of Departmental security policies and understand their personal responsibilities for safeguarding assets and the potential consequences of breaching security rules.	All staff informed of policies and given guidance. Annual training undertaken by all through Civil Srvice Learning.	Further awareness raising with staff
4	Departments and Agencies must have robust and well tested policies, procedures and management arrangements in place to respond to, investigate and recover from security	Head of IT monitors system in place for detecting and responding to security	None

	incidents or other disruptions to core business.	breaches. Business continuity plan in place.	
5	Departments and Agencies must have an effective system of assurance in place to satisfy their Accounting Officer / Head of Department and Management Board that the organisation's security arrangements are fit for purpose, that information risks are appropriately managed, and that any significant control weaknesses are explicitly acknowledged and regularly reviewed.	Head of IT reviews and reports	IT security audit and testing planned
6	Departments and Agencies must have an information security policy setting out how they and any delivery partners and suppliers will protect any information assets they hold, store or process (including electronic and paper formats and online services) to prevent unauthorised access, disclosure or loss. The policies and procedures must be regularly reviewed to ensure currency.	Policies and procedures in place	Further awareness raising and actions to embed
7	Departments and Agencies must ensure that information assets are valued, handled, shared and protected in line with the standards and procedures set out in the Government Security Classifications Policy (including any special handling arrangements) and the associated technical guidance supporting this framework.	The HFEA's assets are all classified OFFICIAL and are appropriately controlled.	None
8	All ICT systems that handle, store and process HMG classified information or business critical data, or that are interconnected to cross-government networks or services (e.g. the Public Services Network, PSN), must undergo a formal risk assessment to identify and	IFQ programme engaged with CLAS consultant. IT security audit of Spring Gardens planned	IT security audit and testing planned

	understand relevant technical risks; and must undergo a proportionate accreditation process to ensure that the risks to the confidentiality, integrity and availability of the data, system and/or service are properly managed.		
9	Departments and Agencies must put in place an appropriate range of technical controls for all ICT systems, proportionate to the value, importance and sensitivity of the information held and the requirements of any interconnected systems.	Access to HFEA data by users strongly controlled by role-specific permissions.	CLAS assessment of IFQ technology.
10	Departments and Agencies must implement appropriate procedural controls for all ICT (or paper-based) systems or services to prevent unauthorised access and modification, or misuse by authorised users.	Policies and staff induction in place.	Records management improvements required
11	Departments and Agencies must ensure that the security arrangements among their wider family of delivery partners and third party suppliers are appropriate to the information concerned and the level of risk to the parent organisation. This must include appropriate governance and management arrangements to manage risk, monitor compliance and respond effectively to any incidents. Any site where third party suppliers manage assets at SECRET or above must be accredited to List X standards.	Delivery partners have provided assurance with regards to information governance and security arrangements	
12	Departments and Agencies must have clear policies and processes for reporting, managing and resolving Information Security Breaches and ICT security incidents.	Policy in place	Promote to staff

13	Departments must ensure that personnel security risks are effectively managed by applying rigorous recruitment controls, and a proportionate and robust personnel security regime that determines what other checks (e.g. national security vetting) and ongoing personnel security controls should be applied.	Recruitment and references provide assurance. No vetting in place.	None
14	Departments and Agencies must have in place an appropriate level of ongoing personnel security management, including formal reviews of national security vetting clearances, and arrangements for vetted staff to report changes in circumstances that might be relevant to their suitability to hold a security clearance.	N/a	
15	Departments must make provision for an internal appeals process for existing employees wishing to challenge National Security Vetting decisions and inform Cabinet Office Government Security Secretariat should an individual initiate a legal challenge against a National Security Vetting decision.	N/a	
16	Departments and Agencies must undertake regular security risk assessments for all sites in their estate and put in place appropriate physical security controls to prevent, detect and respond to security incidents.	Assessment and sufficient controls provided by NICE.	None
17	Departments and Agencies must implement appropriate internal security controls to ensure that critical, sensitive or classified assets are protected against both surreptitious and forced attack, and are only available to those with a genuine “need to know". Physical security measures must be proportionate to level of threat, integrated with other protective	Visitor and entry controls provided by NICE. Lockable furniture provided for storage. Clear desk and clear screen practice in place.	None

	security controls, and applied on the basis of the “defence in depth" principle.		
18	Departments and Agencies must put in place appropriate physical security controls to prevent unauthorised access to their estate, reduce the vulnerability of establishments to terrorism or other physical attacks, and facilitate a quick and effective response to security incidents. Selected controls must be proportionate to the level of threat, appropriate to the needs of the business and based on the “defence in depth" principle.	Sufficient controls in place through NICE	None
19	Departments and Agencies must ensure that all establishments in their estate put in place effective and well tested arrangements to respond to physical security incidents, including appropriate contingency plans and the ability to immediately implement additional security controls following a rise in the Government Response Level.	NICE provide the lead on incidents. HFEA have contingency plans in place that are reviewed annually.	None
20	Departments and Agencies must be resilient in the face of physical security incidents, including terrorist attacks, applying identified security measures, and implementing incident management contingency arrangements and plans with immediate effect following a change to the Government Response Level.	NICE provide the lead on incidents. HFEA have contingency plans in place.	None

Strategic risks

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Audit and Governance Committee		
Agenda item	11		
Paper number	AGC (15/06/2016) 501		
Meeting date	15 June 2016		
Author	Helen Crutcher, Project Risk and Performance Manager		
Output:			
For information or decision?	Information and comment.		
Recommendation	AGC is asked to note the latest edition of the risk register, set out in the annex.		
Resource implications	In budget.		
Implementation date	Strategic risk register and operational risk monitoring: ongoing. CMG reviews risk quarterly in advance of each AGC meeting. AGC reviews the strategic risk register at every meeting. The Authority reviews the strategic risk register periodically.		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: Strategic risk register		

1. Strategic risk register

Latest reviews

1.1. CMG reviewed the risk register on 18 May 2016. CMG discussed risks, their controls, and scores. The Legal and IfQ risks were reviewed in detail by risk owners at separate meetings to provide the current position. Four of the twelve risks are currently above tolerance.

1.2. The strategic risk register is attached at Annex A, and includes an overview of CMG's general discussions about the risk register. The annex includes the graphical overview of residual risks plotted against risk tolerances, which was presented for the first time at the Committee's last meeting.

1.3. The office move has been successfully completed since the last AGC meeting, so that strategic risk has been removed. Residual 'snagging' tasks are still in progress, although now largely complete. Remaining operational actions and risks lie with the relevant teams (largely IT), and a thorough review of these was done at the end of the project to ensure all tasks were appropriately allocated.

2. Recommendation

2.1. AGC is asked to note the above, and to comment on the strategic risk register.

Annex A

HFEA strategic risk register 2016/17

Risk summary: high to low residual risks

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

* This column tracks the four most recent reviews by AGC, CMG, or the Authority (eg,⇧⇔⇩⇔).
Recent review points are: AGC 9 December ⇨ CMG 4 February ⇨AGC 16 March ⇨ CMG 18 May.

[1] Strategic objectives 2014-2017:

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

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

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

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

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

CMG overview – summary from May risk meeting

CMG reviewed the risk register and discussed each risk in detail at its meeting on 18 May. CMG agreed to focus mainly on the risk scores, with detailed review and update of IfQ (IfQ1, IfQ2 and IfQ3) and Legal (LC1) risks being followed up offline with the risk owners.

Since the two head posts that had been vacant for a period have now been filled, this improves the position for several of the risks, in that the controls now have long term owners and are no longer being carried by the relevant Directors. It will take some time for the new appointees to bed in fully, however, so this does not in itself reduce the risk scores.

When reviewing RM2, CMG discussed the records management mitigation which had been assigned to the Head of Corporate Projects who had now left the organisation, meaning this mitigation was no longer in place. We agreed that, in the event, this part of the role had not been made a priority. CMG agreed the organisation's records management practices had not worsened, and the position had not changed for some years, so the risk rating should remain the same. Work is now being planned on records management, probably to be managed as a project. CMG will consider an approach at its June meeting.

CMG noted that since the move, IfQ product owners were finding oversight and day-to-day communication with Reading Room more difficult since colocation is harder to achieve in the HFEA's smaller office, and opportunities for continued colocation at Reading Room's offices are limited. We have agreed that this should be rectified by ensuring 3-4 desks are available to accommodate the contractors when needed. We believe that desk occupancy is now settling down somewhat and that it should usually be possible to find the space needed.

CMG agreed to remove the office move risk (OM 1) from the strategic risk register since the move had been completed and any risks or issues were now operational. All causes had been reviewed and outstanding related actions have been incorporated into an ongoing post-move snagging list where needed, which is being tracked by the Business Planning team.

CMG also considered operational risks (under a different report) and noted that the main theme of each team's operational risk was mainly around resources. This has been the position for some time now. The Finance team is under particular pressure at this time of year, owing to the usual year end peak and the fact that the Director and Head also unavoidably experience this for two organisations at once.

A new operational risk was raised around the potential need for re-licensing of all centres. This risk arises from discussions with DH legal in relation to the European movement of gametes projects. DH feel that implementing the EU Directives will require a licence condition and re-licensing of all the centres. The HFEA holds the view that this could be accomplished as and when licences are renewed, rather than through a major relicensing project, which is always a complex and labour-intensive exercise. If a relicensing project does become necessary this would impact on Compliance and Licensing team capacity. Conversations with DH continue about this risk.

Criteria for inclusion of risks:

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

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

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

Risk scoring system
See last page.

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

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

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Regulatory model RM 1: Quality and safety of care	There is a risk of adverse effects on the quality and safety of care if the HFEA were to fail to deliver its duties under the HFE Act (1990) as amended.	Setting standards: improving the quality and safety of care through our regulatory activities.	Inherent risk level:			⇧ ⇔ ⇔ ⇔	Peter Thompson
			Likelihood	Impact	Inherent risk		
			3	5	15 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			2	**4**	**8 Medium**		
			Tolerance threshold:		8 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Inspection/reporting failure.	Inspections are scheduled for the whole year, using licence information held on Epicentre, and items are also scheduled to committees well in advance.	In place – Sharon Fensome-Rimmer	At tolerance. The Head of Corporate Governance and Chief Inspector have now started in their posts. While they are bedding into the organisation it is likely that some degree of ownership of controls will sit with both the respective Directors as well as the Heads themselves until they are fully trained. The need to manage this training period, together with the action plan being implemented in connection with legal parenthood consent issues, has raised the residual risk likelihood from 1 (very unlikely) to 2 (unlikely) – from November through to at least June 2016.
	Audit of Epicentre conducted to reveal data errors. Queries now routed through Licensing, who hold a definitive list of all licensing details.	Completed October 2015 – Ian Brown	
	Inspector training, competency-based recruitment, induction process, SOPs, QMS, and quality assurance all robust.	In place – Sharon Fensome-Rimmer	
Monitoring failure.	Outstanding recommendations from inspection reports are tracked and followed up by the team.	In place – Sharon Fensome-Rimmer	
Unresponsiveness to or mishandling of non-compliances or grade A incidents.	Update of compliance and enforcement policy.	Completed following Authority approval of new policy March 2016 - Nick Jones	
	Staffing model provides resilience in the inspection team for such events – dealing with high-impact cases, additional incident inspections, etc.	In place – Sharon Fensome-Rimmer	
Insufficient inspectors or licensing staff	Inspection team up to complement. The new Chief Inspector joined the HFEA in early May 2016.	In place – Nick Jones	
	Licensing team up to complement following earlier recruitment. The new Head of Corporate Governance joined the HFEA in March 2016.	In place – Ian Brown	

Recruitment difficulties and/or high turnover/churn in various areas; resource gaps and resource diversion into recruitment and induction, with impacts felt across all teams.	So far recruitment rounds have yielded sufficient candidates, although this has required going beyond the initial ALB pool to external recruitment in some cases.	Managed as needed – Sharon Fensome-Rimmer	
	Additional temporary resources available during periods of vacancy and transition.	In place – Rachel Hopkins	
	Group induction sessions put in place where possible.	In place – Sharon Fensome-Rimmer	
Resource strain itself can lead to increased turnover, exacerbating the resource strain.	Operational performance, risk and resourcing oversight through CMG, with deprioritisation or rescheduling of work an option.	In place – Paula Robinson	
Unexpected fluctuations in workload (arising from eg, very high level of PGD applications received, including complex applications involving multiple types of a condition; high levels of non-compliances either generally or in relation to a particular issue).	Staffing model amended in May 2015, to release an extra inspector post out of the previous establishment. This increased general resilience, enabling more flex when there is an especially high inspection/report writing/application processing workload.	In place – Sharon Fensome-Rimmer	
	Greater sector insight into our PGD application handling processes and decision-making steps achieved in the past few years; coupled with our increased processing times since efficiency improvements were made in 2013 (acknowledged by the sector).	In place – Sharon Fensome-Rimmer	
Some unanticipated event occurs that has a big diversionary impact on key resources, eg, legal parenthood consent issues, or several major Grade A incidents occur at once.	Resilient staffing model in place.	In place – Sharon Fensome-Rimmer	
	Update of compliance and enforcement policy and implementation of new policy and related procedures.	In place – revised policy agreed Spring 2016 – Nick Jones / Sharon Fensome-Rimmer	On legal parenthood, a strong set of actions is in place and continues to be implemented. 10 cases have been determined and 10 cases await determination in the High Court,
	A detailed action plan in response to the legal parenthood judgment is in place. There has been correspondence with clinics, who have completed full audits. PRs are responsible for	In progress – Nick Jones/Sharon Fensome-Rimmer	

	the robustness of the audit. The HFEA has required that clinics support affected patients – using Barts as a good example. In working with clinics, the HFEA has experienced good cooperation. All clinics engaged and have provided assurances about current practice. Through a detailed review of every clinic's responses, a summary list of all concerns is being produced. Management review meetings took place for all clinics at which there are handling concerns or anomalies. Plan of action in place to address all of the concerns identified, with direct follow up with centres who did not respond at all. Where there are engagement concerns, we will do short-notice inspections, focused on parenthood consent. Range of lessons learned identified.		and in Scotland. The inspection team continue to work with colleagues in around 20 licensed centres where there are anomalies. The focus is on ensuring all affected patients are informed and appropriately supported. The policy team is developing a range of tools to support licensed clinics in ensuring patients provide effective consent.

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Regulatory model RM 2: Loss of regulatory authority	There is a risk that the HFEA could lose authority as a regulator, jeopardising its regulatory effectiveness, owing to a loss of public / sector confidence.	Setting standards: improving the quality and safety of care through our regulatory activities.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Peter Thompson
			Likelihood	Impact	Inherent risk		
			3	5	15 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			2	**4**	**8 Medium**		
			Tolerance threshold:		8 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Failures or weaknesses in decision making processes.	Keeping up to date the standard operating procedures (SOPs) for licensing, representations and appeals.	In place – Ian Brown	At tolerance. Although two additional risk sources exist at present (website outages until the new beta website is live and the plan of work to address legal parenthood consent issues), these are being well managed and/or tolerated, and the overall risk score has not increased.
	Learning from past representations and Appeal Committee hearings incorporated into processes.	In place – Ian Brown	
	Appeals Committee membership maintained. Ongoing process in place for regular appointments whenever vacancies occur or terms of office end.	In place – Ian Brown	
	Staffing structure for sufficient committee support.	In place – Ian Brown	
	Decision trees; legal advisers familiar.	In place – Ian Brown	
	Proactive management of quoracy for meetings.	In place – Ian Brown	
	New (ie, first application) T&S licences delegated to ELP. Delegations to be revisited during 2016 review of Standing Orders. Licensing Officer role to take certain decisions from ELP – work on this is continuing, with the preparation of suitable documentation for recording decisions.	To be put in place – Ian Brown Licensing Officer role – this was postponed pending recruitment of Head of Corporate Governance, work is now continuing – Ian Brown Delegations in SOs have been put in place - Spring 2016	
Failing to demonstrate competence as a regulator	Update of compliance and enforcement policy and implementation of new policy and related procedures.	In place – revised policy agreed Spring 2016 – Nick Jones / Sharon Fensome-Rimmer	

	Inspector training, competency-based recruitment, induction process, SOPs, quality management system (QMS) and quality assurance all robust.	In place – Sharon Fensome-Rimmer
Effect of publicised grade A incidents.	Staffing model provide resilience in inspection team for such events – dealing with high-impact cases, additional incident inspections, etc.	In place – Sharon Fensome-Rimmer
	SOPs and protocols with Communications team.	In place – Sharon Fensome-Rimmer
	Fairness and transparency in licensing committee information.	In place – Sharon Fensome-Rimmer
	Dedicated section on website, so that the public can openly see our activities in the broader context.	In place – Sharon Fensome-Rimmer
Administrative or information security failure, eg, document management, risk and incident management, data security.	Staff have annual information security training (and on induction).	In place – Dave Moysen
	TRIM training and guidance/induction in records management in place pending new work on records management to be commenced in mid-2016 (see below).	New work in development as at May 2016 – SMT
	Further work planned on records management in parallel with IT strategy. This piece of work is currently being scoped.	Linked to IT strategy work – in progress – Ian Brown / David Moysen
	Guidance/induction in handling FOI requests, available to all staff.	In place – Ian Brown
	The IfQ website management project has reviewed the retention schedule.	Completed – August 2015 – Juliet Tizzard
Until the IfQ website project has been completed, there is a continued risk of HFEA website outages, as well as difficulties in uploading updates to web pages.	Alternative mechanisms are in place for clinics to get information about materials such as the Code of Practice (eg, direct communications with inspectors, Clinic Focus).	In place – Sharon Fensome-Rimmer
	The IfQ work on the new website will completely mitigate this risk (the new content management system will remove the current instability we are experiencing from using RedDot). This risk is	In progress – beta phase February 2016 – Juliet Tizzard

	informing our decisions about which content to move first to the beta version of the new site.	
Negative media or criticism from the sector in connection with legally disputed issues or major adverse events at clinics.	HFEA approach is only to go into cases on the basis of clarifying legal principles or upholding the standards of care by challenging poor practice. This is more likely to be perceived as proportionate, rational and necessary (and impersonal), and is in keeping with our strategic vision.	In place - Peter Thompson
HFEA process failings that create or contribute to legal challenges, or which weaken cases that are otherwise sound, or which generate additional regulatory sanctions activity (eg, legal parenthood consent).	Licensing SOPs, committee decision trees in place. Mitochondria donation application tools completed.	In place – Ian Brown
	Update of compliance and enforcement policy and implementation of new policy and related procedures.	In place – revised policy agreed Spring 2016 – Nick Jones / Sharon Fensome-Rimmer
	Seeking the most robust possible assurance from the sector with respect to legal parenthood consent issues, and detailed plan in operation to address identified cases and anomalies.	In progress – Nick Jones
	QMS and quality assurance in place in inspection team.	In place – Sharon Fensome-Rimmer

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner
IfQ IfQ 1: Improved information access	If the information for Quality (IfQ) programme does not enable us to provide better information and data, and improved engagement channels, patients will not be able to access the improved information they need to assist them in making important choices.	Increasing and informing choice: ensuring that patients have access to high quality meaningful information.	Inherent risk level: Likelihood: 4 / Impact: 4 / Inherent risk: 16 High **Residual risk level:** Likelihood: **3** / Impact: **4** / Residual risk: **12 High** Tolerance threshold: 8 Medium	⇔ ⇔ ⇔ ⇔	Juliet Tizzard

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Inability to extract reliable data from the Register.	Detailed planning and programme management in place to ensure this will be possible after migration. Migration strategy developed, and significant work being done to identify and cleanse all of the data that will require correction before migration can be done. Decisions have been made about the degree of reliability required in each data field. For those fields where 100% reliability is needed, inaccurate or missing data is being addressed as part of project delivery.	All aspects – detailed project planning in place – Nick Jones	Above tolerance. Managing these risks has formed an intrinsic and essential part of the detailed project planning and tendering, throughout. Following a lengthy delay, we received formal approval for both the data and digital elements of IfQ in late April 2015. The digital side of the programme received only partial approval; full delivery still required an additional gateway approval (ie, prior to commencing beta). The Department of Health gateway review took place in
Stakeholders dislike or fail to accept the new model for CaFC. Stakeholders not on board with the changes.	In-depth stakeholder engagement and extensive user research completed to inform the programme's intended outcomes, products and benefits. This included, consultation, expert groups and Advisory Board and this continues to be an intrinsic part of programme approach.	In place and ongoing – Juliet Tizzard /Nick Jones	
Cost of delivering better information becomes too prohibitive, either because the work needed is larger than	Costs were taken into account as an important factor in consideration of contract tenders and negotiations.	In place – Nick Jones	

anticipated, or as a result of the approval periods associated with required DH/GDS gateway reviews.	Following earlier long timelines and unsuccessful attempts to discuss with GDS, our experience at the Beta gateway has been much improved and feedback was almost immediate. Watching brief being kept.	In place – Nick Jones	November 2015 and awarded a high score to the HFEA, but the formal decision on this was still not made by the Government Digital Service board until mid-January (a month later than expected). This meant that the beta (build) stage initially had to proceed at risk (subsequently resolved). Approval also carried a number of requirements and conditions which need to be added to the delivery. Owing to these delays, it was necessary to extend the timeline for the beta phase from March to June 2016. The live beta gateway approval in May was much more efficient, with approvals received within days of the assessment taking place. However there are a number of requirements to address before we can implement live beta.
Redeveloped website does not meet the needs and expectations of our various user types.	Programme approach and some dedicated resources in place to manage the complexities of specifying web needs, clarifying design requirements and costs, managing changeable Government delegation and permissions structures, etc. User research done, to properly understand needs and reasons. Tendering and selection process included clear articulation of needs and expectations. GDS Beta assessment was passed on all 18 points.	In progress – delivery by end July 2016 – Juliet Tizzard	
Government and DH permissions structures are complex, lengthy, multi-stranded, and sometimes change mid-process.	Initial external business cases agreed and user research completed. Final business case for whole IfQ programme was submitted and eventually accepted. All GDS approvals sought so far have been granted, albeit with some delays to the earlier ones. Additional sprints of work were incorporated in beta, in an attempt to allow sufficient time (and resources) for the remaining GDS gateway review processes and subsequent formal approval mechanisms. The beta timeline was extended by 3 months to compensate for previous and anticipated future delays.	In place – Juliet Tizzard In place – Nick Jones (decision received April 2015) In place – Nick Jones	
Resource conflicts between delivery of website and business as usual (BAU).	Backfilling where possible/affordable to free up the necessary staff time, eg, Websites and Publishing Project Manager post backfilled to free up core staff for IfQ work.	In place – Juliet Tizzard	

Delivery quality is very supplier dependent. Contractor management could become very resource-intensive for staff, or the work delivered by one or more suppliers could be poor quality and/or overrun, causing knock-on problems.	Programme management resources and quality assurance mechanisms in place for IfQ to manage (among other things) contractor delivery. Agile project approach includes a 'one team' ethos and requires close joint working and communication among all involved contractors. Sound project management practices in place to monitor. Previous lessons learned and knowledge exist in the organisation from managing some previous projects where poor supplier delivery was an issue requiring significant hands-on management. Ability to consider deprioritising other work, through CMG, if necessary. Regular contract meetings in place. This remains a challenge.	In place – Juliet Tizzard	
New CMS (content management software) is ineffective or unreliable.	CMS options were scrutinised carefully as part of project. Appropriate new CMS chosen, and all involved teams happy with the selection.	In progress – implemented in beta phase, July 2016 – Juliet Tizzard	
Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedded into new ways of working. Knowledge handover with the contractors will take place.	In place – Nick Jones	
Colocation in the HFEA's smaller office at Spring Gardens is harder to achieve with the risk that Product Owners have less oversight of contractor delivery.	Disruption during the move was minimised through careful planning. Since the move, some colocation has been possible at Reading Room and other options are being explored, including a resumption of colocation at Spring Gardens to the extent possible.	Considered and further action in progress – Nick Jones	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
IfQ IfQ 2: Register data	HFEA Register data becomes lost, corrupted, or is otherwise adversely affected during IfQ programme delivery.	Increasing and informing choice: using the data in the Register of Treatments to improve outcomes and research.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Nick Jones
			Likelihood	Impact	Inherent risk		
			2	5	10 Medium		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			2	**4**	**8 Medium**		
			Tolerance threshold:		8 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Risks associated with data migration to new structure, together with records accuracy and data integrity issues.	IfQ programme groundwork focused on current state of Register. Extensive planning in place, including detailed research and migration strategy.	In place – Nick Jones/Dave Moysen	At tolerance. This risk is being intensively managed – a major focus of IfQ detailed planning work, particularly around data migration.
The firm (Avoca) which was scheduled to provide assurance on data migration has gone out of business.	The HFEA is considering other sources of assurance, and will agree a new plan shortly.	To be resolved. Update to be provided to June AGC – Nick Jones	
Historic data cleansing is needed prior to migration.	A detailed migration strategy is in place, and data cleansing is in progress.	In place – Nick Jones/Dave Moysen	
Increased reporting needs mean we later discover a barrier to achieving this, or that an unanticipated level of accuracy is required, with data or fields which we do not currently focus on or deem critical for accuracy.	IfQ planning work incorporated consideration of fields and reporting needs were agreed. Decisions about the required data quality for each field were 'future proofed' as much as possible through engagement with stakeholders to anticipate future needs and build these into the design.	In place – Nick Jones	
Reliability of existing infrastructure systems – (eg, Register, EDI, network, backups).	Maintenance of desktop, network, backups, etc. core part of IT business as usual delivery.	In place – Dave Moysen	
System interdependencies change / are not recognised	Strong interdependency mapping done between IfQ and business as usual.	Done – Nick Jones	
Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and	In place – Nick Jones	

	embedding into new ways of working. Knowledge handover with the contractors will take place.		
Colocation in the HFEA's smaller office at Spring Gardens is harder to achieve with the risk that Product Owners have less oversight of contractor delivery.	Disruption during the move was minimised through careful planning. Since the move, some colocation has been possible at Reading Room and other options are being explored, including a resumption of colocation at Spring Gardens to the extent possible.	Considered and further action in progress – Nick Jones	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
IfQ IfQ 3: Delivery of promised efficiencies	There is a risk that the HFEA's promises of efficiency improvements in Register data collection and submission are not ultimately delivered.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇔ ⇧ ⇔ ⇔	Nick Jones
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	**4**	**12 High**		
			Tolerance threshold:		9 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Poor user acceptance of changes, or expectations not managed.	Stakeholder involvement strategy in place and user testing being incorporated into implementation phases of projects.	In place – Nick Jones/Juliet Tizzard	Above tolerance. This risk is also affected by GDS approvals and associated requirements (see IfQ1).
Clinics not consulted/involved enough.	Working with stakeholders has been central to the development of IfQ, and will continue to be. Advisory Group and expert groups have ended, but a stakeholder group for the implementation phase is in place. Workshops were delivered with the sector regarding how information will be collected through the clinic portal. From beta live onwards we will receive feedback and iteratively develop the products.	In place – Nick Jones/Juliet Tizzard	
Scoping and specification are insufficient for realistic resourcing and on-time delivery of changes.	Scoping and specification were elaborated with stakeholder input, so as to inform the tender. Resourcing and timely delivery were a critical part of the decision in awarding the contract.	In place and contracts awarded (July 2015) – Nick Jones	
Efficiencies cannot, in the end, be delivered.	Detailed scoping phase included stakeholder input to identify clinic users' needs accurately. Specific focus in IfQ projects on efficiencies in data collected, submission and verification, etc.	In place – Nick Jones	
Cost of improvements becomes too prohibitive.	Contracts only awarded to bidders who made an affordable proposal. Detailed planning for release two (which includes the second iteration of the portal and the	In place (July 2015) – Nick Jones In progress (May 2016) – Nick Jones	

	introduction of the new EDI interface) is in progress and the HFEA will continue to work within agreed costs.	
Required GDS gateway approvals are delayed or approval is not given.	All GDS approvals sought so far have been granted, albeit with some delays to earlier gateways. Our detailed planning includes addressing the requirements laid down by GDS as conditions of alpha and beta phase approval. Additional sprints of work were incorporated into beta, in an attempt to allow sufficient time (and resources) for the remaining GDS gateway review processes and subsequent formal approval mechanisms. The beta timeline was extended by 3 months to compensate for previous and anticipated future delays.	In place – Nick Jones
Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedded into new ways of working. Knowledge handover with the contractors will take place.	In place (June 2015) – Nick Jones
Colocation in the HFEA's smaller office at Spring Gardens is harder to achieve with the risk that Product Owners have less oversight of contractor delivery.	Disruption during the move was minimised through careful planning. Since the move, some colocation has been possible at Reading Room and other options are being explored, including a resumption of colocation at Spring Gardens to the extent possible.	Considered and further action in progress – Nick Jones

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Legal challenge LC 1: Resource diversion	There is a risk that the HFEA is legally challenged in such a way that resources are diverted from strategic delivery.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇔ ⇔ ⇔ ⇩	Peter Thompson
			Likelihood	Impact	Inherent risk		
			4	5	20 Very high		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	**4**	**12 High**		
			Tolerance threshold:		12 High		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Complex and controversial area.	Panel of legal advisors from various firms at our disposal for advice, as well as in-house Head of Legal.	In place – Peter Thompson	At tolerance. **Current cases:** The 'M' case regarding the export of gametes for treatment abroad proceeded to appeal in May 2016. We await the judgment following this. The judgment in 2015 on consents for parenthood has had administrative and policy consequences for the HFEA. Further court cases are coming to light now, and more are also likely, although the HFEA is unlikely to participate in legal proceedings directly. Pre-action protocol letter challenging one discrete element of the IfQ CaFC project. If the case were lost then this would impact on the presentation of data.
	Evidence-based policy decision-making and horizon scanning for new techniques.	In place – Joanne Anton	
	Robust and transparent processes in place for seeking expert opinion – eg, external expert advisers, transparent process for gathering evidence, meetings minuted, papers available online.	In place – Joanne Anton/Juliet Tizzard	
HFE Act and regulations lead to the possibility of there being differing legal opinions from different legal advisers, that then have to be decided by a court.	Panel in place, as above, to get the best possible advice. Case by case decisions regarding what to argue in court cases, so as to clarify the position.	In place – Peter Thompson	
Decisions and actions of the HFEA and its committees may be contested. New guide to licensing and inspection rating on CaFC may mean that more clinics make representations against licensing decisions.	Panel in place, as above.	In place – Peter Thompson	
	Maintaining, keeping up to date and publishing licensing SOPs, committee decision trees etc. consistent decision making at licence committees supported by effective tools for committees Standard licensing pack completely refreshed and distributed to members/advisers (April 2015).	In place – Ian Brown	

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

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner
Data D 1: Data loss or breach	There is a risk that HFEA data is lost, becomes inaccessible, is inadvertently released or is inappropriately accessed.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level: Likelihood: 4 / Impact: 5 / Inherent risk: 20 Very high Residual risk level: Likelihood: **2** / Impact: **5** / Residual risk: **10 Medium** Tolerance threshold: 10 Medium	⇔ ⇔ ⇔ ⇔	Nick Jones

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Confidentiality breach of Register data.	Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality. Secure working arrangements for Register team, including when working at home.	In place – Dave Moysen	At tolerance.
Loss of Register or other data.	As above.	In place – Dave Moysen	
	Robust information security arrangements, in line with the Information Governance Toolkit, including a security policy for staff, secure and confidential storage of and limited access to Register information, and stringent data encryption standards.	In place – Dave Moysen	
Cyber-attack and similar external risks.	Secure system in place as above, with regular penetration testing.	In place – Dave Moysen	
Infrastructure turns out to be insecure, or we lose connection and cannot access our data.	IT strategy agreed, including a thorough investigation of the Cloud option, security, and reliability.	In place – Dave Moysen	
	Deliberate internal damage to infrastructure, or data, is controlled through off-site back-ups and the fact that any malicious tampering would be a criminal act.	In place (March 2015) – Nick Jones	

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

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner
Data D 2: Incorrect data released	There is a risk that incorrect data is released in response to a Parliamentary question (PQ), or a Freedom of Information (FOI) or data protection request.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level: Likelihood: 5 / Impact: 4 / Inherent risk: 20 Very high Residual risk level: Likelihood: **3** / Impact: **3** / Residual risk: **9 Medium** Tolerance threshold: 8 Medium	⇔ ⇧ ⇔ ⇩	Juliet Tizzard

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Poor record keeping	Refresher training and reminders about good records management practice.	In place – SMT	Above tolerance. Although we have some good controls in place for dealing with PQs and other externally generated requests, it should be noted that we cannot control incoming volumes. After a period of reduced volumes at the end of 2015, January and February 2016 saw an increase. This seems to be levelling off again as of May 2016, so in the light of this the residual risk level has been reduced somewhat.
	TRIM review and retention policy implementation work – subsumed by IT strategy.	To sync in with IT strategy – Dave Moysen/Ian Brown	
	Audit of Epicentre to reveal any data errors. All queries being routed through Licensing, who have a definitive list of all licensing details.	Completed October 2015 – Ian Brown Implementation of actions following Epicentre audit planned and to be completed in Q2 2016/17 – Ian Brown	
Excessive demand on systems and over-reliance on a few key expert individuals – request overload – leading to errors	PQs, FOIs and OTRs have dedicated expert staff/teams to deal with them. If more time is needed for a complex PQ, it is occasionally necessary to take the issue out of the very tightly timed PQ process and replace this with a more detailed and considered letter back to the enquirer so as to provide the necessary level of detail and accuracy in the answer. We also refer back to previous answers so as to give a check, and to ensure consistent presentation of similar data. FOI requests are refused when there are grounds for this.	In place – Juliet Tizzard / Nick Jones	

	PQ SOP revised and log created, to be maintained by Committee and Information Officer/Scientific Policy Manager.	In place - Ian Brown
Answers in Hansard may not always reflect advice from HFEA.	The PQ team attempts to catch any changes to drafted wording that may unwittingly have changed the meaning. HFEA's suggested answer and DH's final submission both to be captured in new PQ log.	In place – Ian Brown / Peter Thompson
Insufficient understanding of underlying system abilities and limitations, and/or of the topic or question, leading to data being misinterpreted or wrong data being elicited.	As above – expert staff with the appropriate knowledge and understanding in place.	In place – Juliet Tizzard / Nick Jones
Servicing data requests for researchers - poor quality of consents obtained by clinics for disclosure of data to researchers.	There is a recognised risk of centres reporting research consents inaccurately. Work is ongoing to address consent reporting issues	Inspections now routinely sample check a clinic's performance comparing original consent form with the detail held on the Register, to ensure it has been transcribed effectively. Where the error rate is above tolerance the clinic must undertake a full audit and carry out corrections to the Register as necessary – Nick Jones

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Donor conception DC 1: OTR inaccuracy	There is a risk that an OTR applicant is given incorrect data.	Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Nick Jones
			Likelihood	Impact	Inherent risk		
			3	5	15 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			1	**4**	**4 Low**		
			Tolerance threshold:		4 Low		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Data accuracy in Register submissions.	Continuous work with clinics on data quality, including current verification processes, steps in the OTR process, regular audit alongside inspections, and continued emphasis on the importance of life-long support for donors, donor-conceived people and parents.	In place – Nick Jones	At tolerance (which is very low for this risk).
	Audit programme to check information provision and accuracy.	In place – Nick Jones	
	IfQ work will identify data accuracy requirements for different fields as part of the migration process, and will establish more efficient processes.	In place – Nick Jones	
	If subsequent work or data submissions reveal an unpreventable earlier inaccuracy (or an error), we explain this transparently to the recipient of the information, so it is clear to them what the position is and why this differs from the earlier provided data.	In place – Nick Jones	
Issuing of wrong person's data.	OTR process has an SOP that includes specific steps to check the information given and that it relates to the right person.	In place – Nick Jones	
Process error or human error.	As above.	In place – Nick Jones	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Donor conception DC 2: Support for OTR applicants	There is a risk that inadequate support is provided for donor-conceived people or donors at the point of making an OTR request.	Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Nick Jones
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	**3**	**9 Medium**		
			Tolerance threshold:		9 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Lack of counselling availability for applicants.	Counselling service established with external contractor in place.	In place (June 2015) – Nick Jones	At tolerance. The pilot counselling service has been in place since 1 June 2015, and we will make further assessments based on uptake and the delivery experience. Reporting to the Authority will occur annually during the pilot period, and the first such report will be provided to the July Authority meeting.
Insufficient Register team resource to deal properly with OTR enquiries and associated conversations.	Additional member of staff dedicated to handling such enquiries. However, there is currently also one member of staff on long term sick leave, and this together with work pressures from IfQ delivery means there is still some pressure on team capacity (being discussed by managers).	In place, with current team capacity issue under discussion – Nick Jones	
Risk of inadequate handling of a request.	Trained staff, SOPs and quality assurance in place.	In place – Nick Jones	
	SOPs reviewed by Register staff, CMG and PAC-UK, as part of the pilot set-up. Contract in place with PAC-UK for pilot delivery.	Done (May 2015) – ongoing management of the pilot by Rosetta Wotton.	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Financial viability FV 1: Income and expenditure	There is a risk that the HFEA could significantly overspend (where significantly = 5% of budget, £250k)	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇔ ⇩ ⇔ ⇔	Sue Gallone
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	**3**	**9 Medium**		
			Tolerance threshold:		9 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Fee regime makes us dependent on sector activity levels.	Activity levels are tracked and change is discussed at CMG, who would consider what work to deprioritise and reduce expenditure.	Monthly (on-going) – Sue Gallone	At tolerance. 2015/16 achieved a small under-spend but risk of additional legal costs remains. The increase of per-cycle fees by £5 (to £80) and the end of the small 'eSET discount' for elective single embryo transfer has now been implemented following Treasury approval in February 2016. This should help secure sufficient funds going forward. It is too early for us to tell whether this reduces this risk further. The situation will be clearer following IfQ implementation.
	Fees Group created enabling dialogue with sector about fee levels. Fee increase was agreed and approved by Treasury. This was implemented and the eSET discount ended (April 2016).	In place. Fees Group meeting in October, ongoing – Sue Gallone	
GIA funding could be reduced due to changes in Government/policy	A good relationship with DH Sponsors, who are well informed about our work and our funding model.	Quarterly meetings (on-going) – Sue Gallone	
	Annual budget agreed with DH Finance team alongside draft business plan submission.	December annually – Sue Gallone	
	Detailed budgets for 2016/17 have been agreed with Directors. DH has previously agreed our resource envelope.	In place – Sue Gallone	
Budget setting process is poor due to lack of information from directorates	Quarterly meetings with directorates flags any shortfall or further funding requirements.	Quarterly meetings (on-going) – Morounke Akingbola	
Unforeseen increase in costs eg, legal, IfQ or extra in-year work required	Use of reserves, up to contingency level available. DH kept abreast of current situation and are a final source of additional funding if required. IfQ Programme Board regularly reviews the budget and costs.	Monthly – Sue Gallone Monthly – IfQ Programme Board	

Upwards scope creep during projects, or emerging during early development of projects eg, IfQ.	Periodic review of actual and budgeted spend by IfQ project board and monthly budget meetings with finance.	Ongoing – Wilhelmina Crown	
	Cash flow forecast updated.	Monthly (on-going) – Morounke Akingbola	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Capability C 1: Knowledge and capability	There is a risk that the HFEA experiences unforeseen knowledge and capability gaps, threatening delivery of the strategy.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Peter Thompson
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	**3**	**9 Medium**		
			Tolerance threshold:		6 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
High turnover, sick leave etc. leading to temporary knowledge loss and capability gaps.	People strategy will partially mitigate. Mixed approach of retention, staff development, and effective management of vacancies and recruitment processes.	Done – May 2015 – Rachel Hopkins	Above tolerance. This risk and the set of controls remains focused on capability, rather than capacity. There are obviously some linkages, since managing turnover and churn also means managing fluctuations in capability and ensuring knowledge and skills are successfully nurtured and/or handed over. Since the HFEA is a small organisation, with little intrinsic resilience, it seems prudent to have a low tolerance level for this risk. Both Head vacancies were filled (in March and May 2016 respectively), though there will be a period of bedding in.
	Staff have access to civil service learning (CSL); organisational standard is five working days per year of learning and development for each member of staff.	In place – Rachel Hopkins	
	Organisational knowledge captured via records management (TRIM), case manager software, project records, handovers and induction notes, and manager engagement.	In place – Rachel Hopkins	
The new UK government may implement further cuts across all ALBs, resulting in further staffing reductions. This would lead to the HFEA having to reduce its workload in some way.	The HFEA was proactive in reducing its headcount and other costs to minimal levels over a number of years. We have also been reviewed extensively (including the McCracken review). Turnover is variable, and so this risk will be retained on the risk register, and will continue to receive ongoing management attention.	In place – Peter Thompson	
Poor morale leading to decreased effectiveness and performance failures.	Engagement with the issue by managers. Ensuring managers have team meetings and one-to-one meetings to obtain feedback and identify actions to be taken.	In place – Peter Thompson	

	Staff survey and implementation of outcomes, following up at December 2015 all staff conference.	Survey and staff conference done – Rachel Hopkins Follow-up communications in place (Staff Bulletin etc.) – Peter Thompson
Differential impacts of IfQ-related change and other pressures for particular teams could lead to specific areas of knowledge loss and low performance.	Staff kept informed of likely developments and next steps, and when applicable of personal role impacts and choices.	In place – Nick Jones
	Policies and processes to treat staff fairly and consistently, particularly if people are 'at risk'.	In place – Peter Thompson
Additional avenues of work open up, or reactive diversions arise, and need to be accommodated alongside the major IfQ programme.	Careful planning and prioritisation of both business plan work and business flow through our Committees. Regular oversight by CMG – standing item on planning and resources.	In place – Paula Robinson
	Early emphasis given to team-level service delivery planning, with active involvement of team members. CMG will continue to review planning and delivery.	In place – Paula Robinson
	Planning for 2016/17 prioritises IfQ delivery, and therefore strategy delivery, within our limited resources.	In place as part of business planning (2015 onwards) – Paula Robinson
	IfQ has some of its own dedicated resources.	In place – Nick Jones
	There is a degree of flexibility within our resources, and increasing resilience is a key consideration whenever a post becomes vacant. Staff are encouraged to identify personal development opportunities with their manager, through the PDP process, making good use of CSL.	In place – Peter Thompson
Regarding the recent work on licensing mitochondrial replacement techniques, there is a possible future risk that we will need to increase both capability and capacity in this area, depending on uptake (this is not yet certain).	Future needs (capability and capacity) relating to mitochondrial replacement techniques and licensing applications are starting to be considered now, but will not be known for sure until later. No controls can yet be put in place, but the potential issue is on our radar.	Issue for consideration when applications commence – Juliet Tizzard

Scoring system

The HFEA uses the five-point rating system when assigning a rating to both the likelihood and impact of individual risks:

Likelihood: 1=Very unlikely 2=Unlikely 3=Possible 4=Likely 5=Almost certain
Impact: 1=Insignificant 2=Minor 3=Moderate 4=Major 5=Catastrophic

Risk scoring matrix

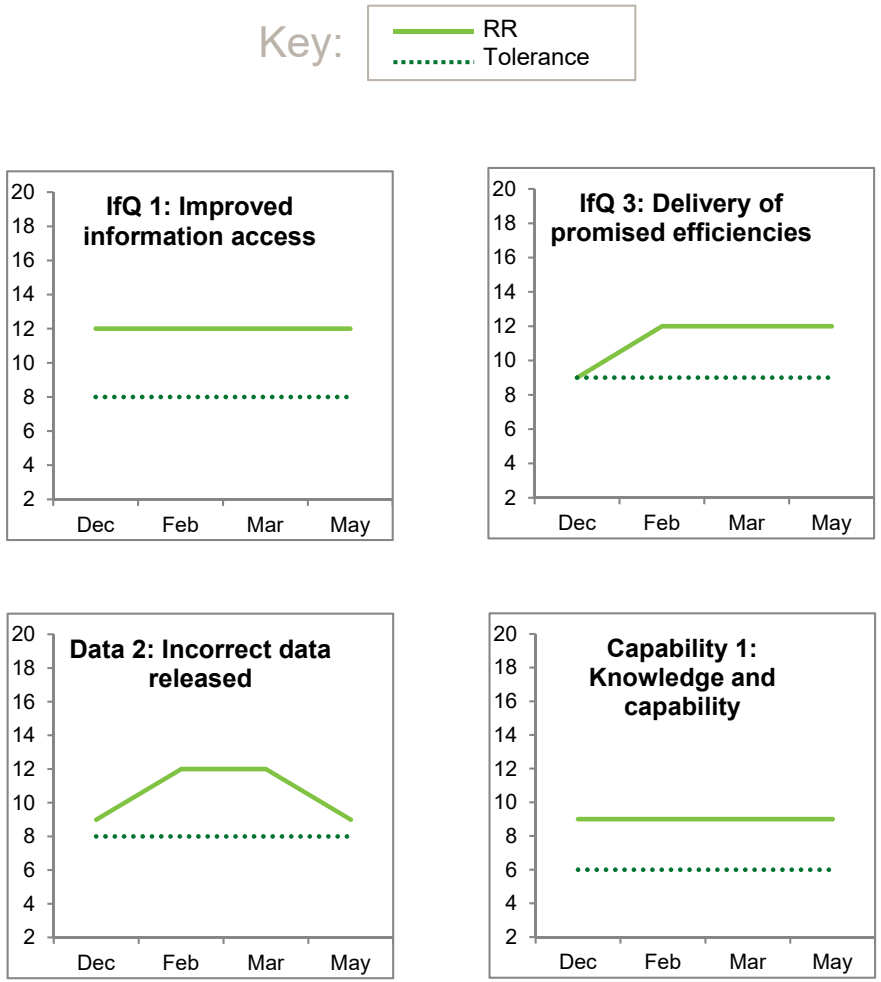
Impact	1. Rare (≤10%)	2. Unlikely (11%-33%)	3. Possible (34%-67%)	4. Likely (68%-89%)	5. Almost Certain (≥90%)
5. Very high	5 Medium	10 Medium	15 High	20 Very High	25 Very High
4. High	4 Low	8 Medium	12 High	16 High	20 Very High
3. Medium	3 Low	6 Medium	9 Medium	12 High	15 High
2. Low	2 Very Low	4 Low	6 Medium	8 Medium	10 Medium
1. Very Low	1 Very Low	2 Very Low	3 Low	4 Low	5 Medium

Risk Score = Impact x Likelihood

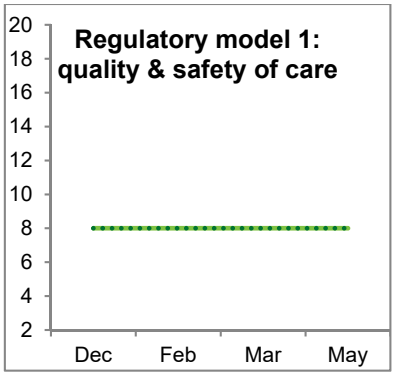
Likelihood

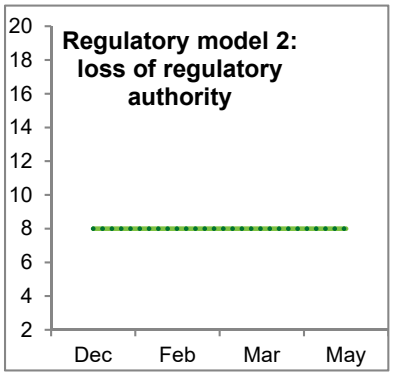
Tolerance vs Residual Risk:

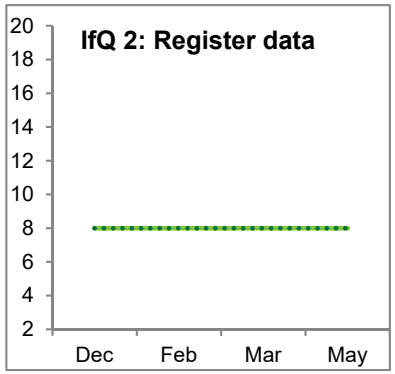
Risks above tolerance

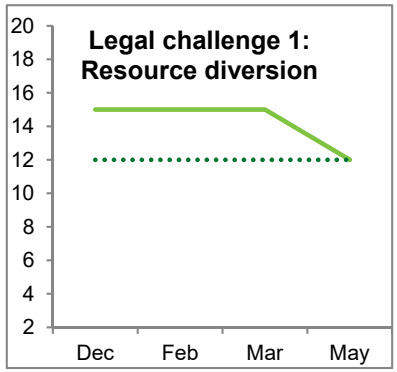


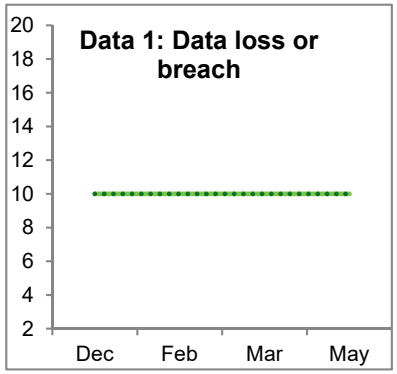
Risks at tolerance

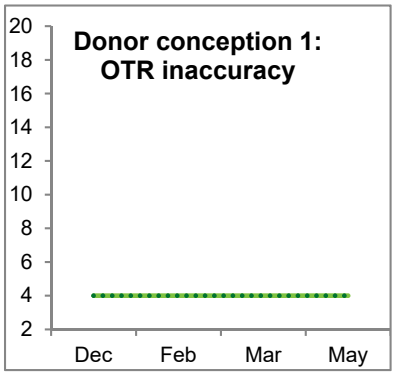


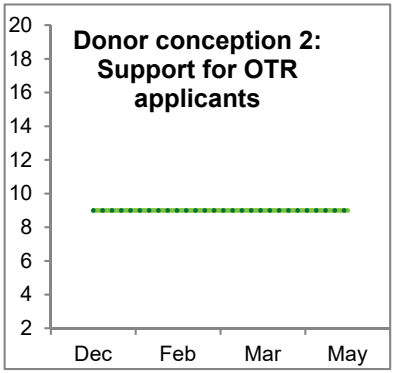


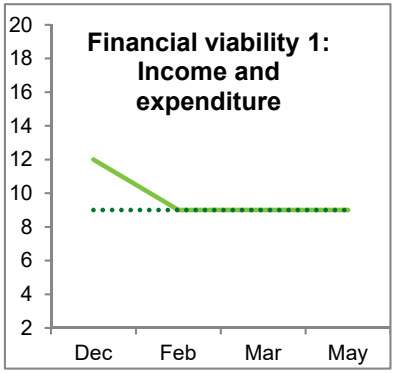












Risk below tolerance

Key: RR, Tolerance

None.

Annual Report and Accounts

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☑ Demonstrating efficiency economy and value
Details:			
Meeting	Audit & Governance Committee		
Agenda item	12		
Paper number	HFEA (15/06/2016) 502		
Meeting date	15 June 2016		
Author	Morounke Akingbola – Head of Finance		
Output:			
For information or decision?	For decision		
Recommendation	The Audit and Governance Committee is invited to recommend that the Chief Executive should sign the Annual Report and Accounts, including the Governance Statement (GS), taking into account the Information Assurance report and the Internal Audit Annual Assurance Statement. All reports that underpin the GS have been presented to the Committee throughout the year.		
Resource implications			
Implementation date	N/a		
Communication(s)			
Organisational risk	☐ Low	☐ Medium	☐ High
Annexes	Annex 1: Draft Annual Report and Accounts		

1. Purpose of this paper

1.1. This paper presents the final draft annual reports and accounts, subject to formatting corrections. Members have seen a previous draft of the Governance Statement. This draft incorporates National Audit Office's (NAO) comments received to 8 June 2016.

1.2. Members are invited to review and challenge where appropriate.

2. The Report

2.1. The attached report is made up of three major sections:

- Performance report comprising; overview and performance analysis
- Accountability report comprising; Corporate governance report (made up of Director's report, Statement of the Accounting Officer's responsibilities and Governance Statement), Remuneration and Staff Report and Parliamentary accountability and audit report (which includes The Certificate and Report of the Comptroller and Auditor General)
- Financial Statements

2.2. Key points to note are as follows:

- The sections of the report have been presented to take into account changes as required by HM Treasury Financial Reporting Manual 2015-16 (FReM). Information has been moved from its previous place in the old report format.
- The most significant change is the Accountability section which previously was the Director's Report. The purpose of this section is to meet key accountability requirements to Parliament. This section brings together information on the organisation of the HFEA, our governance structures and how they support the achievement of our objectives.
- Within the Governance Statement (GS) there is one new addition which relates to the disclosure of our Whistleblowing policy, procedures and arrangements.
- The Remuneration and Staff Report now includes figures to support our staff costs and staff numbers.
- The Parliamentary accountability and audit report now includes three pieces of information that were previously reported within the financial statements. These are:
  - Fees and charges
  - Losses and special payments
  - Remote contingent liabilities.

2.3. Financial Statements

At the meeting, the Finance and Accounting Manager, Wilhelmina Crown, will explain the statements in more detail.

3. Timing and next steps

3.1. The NAO audit was quite late this year and finished w/c 6 June, but review is still ongoing. We have incorporated NAO's notified findings into this version, for AGC review. NAO's report is expected around 10 June and will be sent to AGC as soon as it is available. Any further comments from NAO will be raised at the meeting.

3.2. Following the audit completion report and after AGC, the final annual report and accounts will be sent to the Authority, to ensure they are content, and the Chief Executive will then sign. The signed annual report and accounts will be provided to NAO for certifying and laying at the end of June.

Human Fertilisation and Embryology Authority (HFEA)

Annual report and accounts 2015/16

Presented to Parliament pursuant to sections 6 and 7 of the Human Fertilisation and Embryology Act 1990 as amended by paragraph 3 of schedule 7 of the Human Fertilisation and Embryology Act 2008.

Ordered by the House of Commons to be printed on xx xxx 2016.

HC

This publication is available at www.gov.uk/government/publications

Any enquiries regarding this publication should be sent to us at:

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Contents

1

Performance

Overview

The Human Fertilisation and Embryology Authority (HFEA) is the regulator of fertility treatment and human embryo research in the UK. Our role includes licensing and setting standards for clinics and research centres and providing a range of information for the public, particularly people seeking treatment, donor-conceived people and donors.

The HFEA has had another highly successful year. We continue to regulate around 140 fertility clinics and embryo research centres and have just under 70 members of staff. Our expenditure is around £5m, around 80% of which is funded by fees from those we regulate. We seek continuously to improve and streamline our processes, reducing the regulatory burden and maintaining efficiency. We manage our finances to ensure fees are set to bring in the income we need to spend on regulating. We keep abreast of scientific developments and adopt a proportionate approach to regulation.

We have a strong reputation, both in the UK and internationally, for robust yet proportionate regulation, allowing us to take bold decisions with substantial public support. Our decision making processes are more robust than ever and have stood the test of forensic examination in the courts.

Following the successful passage of the mitochondrial donation regulations through Parliament, we put in place a licensing scheme which has been ready to receive applications since the October 2015 deadline. That work involved considerable engagement with stakeholders and the resulting scheme has been very well received.

This year also saw another significant bio-science innovation with our decision to grant a research licence to use the genome editing technique, CRISPr Cas9, on human embryos. This is the first time that these techniques have been used outside of China, and the first time anywhere in the world within a regulatory framework. The decision attracted international media coverage and was seen as further evidence of the ability of the HFEA's regulatory regime to balance innovation and public confidence.

We made significant progress on Information for Quality (IfQ), our programme to transform our information systems and our communications channels with patients and clinics. The new services flowing from IfQ will be launched during 2016/17.

Due to errors in consent forms completed at clinics, the legal parenthood of some children conceived with donor gametes has been uncertain. We have set out requirements to clinics, monitored the situation and made our expectations clear as to the actions clinics should take in these cases. Some cases have gone to court, where the President of the Family Court has granted parenthood. He has also been highly critical of the clinics involved, and in early cases of the HFEA and the regulatory scheme in general. Legal parenthood is a key priority for us and we now examine these consents at every inspection. To date we have seen no new errors, which suggests that clinics have improved their practice.

During 2015-16 we underwent a Triennial review, which considered both our functions and our form. The report will be published later in 2016 and will make a number of recommendations of performance improvements we could make.

During the year, we also:

- completed a full inspection programme, approved over 50 new conditions for embryo testing and processed over 500 reported incidents
- continued to reduce the incidence of multiple births, the biggest single avoidable health risk to mothers and babies in in vitro fertilisation (IVF) – from 24% in 2008 to around 15% in 2013, without impacting upon success rates
- processed all requests for sensitive personal information from our Register on time and in a way which is compatible with data protection rules and introduced a three-year pilot counselling service from June 2015
- responded to 68 Parliamentary Questions and 99 Freedom of Information requests.

How we work

As set out in our strategy, we:

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

Our legislation and functions

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

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

The 2008 Act extensively amends the provisions of the 1990 Act, which continues to form the main framework governing our duties and responsibilities. However, the

2008 Act also contained new provisions which were not included in the 1990 Act. In particular, these include provisions relating to legal parenthood.

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

- license and inspect clinics carrying out fertility treatment and storage
- license and inspect establishments undertaking human embryo research
- ensure, where a licensed clinic makes use of an external service which does not hold an HFEA licence, that there is a third party agreement in place which is in accordance with any licence conditions imposed by us
- produce and maintain a Code of Practice, providing guidance to clinics and research establishments about the proper conduct of licensed activities
- keep a formal register of information about donors, treatments and children born as a result of those treatments
- maintain a formal register of licences granted
- maintain a register of certain serious adverse events or reactions (as set out in the 1990 Act (as amended))
- investigate serious adverse events and serious adverse reactions and take appropriate control measures
- respond to any request from a competent authority in another European Economic Area (EEA) state to carry out an inspection relating to a serious adverse event or reaction and to take any appropriate control measures
- collaborate with the competent authorities of other EEA states.

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

- promoting compliance with the requirements of the 1990 Act (as amended), the 2008 Act and the Code of Practice
- maintaining a statement of the general principles that we should follow when conducting our functions and by others when carrying out licensed activities
- observing the principles of best regulatory practice, including transparency, accountability, consistency, and targeting regulatory action where it is needed
- carrying out our functions effectively, efficiently and economically
- publicising our role and providing relevant advice and information to donor-conceived people, donors, clinics, research establishments and patients
- reviewing information about:
    - human embryos and developments in research involving human embryos
    - the provision of treatment services and activities governed by the 1990 Act (as amended)
- advising the Secretary of State for Health on developments in the above fields, upon request.

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

Activities

Our objectives for 2015/16 were as follows.

Setting standards

Objective 1: Improving the quality and safety of care through our regulatory activities.

Achievements

Delivering the full compliance cycle to maintain standards for patients

As usual, we undertook our full range of inspection, audit and licensing activities. This ensured that clinics were appropriately inspected and monitored against published performance indicators, and issued with licences for up to four years. We also continued our programme of unannounced inspections. Our compliance activities provide assurance on standards and safety for the public and our other stakeholders.

Identifying and implementing ways of improving the quality and safety of care

We increased our focus on quality and safety of care in our inspection activities – in particular through checking at inspection that properly informed consent, good infection control, medicines management and the use of approved medical equipment were all in place. We also maintained our focus on reducing multiple births rates, using our data to help clinics to identify poor performance and encouraging them to take corrective action.

We also continued to evaluate areas of regulatory concern and identify performance levers. Alongside this we increased our focus on learning from incidents, adverse events and complaints from patients, in dialogue with the sector. This included focused work with individual clinics who reported such events, to assist them in improving. We published our annual report on clinical incidents in 2014.

Making the patient experience integral to the way in which we assess clinics' performance

We increased the amount of patient feedback we obtain before and during inspections, and continued our work through the IfQ programme to increase this still further through our new website, in 2016. Patient experiences are now set out more explicitly in the inspection reports that are submitted to licensing committees, so that such experience informs licensing decisions.

Seeking patients' views, and understanding their perspective, as part of the way we work

Our user research to underpin the IfQ programme enabled us to identify the quality factors that are the most relevant for patients. These findings are being implemented through the IfQ programme (eg, through the revised presentation of Choose a

Fertility Clinic (CaFC)). We will subsequently evaluate the impact of this work and see if the approach needs to be refined.

Identifying the best ways to optimise success rates and developing a common improvement agenda

We have continued to use every opportunity within our role as regulator to maximise the chances of success for patients. We address with clinics any performance alerts in relation to their success rates. We also review emerging procedures and publish any evidence available, working with regulatory partners to ensure there are no inappropriate barriers to the introduction of innovative (safe) new techniques. We have been working towards an improved presentation of our data about success rates on CaFC, through the IfQ programme. We hope this work will collectively lead to improved success rates, over time. We also want to equip patients with a better and more realistic idea of their own chances of success.

In late 2015, we also updated the multiple births information for patients and professionals, to help minimise and reduce the occurrence of multiple births. This information also helps patients to make informed choices about their treatment options and the associated risks and benefits.

Publishing more HFEA data to drive improvements in clinic performance

As a result of the IfQ programme, we will shortly be publishing a wider range of performance data on our website. Work on the programme has taken place throughout 2015/16, with a successful alpha stage between July and November 2015, and the beta stage (where products start to be built) commencing in December 2015 following required Government Digital Service approvals.

Publishing more data is an intrinsic aim of the IfQ programme, so as to increase transparency and empower and inform patients. This work will also increase visibility for clinics of sector-wide data, so that they can assess their own performance against it. Our aim is to encourage best value and the best possible treatment outcomes for patients.

Reviewing and advising on issues relating to mitochondrial donation

This year we implemented a range of agreed statutory changes (further to Parliamentary decisions) to enable clinics to make applications to carry out mitochondrial donation in treatment, for the avoidance of serious mitochondrial disease.

The statutory changes introduced by Parliament were implemented clearly and robustly, with clear information for patients and clinics.

We now await the results of some externally-run safety and efficacy tests, before the first applications can be submitted to us. There will be a further scientific review once the tests have been completed and published.

Maintaining our role as the UK's competent authority for ART in the European Union

We attend twice yearly competent authority events, and implement associated EU decisions as relevant. By participating, the HFEA gains up-to-date intelligence about European matters, and shapes European decisions so that they better reflect UK

practices and perspectives. This year we have begun work on three projects to implement recent EU decisions on the import/export of gametes and on EU coding requirements. This work will continue until April 2017 (the implementation date for the EU Directives).

Objective 2: Improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.

Achievements

Providing information about donor conception directly to patients and donors

Throughout the year, we continued to publish information to ensure that potential donors, recipients and donor conceived people have better access to clear, authoritative impartial information about a range of issues, including a range of leaflets for those accessing identifiable information about their donor.

Ensuring that clinics prepare patients adequately for donation and fully understand their role and importance as a lifelong information provider; and that egg and sperm donors are well supported and understand the lifelong commitment that follows from donation

By continuing to promote the Lifecycle information leaflets and the pack about donor information produced in 2014/15 for clinics, we have achieved improved clarity of role and performance for clinics in relation to donation and associated information guardianship. We have also improved the overall experience for donors, donor-conceived people seeking information and patients and their families.

Collecting and publishing information regarding donor egg and sperm availability in the UK and addressing impacts for patients (for example, by providing more information about the implications of treatment abroad)

Following consultation as part of the IfQ programme in 2014/15, we further explored with stakeholders and professional organisations how best to collect and use UK data on the availability of donated eggs and sperm. We will continue to progress this work as we conclude the redevelopment of our website in 2016/17.

Improving the provision of counselling support for donor-conceived people wishing to access information held on the HFEA Register

This year we began a three-year pilot providing support services for applicants to the Register. Counselling support is now offered for all Opening the Register (OTR) applicants (those seeking non-identifying information) and for donor-conceived applicants receiving donor identifying information. Mediation services are also in place for when donors and donor-conceived people meet. Basic mediation training and systems are in place for dealing with identity release to donors and donor-conceived people. Our aim is to ensure that OTR applicants feel more supported and are prepared to deal with the information they receive from us.

As before, we also continued to facilitate timely access to information from the Register for those who are entitled to it. Opening the Register requests continued to

be met in a sensitive manner and within required time limits (20 working days, excluding time for counselling), throughout the year.

Increasing and informing choice

Objective 3: Using the data in the HFEA Register of Treatments to improve outcomes and research.

Achievements

Publishing and supplying the information we hold, for the benefit of stakeholders

We continued to regularly update CaFC information, so as to assist patient choice. This involves a six monthly verification and publication schedule, to maintain the provision of up-to-date and accurate information.

Through the IfQ programme, we are working on improving the presentation of clinic comparison information on CaFC. This work has been based on extensive user research, and the beta phase of work (the building phase) commenced in December 2015. The aim is for the published outcome data to be more useful and easier to understand and to set up positive incentives for improvements, as well as increased consumer choice and clinic comparability.

We continued to deepen our relationships with relevant other bodies, such as the Government Digital Service (GDS) the Health and Social Care information Centre (HSCIC) and being an active member of the National Information Board (NIB). This helps us to contribute to the objectives of the wider health system, with respect to information management, and to learn from best practice in data management, systems integrity and security.

We continued our information provision for researchers requesting access to Register data, providing the requested information within 90 calendar days of approval. Our aim is to ensure that Register information is used to best effect, promoting understanding and facilitating good research, ultimately for patient benefit.

Maintaining the Register of Treatments and Outcomes and supporting clinics in reporting the data

Register data and forms continued to be processed and quality assured throughout the year, through liaison with clinics on errors and omissions and through validation and verification of Register entries. This ongoing process ensures that high quality data is available to develop patient information and to support risk-based regulation and evidence-based policy-making.

Publishing reports on the information we hold for the benefit of stakeholders

We continued to publish statistical and other reports during the year. These included:

- The 'Fertility treatment in 2014' report covering 2013–2014. This report provides patients, clinic staff and others with up-to-date information about a range of topics, and carries 'official statistics' status.

- Statistical report on multiple births. This provides up-to-date information on progress in reducing the incidence of multiple births following ART.
- Report on incidents and alerts. This report contributes to a culture of openness and information sharing where clinic staff are empowered to report mistakes and learn from each other. It also promotes transparency and maximises opportunities for learning from incidents to improve quality of care for patients.

In addition, we continued throughout the year to manage the ongoing work of the register research panel, which considers applications from researchers to use our register data for linkage studies, which result in publications about health outcomes and success rates.

Objective 4: Ensuring patients have access to high quality meaningful information.

Achievements

Improved HFEA information about treatments available, scientific research, embryo and stem cell research and other fertility subjects

Through the IfQ programme, we commenced the redevelopment of the content of our website to provide an expanded range of educative and scientific information about current treatments and fertility issues. This will lead to increased information for patients and others. The new website will ensure that our information is accessible, engaging and meaningful, so that patients are better informed and better placed to deal with treatment issues and decisions. Our aim is to ensure that patients feel safe and know they can expect certain standards in clinics, and that prospective patients have clearer information and signposting, and are more aware of the potential risks of new and different treatments as well as the possible benefits.

Enhancing the patient voice in all of our work, including information provision

Following a consultation to inform the IfQ programme in 2014/15, we established patients' views and information needs which are fundamental to the redesign of our website. Over time, we will be able to make better use, via the new website, of feedback mechanisms, video and integration with social media platforms.

The new website will enable increased feedback opportunities for patients, and easier interaction with us.

Working with clinics and scientific experts to publish information about new treatments

In redesigning the website, we have also begun to establish improved mechanisms for producing and publishing accessible information when new treatment options emerge, working in collaboration with clinics and experts where necessary (including the professional bodies we work with regularly, and whose input is essential to this process). This will enable us to increase public understanding of emerging new science and future treatment possibilities. It will also ensure patients are better

informed and better placed to deal with treatment issues and decisions when such treatments begin to be offered by clinics, and that they are better placed to judge the merits of any media speculation about new treatments.

Our ongoing annual scientific horizon scanning work also feeds into this, ensuring that early consideration is given to emerging scientific issues and developments.

Enhancing Choose a Fertility Clinic (CaFC) by including user experience scores

We have developed a method for incorporating patient ratings on the newly-redesigned CaFC tool. This will enable patients to take into account other patients' experiences to help them decide on a clinic.

Ensuring that clinics prepare and support patients and donors through the information they give them

We continued throughout the year to encourage clinics to provide accurate and sufficient information in their websites, publications and other materials given to patients. We do this so that patients and donors can have confidence in the information clinics give them and are in a better position to compare and choose between clinics.

Through asking patients directly (eg, on inspection) and conducting desk-based research, we provided factual feedback to clinics and encouraged best practice, making recommendations for improvements whenever problems were found.

Efficiency, economy and value

Objective 5: Ensuring the HFEA remains demonstrably good value for the public, the sector and Government

Achievements

Ensuring the HFEA is easy to deal with and offers a professional and cost-effective service in all that it does

We achieved this through various means in 2015/16. We continued to use our strategy to help us to prioritise our activities and manage our limited resources to best effect.

We continued our engagement arrangements with clinics on fees charged, established in 2014/15. This gives accountability and transparency in respect of the fees we charge clinics. Towards the end of the year, the Authority agreed the first change in fees for several years, which, following Department of Health and Treasury approval, will come into effect in April 2016, and will enable us to balance our budget.

We continued to maintain efficient and effective decision-making through our committees, ensuring governance tools underpinning licensing and other decisions were in place and effective.

The HFEA continued to receive a large number of requests for access to information, under various regimes, and we ensured legal and Parliamentary requirements were met.

We maintained our existing relationships and service level agreements (SLAs) with other Arm's Length Bodies (ALBs), in the interests of efficiencies. These include sharing finance resources with the Human Tissue Authority (HTA), and SLAs for certain HR and facilities services.

These arrangements ensure our infrastructure is effective and supports the delivery of our strategic vision. Our central systems, processes and tools continued to be efficiently run, giving good value and service. At the start of the 2016/17 business year, the HFEA moved to new office premises, alongside another ALB. This move enables best use to the made of Crown Estate property, and is in keeping with the wider interests of government property strategy. Plans for the move began in November 2015 and continued until the move took place in April 2016.

Modifying our ways of working to ensure the organisation is responsive, agile, innovative and effective in achieving its strategic and statutory goals

We continued our focus on building our staff capacity and skills and maintaining a high quality workforce, in keeping with our people strategy, which supports the delivery of the overall HFEA strategy for 2014 to 2017.

We continued to ensure that our internal compliance processes and systems were up to date and effective, so that regulatory efficiency and quality was maintained and improved. We also maintained an overview of emerging scientific, clinical and legal developments, to ensure that evidence-based decision-making continued to be supported.

The HFEA also participates in the 'One Stop Shop' for life sciences, which was launched in 2014. This initiative brings together expertise from the HFEA, the HTA, the Health Research Authority (HRA) and the Medicines and Healthcare Products Regulatory Authority (MHRA) to provide regulatory advice to those working in the life sciences industry.

Improving the methods used to submit and verify register data

We began the process of modernising our Register function and processes, through the IfQ programme. The work to date has been extensive, and continues into the next business year. We have developed a new data dictionary, which will be incorporated into the new Register structure and will then need to be maintained. We have begun to redevelop our data submissions processes and the clinic portal (used by clinics to view, and to provide us with, key information and licensing applications).

We have also started our review of the verification processes for clinic outcomes appearing on CaFC.

Our ultimate aim is to reduce transactional costs for clinics and increase user satisfaction, through achieving 'right first time' data quality, and reducing unnecessary effort by clinics in submitting the required data.

Risks as at 31 March 2016

Below are the main risks we face that, should they occur, would have the greatest material effect on the functioning of the HFEA as a whole.

By considering such risks, we can assess the continuing viability of our strategy and business plan against changes in circumstance, and make adjustments when necessary. This does not mean we expect the risks to materialise – instead it indicates that these are areas of risk of which we need to be aware and to consider our response to in order to perform our role effectively.

Further information on our approach to managing strategic risks can be found in the Governance Statement.

Risk area	Main strategic risks monitored	Related strategic theme
Regulatory model	Quality and safety of care	Setting standards: quality and safety
	Loss of regulatory authority	
IfQ programme	Improved information access	Increasing and informing choice: information
	Register data	Increasing and informing choice: Register data
	Delivery of promised efficiencies	Efficiency, economy and value
Data	Data loss or breach	Efficiency, economy and value
	Incorrect data released	
Donor conception	Inaccuracy in response to an 'Opening the Register' (OTR) request	Setting standards: donor conception
	Support for OTR applicants	
Financial viability	Income and expenditure	Efficiency, economy and value
Capability	Knowledge and capability	Efficiency, economy and value
Legal challenge	Resource diversion	Efficiency, economy and value
Office move (April 2016)	Business continuity during and after an office move	Efficiency, economy and value

Going concern

We consider the use of the going concern basis of accounting is appropriate because there are no material uncertainties related to events or conditions that may cast significant doubt about the ability of the organisation to continue as a going concern.

Performance analysis

Measuring performance

Each year, we agree a business plan with our sponsor department, the Department of Health (DH) that includes strategic aims, high level objectives and key performance indicators covering delivery of our strategic plan.

We record achievement of key performance indicators monthly and review achievement and action needed at the Corporate Management Group (CMG) meeting. A report is made to the Authority every two months and DH every quarter.

Analysis of performance over the year

Performance indicators 2015/16

Performance indicators	Target 2015/16	Performance 2015/16
A. Compliance		
Average number of working days taken for the whole licensing process, from the day of inspection to the decision being communicated to the centre	**70 working days or less**	69 working days
Percentage of PGD applications processed within three months (66 working days)	**100%**	100%
B. Communication and information		
Opening the Register requests responded to within 20 working days	**100%**	100% (23 requests)
Requests for contributions to Parliamentary questions (PQs) answered within Department of Health deadlines	**100%**	100% (68/68 PQs within deadline)
C. Corporate		
Staff sickness absence rate (%)	Under 3.0%	2.1%
Cash and bank balance	To continue to move further towards the Department of Health's agreed minimum cash reserve of £1.52m	£2.16m (compared to 2014/15 £2.02m)
Percentage of invoices paid within 10 calendar days	70%	98%
Debts collected within 60 calendar days	85%	90%

Financial review

We are funded from two main sources:

- licence and treatment fees from the establishments we licence (79%), and
- Grant-in-aid from the DH (21%).

72% of our expenditure is on staff costs. Our other administrative costs include spend on our IfQ programme (9% of total spend), legal costs (4%) and facilities expenses (5%).

Summary position as at 31 March 2016

	2015/16	2014/15
	£'000s	**£'000s**
Expenditure		
Staff costs	3,692	3,900
General administrative costs	1,453	1,816
Total expenditure	**5,145**	**5,716**
Income		
Licence fees	4,215	4,035
Other income	1	53
Total income	**4,216**	**4,088**
Net (expenditure)/income before interest and tax	**(929)**	**(1,628)**

Our financial results are included in the accounts on pages 46 to 63 and show that the deficit after interest and tax was £885,482 (2014/15 a deficit of £1,623,176).

The DH provided Grant-in-aid towards the financing of resource expenditure of £1,120,000 (2014/15: £920,000) and £100,000 towards the purchase of fixed assets (2014/15: £Nil). Taking into account the resource financing, and after interest and tax, we had a surplus of £234,518. This arose due to staff vacancies and less legal expenditure than expected. There was also more fee income than forecast in the final months of the year.

The surplus, most of which is funded from fee income, is added to our accumulated reserves. The IfQ programme, which is funded from accumulated reserves, cost £440,568 (2014/15 £564,500) and has been transferred to our balance sheet for capitalisation in 2016/17. There will be further spend on IfQ in 2016/17 from reserves.

Supplier payments

We aim to pay all undisputed invoices in accordance with suppliers' terms of payment, which are usually within 30 days. During the financial year 2015/16, we settled 100% of all invoices received within 30 days (£1,814,066 in value), whilst 98% of invoices received were paid within 10 days.

We bill clinics promptly and at the end of the year 90% of debts had been collected within 60 days.

Recruitment

We have, like other public bodies, been subject to a recruitment freeze over the past five years. Within that freeze we have the ability, under delegated responsibility, to re-appoint to posts designated 'front-line' and/or business critical. All appointments are made in accordance with our recruitment and selection policy (revised April 2014). The aim is to ensure that all appointments of staff are made on the basis of merit and in accordance with equal opportunities.

Learning and development

We actively promote the development of our staff and encourage all staff to take up their entitlement to five days a year learning. We subscribe to Civil Service Learning, a service which provides courses and resources for developing skills common to all UK civil servants. This supports a blended approach to learning which is also convenient and cost-effective. Individual needs are set out in personal development plans and are met through appropriate means, including e-learning, face-to-face learning and taking part in projects, coaching and job shadowing.

Staff engagement and wellbeing

We promote staff engagement through various channels including all staff and team meetings, the Staff Forum, our annual staff conference and ad hoc working groups. Staff surveys ensure a more formal feedback mechanism to obtain and respond to staff feedback. All staff have access to an employee assistance provider for confidential advice and support if necessary.

Disabled employees

In 2007-08 we achieved ✓✓ 'positive about disabled people' disability symbol status. We have a specific policy of inviting to interview any candidate with a disability who meets essential criteria. Support is provided for all staff who have, or develop, a disability including making any reasonable adjustments to the workplace or work processes and having advice available through the occupational health service.

Equality Act 2010 – equality and diversity on pay

We remain compliant with the requirements of the Equality Act 2010 and there is an equality champion on the Authority (our board of directors and appointed members). We continue collectively to ensure, throughout the year, that we fulfil our obligations under the Equality Act.

All posts are systematically evaluated, against a formal job evaluation scheme 'Paypoints II', aiming to ensure that salaries are internally consistent, fair and equitable.

Our gender breakdown at 31 March 2016, of Authority members, permanent and seconded staff, is as follows:

	Male	Female	Total
Authority members	5	7	12
Senior Management Team (SMT)	2	2	4

All staff (including SMT, excluding Authority)	23	42	65

Social, community, sustainability, human rights and environmental issues

During 2015/16 we were sub-tenants of the Care Quality Commission (CQC), in Finsbury Tower.

We colloborated with the CQC on a number of issues, including health and safety services - we have adopted the CQC's online system for individual workplace assessment and follow the CQC lead on fire evacuation procedures and fire warden liaison.

We recycle paper, card, glass, plastic cups, containers and bottles, metal cans and toner cartridges. There are two multi-function devices (for secure printing, scanning and photocopying) that are pre-set to print on both sides of the paper and in black and white. IT equipment is re-used and working lives extended where possible, and is switched off when not in use. Surplus equipment is either sold or donated. Many staff are enabled to work from home, reducing the impact on the environment.

We are aware of the green agenda in relation to procurement and we use the Crown Commercial Service and other frameworks which have sustainability factored in.

Mr Peter Thompson
Chief Executive
Accounting Officer

XX 2016

2
ACCOUNTABILITY

Corporate Governance Report

Directors report

Our board (the Authority)

Our board is made up of 12 members appointed through an open public process. Authority members during 2015/16 are set out below. Biographies for each can be found on our website.

Authority member	Appointment start date	Appointment end date
Sally Cheshire (Chair)	7 November 2006	31 March 2017
David Archard (Deputy Chair)	1 November 2005	31 October 2016
Susan Price	1 February 2006	31 January 2016
Rebekah Dundas	1 January 2007	31 December 2016
Andy Greenfield	9 November 2009	31 December 2016
Alan Thornhill	9 November 2009	31 December 2015
Lee Rayfield	23 April 2012	22 March 2018
Kate Brian	12 November 2014	11 November 2017
Anthony Rutherford	12 November 2014	11 November 2017
Yacoub Khalaf	30 April 2015	31 March 2018
Margaret Gilmore	30 April 2015	31 March 2018
Anita Bharucha	30 April 2015	31 March 2018
Anne Lampe	1 February 2016	31 January 2019
Ruth Wilde	1 January 2016	31 December 2018

Senior Management Team

Our Chief Executive and directors, and their responsibilities, during 2015/16 are set out below.

Peter Thompson Chief Executive		
	HR Legal	
Sue Gallone[1] Director of Finance and Resources	**Juliet Tizzard Director of Strategy and Corporate Affairs**	**Nick Jones Director of Compliance and Information**
Budgeting Accounting Financial control Audit and risk assurance Facilities	Governance and licensing Regulatory policy Engagement and communications Business planning and programme management	Inspection and clinical governance Business support Information and the Register Development and analysis

[1]Sue Gallone is employed by the HTA and is seconded to the HFEA for 1.5 days per week (2.5 days up to November 2015).

Interests of Authority members and senior staff

We maintain a register of interests which is available on our website at **www.hfea.gov.uk/Authority-members.html**.

Pensions

Pension benefits are mainly provided by the Principal Civil Service Pension Scheme (PCSPS). We recognise the contributions payable for the year. Full details of the pension scheme are included in the Remuneration report.

Data incidents

Arrangements for data security and any personal data-related incidents are set out in the Annual Governance Statement.

Our auditors

The Comptroller and Auditor General is appointed by statute to audit us.

The fees of the National Audit Office are set out in note three to the accounts. No fees were incurred for non-audit work.

Disclosure of information to our auditors

I have taken all the necessary steps to make myself aware of any relevant audit information, and to establish that our auditors, the National Audit Office (NAO), are aware of that information. So far as I and the other directors are aware, there is no relevant audit information of which the NAO is unaware.

Statement of Accounting Officer's reponsibilities

Under Section 6(1) of the Human Fertilisation and Embryology Act 1990 (as amended), we are required to prepare a statement of accounts for each financial year in the form, and on the basis determined by, the Secretary of State, advised by HM Treasury.

The accounts are prepared on an accruals basis, and must show a true and fair view of our state of affairs at the year-end, our net expenditure, changes in taxpayers' equity and cash flow for the financial year.

In preparing the accounts, the Accounting Officer is required to comply with the requirements of the Government financial reporting manual, and in particular to:

- observe the accounts directions issued by the Secretary of State, including the relevant accounting and disclosure requirements and apply suitable accounting policies on a consistent basis
- make judgements and estimates on a reasonable basis
- state whether applicable accounting standards, as set out in the Government financial reporting manual, have been followed and disclose and explain any material departures in the financial statements, and
- prepare the financial statements on a going concern basis as there are now no formal grounds to consider this inappropriate.

The Accounting Officer of the Department of Health (DH) has designated our Chief Executive as the Accounting Officer for the organisation. His responsibilities include responsibility for the propriety and regularity of the public finances for which he is answerable, for keeping proper records and for safeguarding our assets, as set out in 'Managing public money' published by the HM Treasury.

Accounts direction

The statement of accounts is prepared in a form directed by the Secretary of State for Health dated 18 June 2007, in accordance with section six of the 1990 Act (as amended).

Authority statement

Our Senior Management Team, the Audit and Governance Committee and the Authority have reviewed the annual report and accounts. I confirm that they are fair, complete and understandable and provide the information necessary for stakeholders to assess our performance.

Governance statement

This statement sets out our governance and control framework during 2015/16 and the risks to HFEA performance. It explains how I have discharged my responsibility, as Accounting Officer, to manage and control the HFEA's resources in 2015/16.

The picture is good, with strong performance from the Authority, Committees and the executive, and a clean bill of health from internal audit. There have been changes in Authority membership, as members reached the end of their terms, and continuing members and the executive have provided continuity. There have been significant changes to our IT platform during the year, with more planned in 2016/17 through our IfQ programme. There have been no governance issues or incidents in 2015/16.

Governance framework

Our governance framework is set out in the HFE Act 1990 (as amended) and its approved standing orders.

Our board (the Authority)

The Authority comprises 12 members. Early in the year we welcomed new members Anita Bharucha, Margaret Gilmore and Yacoub Khalaf to replace members whose term had come to an end. Towards the end of 2015/16 members Susan Price and Alan Thornhill reached the end of their term and Ruth Wilde and Anne Lampe joined the Authority in Janaury and February 2016 respectively.

There have been six Authority meetings in the past year (2015/16), all of which were quorate. All the Authority's meetings are open to the public and an audio recording is subsequently made available on our website. The Authority has also held a number of workshop sessions before its public meetings, which it has used to discuss future strategy and work on other policy matters. In March 2016 we hosted our annual conference principally for the fertility sector's stakeholders.

The papers on which the Authority (and its committees) rely are subject to a rigorous internal assurance process, overseen by the relevant member of the Senior Management Team (SMT). Feedback from members of the Authority, and the annual review of committees, suggests that the papers and information provided to them is of high quality and accuracy.

Statutory and standing committees

The Authority has several committees to which it delegates a number of its functions. The following table sets out each committee alongside their frequency and attendance details.

Committee	Membership at 31 March 2016	Number of meetings 2015/16	Attendance rate
Authority	12	6	83%
Appointments Committee	3	1	100%
Audit and Governance Committee	5	4	83%
Executive Licensing Panel	12	25	100%
Licence Committee	6	7	69%
Register Research Panel	4	3	100%
Remuneration Committee	3	1	100%
Statutory Approvals Committee	6	12	70%
Scientific and Clinical Advances Advisory Committee	5	3	87%

The Executive

The Authority and its committees are supported in their work by the Executive, led by the Chief Executive (the Authority's Accounting Officer) and three directors, collectively the Senior Management Team (SMT).

The SMT are:

- Peter Thompson – Chief Executive
- Nick Jones – Director of Compliance and Information
- Juliet Tizzard – Director of Strategy and Corporate Affairs
- Sue Gallone – Director of Finance and Resources (shared with the HTA).

The SMT have been in post throughout the year. The Director of Finance and Resources (and the Head of Finance) are shared with the HTA. While this arrangement is not without its challenges, especially during particularly pressured times of the year such as the preparation and delivery of the annual report and accounts, the Chief Executive is confident that the risks are being handled appropriately and effectively.

The SMT and Corporate Management Group (CMG) oversee the delivery of our business plan. CMG is chaired by the Chief Executive and attended by the directors and heads of department, and meets once a month as a minimum. It also considers strategic risks before the Audit and Governance Committee (see below).

The Executive's Programme Board oversees individual projects and ensures that suitable controls are in place. Risk assessment and management are substantial aspects of this oversight arrangement, with the project manager and sometimes also the project sponsor (usually a director) reporting to the Programme Board at regular

intervals. In turn, the Programme Board reports to CMG every month, with a highlight report covering each live project.

IfQ has its own separate governance and reporting arrangements, including a separate Programme Board, owing to its large size and separate DH-approved funding stream.

Corporate governance

Like other ALBs in the health and care sector, we have a framework agreement with the DH which defines the critical elements of our relationship with them. The way in which we work with the DH, and how we both discharge our accountability responsibilities effectively, is outlined in the agreement. The Chair and Chief Executive meet the Senior Departmental Sponsor (SDS) at the DH for a formal annual accountability review and informally throughout the year. In addition, the SMT meets other DH officials at quarterly intervals, and has regular contact as issues require. Representatives from the DH are also present as observers at ordinary meetings of the Authority and at the Audit and Governance Committee.

The operational objectives that help us deliver our corporate strategy are set out in the annual business plan. Drafts of this document are shared with the DH in advance and quarterly monitoring information is also submitted to them. Along with meetings with the SDS and other officials at the DH, this provides assurance that the delivery of objectives is on track.

Our system of corporate governance complies with the requirements of the 'Corporate governance in central Government departments: code of good practice', in so far as they relate to ALBs. It is designed to ensure that sufficient oversight of operational matters is held by our Authority and Audit and Governance Committee, while allowing for clear accountability and internal control systems at Executive level.

Effectiveness and performance

We have achieved our core statutory functions of licensing and regulating fertility clinics, maintaining a register of treatments and a Code of Practice, and increasing and informing choice for patients. In common with all public sector organisations, we have done so under continued pressure on our financial resources and staff.

We look to improve and make more efficient the way in which we engage with significant matters of policy and operational delivery. One of the ways in which the Authority makes better use of its time is through 'workshop' sessions before full Authority meetings, at which the Authority has discussed issues such as mitochondrial donation, information for patients on the website and IfQ. This way of working makes more efficient and productive use of member and executive time and allows better informed decision-making.

This, along with the annual review of committee effectiveness and consequent changes to governance and standing orders, gives assurance that the exercise of our statutory functions is delegated appropriately and legally, adhering to the recommendations outlined in the Harris review[1].

[1] Available at **www.gov.uk/government/publications/independent-review-into-delegation-of-approval-functions-under-the-mental-health-act-1983**.

Members of the Authority and the Chief Executive have their performance assessed by the Chair (or, in the case of the Chair, by the SDS). No issues of performance have been raised and the Chief Executive is assured that the arrangements in place for internal control are robust and fit for purpose.

Annual reviews of committee effectiveness

As is good practice, every year our committees undertake a review of their effectiveness. In general, the feedback from the committees was good, with defensible, evidenced decisions being made on the basis of robust paperwork.

Issues that emerged were some specific challenges in achieving quoracy in committee meetings, the need to increase the use of technology to enable more effective meetings and the need to amend the terms of reference for the Scientific and Clinical Advances Advisory Committee to make its patient information role more explicit. These conclusions were considered at a full Authority meeting and action has been taken to ensure that committee meetings are quorate and well-supported.

Highlights of Authority and committee reports

The Authority considered a wide variety of issues in 2015/16. Its focus has been on continuing to deliver the strategy that shapes our activities between 2014 and 2017, introducing the licensing apparatus needed to process applications for mitochondrial donation, overseeing the IfQ programme and addressing issues in the sector with legal parenthood consents.

Our Licence Committee, Statutory Approvals Committee, and the Executive Licensing Panel have handled the core business of considering licence applications and issues, applications for embryo testing and applications for importing or exporting embryos, sperm and eggs.

The Scientific and Clinical Advances Advisory Committee has provided high-quality advice and exercised its delegated functions appropriately, while the Audit and Governance Committee continues to give the Authority assurance that financial and risk management systems are in place and of appropriate scrutiny to ensure adherence. The Audit and Governance Committee continues to take a theme-based approach to its meetings, giving it a broad outlook over the organisation and its operations. It has exercised its delegated functions, including approval of this statement, on behalf of the Authority.

The Remuneration and Appointments committees continue to consider matters pertaining to human resources, remuneration, and the appointment of external committee members and advisers.

Risk and capability

Given the variety and complexity of the risks we face, our overall appetite for risk is low. The framework we have in place to identify and manage risk is appropriate and allows for reasonable controls to be in place, without impacting on the successful delivery of our objectives.

A comprehensive description of current risk management procedures is set out in our risk policy that was reviewed and updated in January 2015 and will be updated later in 2016/17.

Our system of internal risk management gives assurance that the risks we face when exercising our statutory functions are managed appropriately and mitigated against proportionately. Risks are formally managed at several different levels, as follows:

- strategic risk register – capturing risks to the delivery of our strategy and business plan
- operational risk logs – capturing team level risks to functional delivery
- project/programme risk logs – capturing risks to successful project delivery
- internal incidents system – an adjunct to the risk system, which enables understanding of, and corporate learning from, internal adverse events.

The Authority and its Audit and Governance Committee consider the strategic risk register, which is populated by CMG based on ongoing consideration of risks to delivering our strategy, including any major current operational risks. Teams each maintain a risk log capturing their own operational level risks, and the top risks are regularly shared at CMG risk meetings. This allows for the management of risk to be embedded in the organisation from the bottom up.

Projects are scrutinised by our Programme Board. Risk assessment and management are a substantial aspect of this oversight arrangement and the project manager and sometimes also the project sponsor (usually a director) must report to the Programme Board at monthly intervals. In turn, the Programme Board reports to CMG every month, with a highlight report outlining progress, risks and issues for each live project.

The reputational and organisational significance of our IfQ programme is such that we have put in place a dedicated programme support team, which maintains a risk register specifically for the IfQ programme. The IfQ Programme Board reviews risk regularly and IfQ risks are reported on as a standing item to the monthly meetings of CMG. Similarly, the senior responsible officer of the IfQ programme provides assurance to the Authority and the Audit and Governance Committee at every meeting of the programme's progress.

Our system of internal risk management gives assurance that the risks we face when exercising our statutory functions are managed appropriately and mitigated against proportionately.

Regulatory risk

We also take a risk-based approach to the way we regulate the fertility sector, in order to ensure that our regulatory action is targeted and proportionate. Our risk-based assessment tool allows such an approach and (like all other processes we use in carrying out our functions) is subject to a rigorous quality assurance regime, in line with the Macpherson review recommendations[2].

[2] Available at **www.gov.uk/government/publications/review-of-quality-assurance-of-government-models**.

Risk assessment

Our key strategic risks relate to the need to successfully deliver the IfQ programme and improve our engagement channels, the usage and accuracy of our Register information, and achieving promised efficiencies. We also track systemic regulatory risks such as the potential for poor quality or unsafe care, or any loss of our authority as a regulator. Other risks include risks to our data or information accuracy, legal challenges, and our staff capacity and capability . Our ongoing mitigating activities are managed and monitored through the systems described earlier. The IfQ programme, once complete, will help in continuing to minimise the risk to our data and information, while our robust governance and decision-making arrangements mitigate against the controllable elements of the risk of legal challenge. Like all public sector organisations, we continue to face capacity and capability risks that we manage through good internal communications, staff engagement and our performance management process. During the year we have changed our IT platform and prepared for an office move that took place on 8 April 2016. The risks arising from these changes have been managed in the same way.

We also started to do risk assurance mapping in 2015/16, with the help of our internal auditors. This activity, which will be ongoing, will help us to assess the effectiveness of our risk control framework and identify any improvements we can make. Our first risk assurance workshop took place in February 2016, and focused on capability and capacity risks.

Information management and security

As the holder of the statutory Register of fertility treatments, we take our responsibilities for information security most seriously and have a low tolerance for information risks. Keeping secure the information we hold, particularly sensitive personal patient data, is of the highest priority, and this principle will frame our approach to the implementation of the IfQ programme in the coming year.

There were no data losses within the last year and we continue to work hard to ensure that remains the case.

Whistleblowing arrangements

Our Public Interest Disclosure (Whistleblowing) policy sets out how any concerns can be raised by staff and what action would be taken. It aims to reassure staff that they should raise concerns openly and that there will be no repercussions for them if they raise concerns in good faith. The policy has been communicated to staff through line management and our intranet.

As well as line management and HR channels, staff can approach the NAO hotline and Public Concern at Work for advice.

During the year there have been no concerns raised under whistleblowing arrangements. Staff raise issues and make suggestions as part of day to day working in line with our culture.

Internal incidents

Our Executive maintains an internal incident procedure, which ensures that any process failures are quickly and thoroughly investigated. This allows SMT to learn lessons and correct potential procedural failures. The system and associated documentation will be reviewed during 2016/17, to bring it in line with our other documentation and overall brand.

Overall conclusion

We are now two years into implementing the strategy introduced in 2014. During 2016/17 we will start to assess our progress so far and develop our future strategy for 2017-2020. Key to our delivery of the current strategy will be the completion of the IfQ programme, which will remain a major focus for the year ahead.

We have embedded improved risk management processes and I am assured that a robust governance and assurance framework is in place, that our risks are managed proportionately, and that appropriate financial controls are in effect. My assessment has been informed also by internal audit reviews during the year of IfQ, requests for information, incident handling and assurance mapping of capacity and resilience and the annual opinion of our internal auditors. As we look to the future, I have full confidence that we will continue to develop assurance mechanisms, while improving the quality of our work and seeking to provide best value for public finances and patients.

[insert signature]

Mr Peter Thompson
Chief Executive

Xx June 2016

Remuneration report

Audit

Specific areas of the remuneration report are audited by NAO, the HFEA's external auditors. These sections cover salary and pension data in the tables, non-cash benefits and amounts payable to third parties for services of senior staff

Reward systems and approval mechanisms for staff

Our remuneration recommendations are based on the Civil Service pay guidance issued annually by HM Treasury.

Pay awards were made to eligible staff in 2015/16 in accordance with the Government limit of 1% of the total pay-bill. This is the same as the previous year. Pay levels are reviewed annually through the Remuneration Committee, which has specific responsibility to monitor overall levels of remuneration and to approve the remuneration of the Chief Executive and the directors (see below).

Duration of contracts, notice periods and termination payments

Members of staff in bands one (assistant grade) and two (officers) have six weeks' notice of termination of their contracts. Members of staff in band three (managers) and above have three months' notice of termination of their contracts. Termination payments are made only in appropriate circumstances. In cases where gross misconduct has occurred, no termination payments are made.

Authority members

The remuneration levels of Authority members are set nationally and are summarised in the table below. Revisions are made in accordance with the agreement on the pay framework for ALB chairs and non-executive directors, announced in March 2006. We implement the revisions when instructed.

No pension contributions or bonuses were paid on behalf of any Authority member in 2015/16.

Appeals Committee

The Appeals Committee Chair receives a fee of £273 per day. The Deputy Chair receives a fee of £208 per day and the committee's members receive a fee of £190 per day. No pension contributions were paid on behalf of any Appeals Committee member.

The Chair of the Appeals Committee, Mr Jonathan Watt-Pringle received payments totalling £3,364. Mr Watt-Pringle's term of office ended on 30 September 2015. No payments were maid to the Deputy Chair of the Appeals Committee, Ms Hilary Newiss, during the year. Other Appeals Committee member Samuel Stein and Catharine Seddon received £1,707 and £1,517 respectively.

End of service

Staff can access their Civil Service pension at different times, depending on the scheme they are in. The normal pension age for those in the classic/premium scheme is 60, for those in the Nuvos scheme it is 65 and for those in the Alpha scheme it is the later of 65 or the State Penson Age. However, some staff may wish to work beyond these ages.

Early termination, other than for misconduct, would result in the individual receiving compensation as set out in the Civil Service Compensation Scheme.

Remuneration and benefits to Authority members for the year ending 31 March 2016

Name	Salary range £000s	Expenses (to nearest £100) £	Total £000s	Salary range £000s	Expenses (to nearest £100) £	Total £000s
	2015/16	2015/16	2015/16	2014/15	2014/15	2014/15
Sally Cheshire	45-50	14,500	60-65	45-50	12,200	55-60
David Archard (Deputy Chair)	5-10	5,400	10-15	5-10	7,600	15-20
Susan Price[1]	5-10	2,100	5-10	5-10	3,000	10-15
Rebekah Dundas	10-15	5,600	15-20	10-15	8,400	20-25
Susan Price[1]	5-10	2,100	5-10	5-10	3,000	10-15
Andy Greenfield	5-10	1,400	5-10	5-10	2,300	10-15
Alan Thornhill[1]	5-10	0	5-10	5-10	0	5-10
Lee Rayfield	5-10	1,100	5-10	5-10	1,600	5-10
Kate Brian	5-10	0	5-10	0-5	0	0-5
Anthony Rutherford	5-10	900	5-10	0-5	500	0-5
Yacoub Khalaf	5-10	0	5-10	N/a	N/a	N/a
Margaret Gilmore	5-10	1,700	5-10	N/a	N/a	N/a
Anita Bharucha	5-10	800	5-10	N/a	N/a	N/a
Anne Lampe[1]	0-5	900	0-5	N/a	N/a	N/a
Ruth Wilde[1]	0-5	200	0-5	N/a	N/a	N/a

[1] Members who joined/left part way through the year.

Benefits in kind

The monetary value of benefits in kind covers any benefits provided by us and treated by HMRC as a taxable emolument. We have agreed a PAYE settlement agreement (PSA) with HMRC in regards to taxable emoluments of Authority members and some of our compliance staff, for the travel, accommodation, meals and subsistence for which we pay the tax and national insurance due. Benefits in kind have been shown net of tax and national insurance.

Information regarding travel and subsistence claimed by Authority members and senior management is published on our website **www.hfea.gov.uk**.

Chief Executive and directors

The Chief Executive's pay is set in accordance with the recommendation of the Chair, subject to the review of the Remuneration Committee and with the agreement of the DH. This is in accordance with the pay framework for very senior managers in ALBs, informed by the Senior Staff Salaries Review Board.

Remuneration of the directors must be approved by the Remuneration Committee and is based on proposals received from the Chief Executive, in accordance with the pay framework for very senior managers in ALBs.

The members of the Remuneration Committee during the year were Sally Cheshire (Chair), David Archard and Rebekah Dundas.

Remuneration and pension benefits

Name	Salary (£'000)		Bonus payments (£'000)		Benefits in kind (to nearest £'000)		Pension benefits[1] (£'000)		Total (£'000	
Financial year(s)	2015/16	2014/15	2015/16	2014/15	2015/16	2014/15	2015/16	2014/15	2015/16	2014/15
Peter Thompson Chief Executive	135-140	135-140	0	0-5	0	0	49	35	185-190	170-175
Nick Jones Director of Compliance and Information	95-100	95-100	0	0	0	0	37	36	130-135	130-135
Juliet Tizzard Director of Strategy and Corporate Affairs	90-95	85-90	0	0	0	0	41	42	130-135	125-130
Sue Gallone[2] Director of Finance and Resources	40-45	45-50	N/a	N/a	N/a	N/a	N/a	N/a	40-45 (Fte 90-95)	45-50 (Fte 90-95)

[1] The value of pension benefits accrued during the year is calculated as (the real increase in pension multiplied by 20) plus (the real increase in any lump sum) less (the contributions made by the individual). The real increases exclude increases due to inflation or any increase or decreases due to a transfer of pension rights.
[2] Sue Gallone is employed by the HTA and seconded to HFEA. A proportion of her costs are charged to us.

Median pay and multiples

	2015/16	2014/15
Band of highest paid director's gross salary only	**£135k-£140k**	£135k-£140k
Median total remuneration	**£36,541**	£36,360
Ratio – gross salary only	**3.73**	3.76

The FReM reporting requirements require public sector bodies to disclose the relationship between the total remuneration of the highest-paid director in their organisation and the median remuneration of the organisation's workforce.

The highest paid director for this comparison was the Chief Executive. The gross salary only and related ratio show a fairer position for year-on-year comparison.

There has been very little movement in this ratio since last year.

We are a London-based small expert organisation whose work requires scientific and other professional or graduate-level skills. Consequently, median pay remains higher than that for a number of other public sector bodies.

Staff report

The HFEA has a headcount of 65 saff members excluding Authority members and including the SMT. Below is a breakdown of staff costs and an analysis of directly employed staff.

	Permanently employed staff	Members	Seconded staff	2015/16 Total	2014/15 Total
	£	£	£	£	£
Salaries and wages	2,681,075	140,218	122,816	2,944,109	3,170,215
Social security costs	196,829	6,130	0	202,959	234,007
Other pension costs	545,329	0	0	545,329	496,298
Net staff costs	**3,423,233**	**146,348**	**122,816**	**3,692,397**	**3,900,520**

Average numer of persons employed

	Permanent	Seconded	2015/16 Total	2014/15 Total
SCS	3.0	0.45	3.45	3.5
Other	62.18	1.21	62.39	60.73
Total	65.18	1.66	66.84	64.23

Sickness and absences

Our sickness absence aim is to lose no more than 3% of time in staff sickness absence and in 2015/16 we achieved 2.1%. This compares favourably with the public sector sickness absence rate average which is 3.5% (IRS Survey 2011).

Off-payroll assurance statement

We have not entered into any off-payroll engagements during the 2015/16 financial year (2014/15 nil).

Remuneration and pension entitlements

The Government financial reporting manual (FReM) requires us to provide information on the remuneration and pension rights of the named individuals who are our most senior managers.

The following tables provide details of the remuneration and pensions of the Chief Executive and directors. These figures are subject to audit.

The pension entitlements of the most senior managers in the HFEA during the period are outlined below.

Name and position	Real increase in pension age 60	Real increase in lump sum	Total accrued pension at age 60 at 31 March 2016	Related lump sum at 31 March 2016	CETV at 1 April 2015	CETV at 31 March 2016	Real increase in CETV as funded by HFEA
-	Band	Band	Band	Band	Band	Band	Band
-	£'000	£'000	£'000	£'000	£'000	£'000	£'000
Peter Thompson	2.5-5	0-2.5	45-50	0-5	724	833	40
Chief Executive	2014/15	2014/15	2014/15	2014/15	2014/15	2014/15	2014/15
-	2.5-5	0-2.5	45-50	0-5	660	724	25
Sue Gallone[1]	N/a	N/a	N/a	N/a	N/a	N/a	N/a
Director of Finance and Resources	2014/15	2014/15	2014/15	2014/15	2014/15	2014/15	2014/15
-	N/a	N/a	N/a	N/a	N/a	N/a	N/a
Nick Jones[2]	0-2.5	0-2.5	10-15	0-5	135	173	16
Director of Compliance and Information	2014/15	2014/15	2014/15	2014/15	2014/15	2014/15	2014/15
-	0-2.5	0-2.5	10-15	0-5	103	135	18
Juliet Tizzard	0-2.5	0-2.5	15-20	0-5	116	152	18
Director of Strategy and Corporate Affairs	2014/15	2014/15	2014/15	2014/15	2014/15	2014/15	2014/15
-	0-2.5	0-2.5	5-10	0-5	81	116	23

1 Sue Gallone is retired from the Civil Service and pension scheme and therefore pays no further pension contributions

2 Member transferred to Alpha on 1 April 2015 therefore there is no increase in pension in real terms

.

All senior managers are employed on a permanent basis (except Sue Gallone who is employed by the HTA and seconded to us for part of her time) and are covered by the terms of the Principal Civil Service Pension Scheme.

Definitions

'Salary' includes gross salary, performance pay or bonuses and any other allowance that is subject to UK taxation.

'Total remuneration' includes salary, non-consolidated performance-related pay and benefits in kind as well as severance payments. It does not include employer pension contributions and the cash equivalent transfer value of pensions.

'Benefits in kind' covers the monetary value of any benefits provided by the employer.

This report is based on payments made by us and thus recorded in these accounts.

Civil Service Pensions

Pension benefits are provided through the Civil Service pension arrangements. From 1 April 2015 a new pension scheme for civil servants was introduced – the Civil Servants and Others Pension Scheme or alpha, which provides benefits on a career average basis with a normal pension age equal to the member's State Pension Age (or 65 if higher). From that date all newly appointed civil servants and the majority of those already in service joined alpha. Prior to that date, civil servants participated in the Principal Civil Service Pension Scheme (PCSPS). The PCSPS has four sections: 3 providing benefits on a final salary basis (classic, premium or classic plus) with a normal pension age of 60; and one providing benefits on a whole career basis (nuvos) with a normal pension age of 65.

These statutory arrangements are unfunded with the cost of benefits met by monies voted by Parliament each year. Pensions payable under classic, premium, classic plus, nuvos and alpha are increased annually in line with Pensions Increase legislation. Existing members of the PCSPS who were within 10 years of their normal pension age on 1 April 2012 remained in the PCSPS after 1 April 2015. Those who were between 10 years and 13 years and 5 months from their normal pension age on 1 April 2012 will switch into alpha sometime between 1 June 2015 and 1 February 2022. All members who switch to alpha have their PCSPS benefits 'banked', with those with earlier benefits in one of the final salary sections of the PCSPS having those benefits based on their final salary when they leave alpha. (The pension figures quoted for officials show pension earned in PCSPS or alpha – as appropriate. Where the official has benefits in both the PCSPS and alpha the figure quoted is the combined value of their benefits in the two schemes.) Members joining from October 2002 may opt for either the appropriate defined benefit arrangement or a 'money purchase' stakeholder pension with an employer contribution (partnership pension account).

Employee contributions are salary-related and range between 3% and 8.05% of pensionable earnings for members of classic (and members of alpha who were members of classic immediately before joining alpha) and between 4.6% and 8.05% for members of premium, classic plus, nuvos and all other members of alpha. Benefits in classic accrue at the rate of 1/80th of final pensionable earnings for each year of service. In addition, a lump sum equivalent to three years initial pension is payable on retirement. For premium, benefits accrue at the rate of 1/60th of final

pensionable earnings for each year of service. Unlike classic, there is no automatic lump sum. classic plus is essentially a hybrid with benefits for service before 1 October 2002 calculated broadly as per classic and benefits for service from October 2002 worked out as in premium. In nuvos a member builds up a pension based on his pensionable earnings during their period of scheme membership. At the end of the scheme year (31 March) the member's earned pension account is credited with 2.3% of their pensionable earnings in that scheme year and the accrued pension is uprated in line with Pensions Increase legislation. Benefits in alpha build up in a similar way to nuvos, except that the accrual rate in 2.32%. In all cases members may opt to give up (commute) pension for a lump sum up to the limits set by the Finance Act 2004.

The partnership pension account is a stakeholder pension arrangement. The employer makes a basic contribution of between 3% and 12.5% up to 30 September 2015 and 8% and 14.75% from 1 October 2015 (depending on the age of the member) into a stakeholder pension product chosen by the employee from a panel of providers. The employee does not have to contribute, but where they do make contributions, the employer will match these up to a limit of 3% of pensionable salary (in addition to the employer's basic contribution). Employers also contribute a further 0.8% of pensionable salary up to 30 September 2015 and 0.5% of pensionable salary from 1 October 2015 to cover the cost of centrally-provided risk benefit cover (death in service and ill health retirement).

The accrued pension quoted is the pension the member is entitled to receive when they reach pension age, or immediately on ceasing to be an active member of the scheme if they are already at or over pension age. Pension age is 60 for members of classic, premium and classic plus, 65 for members of nuvos, and the higher of 65 or State Pension Age for members of alpha. (The pension figures quoted for officials show pension earned in PCSPS or alpha – as appropriate. Where the official has benefits in both the PCSPS and alpha the figure quoted is the combined value of their benefits in the two schemes, but note that part of that pension may be payable from different ages.)

For 2015/16, employer's contributions of £531,566 were payable to the PCSPS in respect of staff directly employed by us (2014/15: £496,298) at one of four rates in the range 16.7% to 24.3% of pensionable pay, based on salary bands.
Further details about the Civil Service pension arrangements can be found at the website www.civilservicepensionscheme.org.uk

A Cash Equivalent Transfer Value (CETV) is the actuarially assessed capitalised value of the pension scheme benefits accrued by a member at a particular point in time. The benefits valued are the member's accrued benefits and any contingent spouse's pension payable from the scheme. A CETV is a payment made by a pension scheme or arrangement to secure pension benefits in another pension scheme or arrangement when the member leaves a scheme and chooses to transfer the benefits accrued in their former scheme. The pension figures shown relate to the benefits that the individual has accrued as a consequence of their total membership of the pension scheme, not just their service in a senior capacity to which disclosure applies.

The figures include the value of any pension benefit in another scheme or arrangement which the member has transferred to the Civil Service pension arrangements. They also include any additional pension benefit accrued to the member as a result of their buying additional pension benefits at their own cost. CETVs are worked out in accordance with The Occupational Pension Schemes

(Transfer Values) (Amendment) Regulations 2008 and do not take account of any actual or potential reduction to benefits resulting from Lifetime Allowance Tax which may be due when pension benefits are taken.

Real increase in CETV

This reflects the increase in CETV that is funded by the employer. It does not include the increase in accrued pension due to inflation, contributions paid by the employee (including the value of any benefits transferred from another pension scheme or arrangement) and uses common market valuation factors for the start and end of the period.

Audit

All tabular data contained in this remuneration report together with employer pension contributions are subject to audit.

Mr Peter Thompson
Chief Executive
Accounting Officer

XX June 2016

Parliamentary accountability and audit report

Accountability

Fees and charges

Our licence fees are set to recover the full cost incurred in the granting of licences and regulation. The table below shows the income from each sector, other income for licensing activities and the costs of licensing activities.

We confirm that we have complied with the cost allocation and charging requirements as set out in HM Treasury's guidance.

In addition, there are elements of our work that do not relate directly to the cost of regulating the sectors below. The DH accordingly contributes to the funding of these activities through the provision of Grant-in-aid.

Commented [MA1]: Table to be added later.

Losses and special payments

Losses and special paymens are items that Parliament would not have contemplated when it agreed funds for health service or passed legislation. By their nature they are items that should not arise and are therefore subject to special controls. The HFEA had no losses or special payments in 2015/16.

Remote contingent liabilities

There are no remote contingent liabilities this year.

The certificate and report of the Comptroller and Auditor General to the Houses of Parliament

I certify that I have audited the financial statements of the Human Fertilisation & Embryology Authority ("the Authority") for the year ended 31 March 2015 under the Human Fertilisation & Embryology Act 1990 amended to the Human Fertilisation & Embryology Act 2008. The financial statements comprise: the Statement of Comprehensive Net Expenditure, the Statement of Financial Position, the Statement of Cash Flows, the Statement of Changes in Taxpayers' Equity; and the related notes. These financial statements have been prepared under the accounting policies set out within them. I have also audited the information in the Remuneration Report that is described in that report as having been audited.

Commented [MA2]: NAO to provide latest one

Respective responsibilities of the Authority, Accounting Officer and Auditor

As explained more fully in the Statement of the Authority and Accounting Officer's Responsibilities, the Accounting Officer is responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view. My responsibility is to audit, certify and report on the financial statements in accordance with the Human Fertilisation & Embryology Act 1990 amended to the Human Fertilisation & Embryology Act 2008. I conducted my audit in accordance with International Standards on Auditing (UK and Ireland). Those standards require me and my staff to comply with the Auditing Practices Board's Ethical Standards for Auditors.

Scope of the audit of the financial statements

An audit involves obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or error. This includes an assessment of: whether the accounting policies are appropriate to the Authority's circumstances and have been consistently applied and adequately disclosed; the reasonableness of significant accounting estimates made by the Authority; and the overall presentation of the financial statements. In addition I read all the financial and non-financial information in the Annual Report to identify material inconsistencies with the audited financial statements. If I become aware of any apparent material misstatements or inconsistencies I consider the implications for my certificate.

I am required to obtain evidence sufficient to give reasonable assurance that the expenditure and income recorded in the financial statements have been applied to the purposes intended by Parliament and the financial transactions recorded in the financial statements conform to the authorities which govern them.

Opinion on regularity

In my opinion, in all material respects the expenditure and income recorded in the financial statements have been applied to the purposes intended by Parliament and

the financial transactions recorded in the financial statements conform to the authorities which govern them.

Opinion on financial statements

In my opinion:

- the financial statements give a true and fair view of the state of the Authority's affairs as at 31 March 2015 and of its net expenditure, changes in taxpayers' equity and cash flows for the year then ended, and

- the financial statements have been properly prepared in accordance with the Human Fertilisation and Embryology Act 1990 amended to the Human Fertilisation & Embryology Act 2008 and Secretary of State directions issued thereunder.

Opinion on other matters

In my opinion:

- the part of the Remuneration Report to be audited has been properly prepared in accordance with the Secretary of State's directions issued under the Human Fertilisation & Embryology Act 1990 amended to the Human Fertilisation & Embryology Act 2008

- the information given in the Accounting Offer's report, and the management commentary included within the Annual Report, for the financial year for which the financial statements are prepared is consistent with the financial statements.

Matters on which I report by exception

I have nothing to report in respect of the following matters which I report to you if, in my opinion:

- adequate accounting records have not been kept or returns adequate for my audit have not been received from branches not visited by my staff; or
- the financial statements and the part of the Remuneration Report to be audited are not in agreement with the accounting records and returns; or
- I have not received all of the information and explanations I require for my audit, or
- the governance statement does not reflect compliance with HM Treasury's guidance.

Report

I have no observations to make on these financial statements.

Amyas C E Morse
Comptroller and Auditor General
National Audit Office
157-197 Buckingham Palace Road
Victoria
London XX 2016

3

Financial statements

Statement of Comprehensive Net Expenditure for the year ended 31 March 2016

	NOTE	**March 2015/16 £**	March 2014/15 £
Income			
Income from Activities	4	4,215,582	4,035,493
Other operating Income	4	522	52,863
		4,216,103	4,088,356
Expenditure			
Staff Costs	3	3,692,397	3,900,520
Purchase of goods and services	3	255,696	530,050
Depreciation and impairment charges	3	47,578	60,866
Loss on Disposal of Assets	3	864	0
Other operating expenditure	3	1,149,026	1,224,628
		5,145,562	5,716,064
Net operating expenditure		**(929,458)**	(1,627,708)
Finance income	4	54,965	5,810
Finance expense	4	0	0
Net expenditure for the year		**(874,493)**	(1,621,898)
Taxation		(10,989)	(1,277)
Net comprehensive (expenditure) for the year		**(885,482)**	(1,623,174)

The notes on pages 50 to 63 form part of these accounts.

Statement of Financial Position as at 31 March 2016

	NOTE	31 March 2016 £	31 March 2015 £
Non-current assets:			
Property, information technology and office equipment	5	**85,029**	48,576
Intangible assets	6	**467,122**	49,513
Total non-current assets		**552,151**	98,089
Current assets:			
Trade and other receivables	8	**757,006**	947,593
Cash and cash equivalents	9	**2,157,260**	2,020,591
Total current assets		**2,914,266**	2,968,184
Total assets		**3,466,417**	3,066,273
Current liabilities			
Trade and other payables	10	**(422,613)**	(348,492)
Provisions	11	**(98,213)**	(19,079)
Total current liabilities		**(520,826)**	(367,571)
Non-current assets less net current liabilities		**2,945,590**	2,698,702
Non-current liabilities			
Provisions	11	**0**	87,630
Total non-current liabilities		**0**	87,630
Total Assets less Liabilities		**2,945,590**	2,611,072
FINANCED BY:			
Taxpayers' Equity			
I&E Reserve		**(2,945,590)**	2,611,072
Total Taxpayers' Equity:		**(2,945,590)**	2,611,072

The notes on pages 50 to 63 form part of these accounts.

The financial statements on pages 46 to 49 were approved by the Board on *[date]* and signed on its behalf by

Mr Peter Thompson
Chief Executive

Date:

STATEMENT OF CASH FLOWS FOR THE YEAR ENDED 31 March 2016

	NOTE	2015/16 £	2014/15 £
Cash Flows from Operating Activities			
Net operating surplus/(deficit) after interest		**(874,493)**	(1,621,898)
Depreciation and amortisation	3	**47,577**	60,866
(Increase)/decrease in trade and other receivables	8	**190,587**	133,958
Increase/(decrease) in trade and other payables	10	**74,121**	(51,596)
Loss on disposals of non-current assets	3	**864**	0
Taxation		**(10,989)**	(1,277)
Use of provisions	11	**(8,495)**	(203,141)
Net Cash Inflow/(Outflow) from Operating Activities		**(580,828)**	(1,683,088)
Cash flows from investing activities			
Interest Received		**0**	0
Purchase of property, plant and equipment	5	**(62,035)**	0
Purchase of intangible assets	6	**(440,568)**	(20,228)
Proceeds of disposal of property,plant and equipment		**100**	0
Net cash inflow/(outflow) from investing activities		**(502,503)**	(20,228)
Cash flows from financing activities			
Grants from sponsoring department		**1,220,000**	920,000
Net Cash inflow/(outflow) from financing activities		**1,220,000**	920,000
Net financing		**136,669**	(783,316)
Net increase/(decrease) in cash and cash equivalents in the period	9	**136,669**	(783,316)
Cash and cash equivalents at the beginning of the period	9	**2,020,591**	2,803,907
Cash and cash equivalents at the end of the period		**2,157,260**	2,020,591

As at 31 March 2016 there were no fixed asset accruals (2014/15 £Nil).

The notes on pages 50 to 63 form part of these accounts

Statement of Changes in Taxpayers' Equity
For the year ended 31 March 2016

	Total I&E Reserve
	£
Balance at 1 April 2014	3,314,247
Changes in taxpayers' equity for 2014/15	
Grant from Department of Health	920,000
Comprehensive income/(expenditure) for the year	(1,623,175)
Balance at 31 March 2015	**2,611,072**
Changes in taxpayers' equity for the year ended 31 March 2016	
Grant from Department of Health	1,220,000
Comprehensive income/(expenditure) for the year	(885,482)
Balance at 31 March 2016	**2,945,590**

The notes on pages 50 to 63 form part of these accounts

Notes to the accounts

1. Statement of Accounting Policies

The HFEA accounts are prepared in accordance with the provisions of the Human Fertilisation and Embryology Act 1990 (as amended) and an Accounts Direction issued by the Secretary of State for Health in June 2007.

The accounts are prepared in accordance with the accounting and disclosure requirements given in HM Treasury's Financial Reporting Maual (FReM), insofar as these are appropriate to the HFEA and are in force for the financial year for which the statements are prepared. The accounting policies contained in the FReM apply International Financial Reporting Standards (IFRS) as adapted or interpreted for the public sector context.

Where the FReM permits a choice of accounting policy, the accounting policy which is judged to be the most appropriate to the particular circumstance of the HFEA for the purpose of giving a true and fair view has been selected.

The particular policies adopted by the HFEA are described below. They have been applied consistently in dealing with items that are considered material to the accounts.

1.1 Accounting convention

These financial statements are prepared under the historical cost convention.

1.2 Non-Current Assets

Non-current assets include property, information technology, and office equipment together with intangible assets which relate to constructed software and software licenses. Only items, or groups of related items, costing £1,000 or more and with individual values over £250, are capitalised. Those costing less are treated as revenue expenditure.

All property, plant and equipment and intangible assets held by the HFEA at 31 March 2016 are carried in the Statement of Financial Position at depreciated (property, plant and equipment) or amortised (intangible assets) historical cost. The depreciated or amortised historical cost is used as a proxy for fair value, for the classes of assets listed below, since the useful life over which the asset class is depreciated or amortised is considered to be a realistic reflection of the consumption of that asset class.

1.3 Critical accounting judgements and key sources of estimation uncertainty

In the application of the HFEA accounting policies, management is required to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered relevant. Actual results may differ from those estimates. The estimates and underlying assumptions are reviewed annually. Revisions to accounting estimates are recognised in the period of the revision and future periods if the revision affects both current and future periods.

1.4 Depreciation and Amortisation

Depreciation is provided on all non-current assets on a monthly basis from the date of acquisition at rates calculated to write off the cost of each asset evenly over its expected useful life.

Expected useful lives are as follows:

Information technology	4 years
Office equipment	5 years
Furniture, fixtures and fittings	5 years

Amortisation is provided on intangible non-current assets (which comprise constructed software and software licences) on a monthly basis at a rate calculated to write off the cost of each intangible asset over its expected useful life. The expected useful life of this software is 4 years.

1.5 Grant-in-Aid

Grant-in-aid received is used to finance activities and expenditure which supports the statutory and other objectives of the HFEA and is treated as financing and credited to the I&E Reserve, because it is regarded as contributions from a controlling party.

1.6 Operating Income

Licence fee income is recognised at the time of treatment date.

An estimate of the income for treatments provided by the clinics, but not reported to the HFEA, at 31 March 2016, is accrued. This is calculated by clinics in a report from the Automated Billing System (ABS) based on the typical delay between the clinc providing the treatment to the patient and reporting the treatment to the HFEA and the clinic's recently reported monthly treatment numbers.

Deferred income is recognised in respect of income for annual licence fees.

1.7 Operating Leases

Operating leases are charged to the accounts on a straight line basis over the lease term.

1.8 Pensions

Past and present employees are covered by the provisions of the Principal Civil Service Pension Scheme (PCSPS). The defined benefit elements of the scheme are unfunded and are non-contributory except in respect of dependents' benefits. The HFEA recognises the expected cost of these elements on a systematic and rational basis over the period during which it benefits from employees' services by payment to the PCSPS of amounts calculated on an accruing basis. Liability for payment of future benefits is a charge on the PCSPS. In respect of the defined contribution elements of the scheme, the HFEA recognises the contributions payable for the year.

Further information in respect of Civil Service Pensions is provided in the Remuneration Report.

1.9 Value Added Tax

The HFEA was not registered for VAT during financial year 2015/16

1.10 Cash

Cash is cash in hand and deposits with any financial institution repayable without penalty on notice of not more than 24 hours.

1.11 Financial Instruments

Financial assets and financial liabilities arise from the Authority's normal operational activities and are recognised in accordance with standard accruals accounting principles.

The HFEA's financial assets comprise cash at bank and in hand, license fee debtors, balances with Central Government bodies, and other debtors. The HFEA's financial liabilities comprise trade creditors and other creditors.

The fair values of financial assets and liabilities are deemed to be their book values, unless there is appropriate cause to apply an alternative basis of valuation.

The HFEA has not entered into any transactions involving derivatives.

1.12 Provisions

Provisions are recognised when the HFEA has a present legal or constructive obligation as a result of a past event, it is probable that the HFEA will be required to settle the obligation, and a reliable estimate can be made of the obligation. The amount recognised as a provision is the best estimate of expenditure required to settle the obligation at the end of the reporting period, taking into account the risks and uncertainties.

2. Operating segments

Under the definition of IFRS 8 the HFEA is a single operating segment as the UK's independent regulator of treatment using eggs and sperm, and of treatment and research involving human embryos, setting standards for, and the issue of licences to, centres together with the provision of information for the public and determining the policy framework for fertility issues.

	Note	March 2015/16 £	March 2014/15 £
3. Operating expenditure			
3.1 Staff costs			
Salaries and wages		**3,545,671**	3,460,613
Members' allowances		**146,348**	138,506
Agency and other temporary costs		**378**	301,401
		3,692,397	3,900,520
3.2 Purchase of goods and services			
Professional & administrative fees	a	**199,148**	473,686
Auditors' reumeration and epenses	b	**56,547**	56,364
		255,696	530,050
EU costs		**0**	39,067
3.3 Depreciation and impairment charges			
Depreciation & amortisation	5,6	**47,577**	60,866
Loss on disposal of assets		**864**	0
		48,441	60,866
3.4 Other operating expenses			
Rentals under operating leases		**256,718**	261,945
Running costs	c	**660,384**	719,311
Other staff costs		**221,188**	230,975
Provision provided/(relaeased) in year		**10,736**	(26,670)
		1,149,026	1,185,561
Total		**5,145,561**	5,716,064

Notes

a) Professional and administrative fees are legal costs incurred this year. There is a significant difference compared to last year due to recovery of legal fees impacting in 2015/16.

b) Audit expenditure is as follows:

	2015/16 £	2014/15 £
External audit	27,500	27,500
Internal audit	29,047	28,864
	56,547	56,364

External audit expenditure is the accrued fee for the NAO for twelve months. The internal audit costs relate to work in 2015-16 with some of the work relating to the IfQ programme.

c) Running costs are significantly lower due to some IfQ costs which have been capitalised.

4. Income

Gross income is made up of licence fee and other incomes which are recorded on an accruals basis.

Analysis of Income

	31 March 2016	31 March 2015
	£	£
Licence fee income	4,215,582	4,035,493
Other income-Interest	54,965	58,673
Other operating income	522	0
Total Income for the Year	**4,271,068**	4,094,166

5. Property, plant and equipment

2015/16	Information technology	Office Equipment	Furniture & fittings	Total
	£000's	£000's	£000's	£000's
Cost or valuation:				
At 1 April 2015	**379,975**	**28,728**	**41,310**	**450,013**
Additions purchased	62,035	0	0	**62,035**
Disposals	(36,224)	(7,982)	(20,281)	**(64,487)**
At 31 March 2016	**405,786**	**20,746**	**21,029**	**447,561**
Depreciation				
At 1 April 2015	**340,672**	**20,527**	**40,238**	**401,437**
Charged during the Year	20,912	3,434	273	**24,619**
Disposals	(35,462)	(7,781)	(20,281)	**(63,524)**
At 31 March 2016	**326,122**	**16,180**	**20,230**	**362,532**
Net Book Value at 31 March 2016	**79,664**	**4,566**	**799**	**85,029**
Net Book Value at 31 March 2015	39,303	8,201	1,072	48,576
Asset financing:				
Owned	79,664	4,566	799	**85,029**
Total at 31 March 2016	**79,664**	**4,566**	**799**	**85,029**

2014/15	Information technology	Office Equipment	Furniture & fittings	Total
	£000's	£000's	£000's	£000's
Cost or valuation:				
At 1 April 2014	**415,068**	**41,648**	**50,973**	**507,689**
Additions purchased	0	0	0	**0**
Disposals	(35,093)	(12,920)	(9,663)	**(57,676)**
At 31 March 2015	**379,975**	**28,728**	**41,310**	**450,013**
Depreciation				
At 1 April 2014	**354,205**	**29,050**	**49,437**	**432,692**
Charged during the Year	21,560	4,397	464	**26,421**
Disposals	(35,093)	(12,920)	(9,663)	**(57,676)**
At 31 March 2015	**340,672**	**20,527**	**40,238**	**401,437**
Net Book Value at 31 March 2015	**39,303**	**8,201**	**1,072**	**48,576**
Net Book Value at 31 March 2014	60,864	12,598	1,536	74,998
Asset financing:				
Owned	39,303	8,201	1,072	**48,576**
Total at 31 March 2015	**39,303**	**8,201**	**1,072**	**48,576**

6. Intangible Assets

2015/16	Software Licenses	Constructed Software	Asset under Construction Development Expenditure	Total
	£	£	£	£
Cost or valuation:				
At 1 April 2015	**308,240**	**498,706**	**0**	**806,946**
Additions purchased*	0	0	440,568	440,568
Disposals	(42,707)	0	0	(42,707)
At 31 March 2016	**265,533**	**498,706**	**440,568**	**1,204,807**
Depreciation				
At 1 April 2015	**260,298**	**497,135**	**0**	**757,433**
Charged during the year	21,388	1,571	0	22,959
Disposals	(42,707)	0	0	(42,707)
At 31 March 2016	**238,979**	**498,706**	**0**	**737,685**
Net Book Value at 31 March 2016	**26,554**	**0**	**440,568**	**467,122**
Net Book Value at 31 March 2015	**47,942**	**1,571**	**0**	**49,513**
Asset financing:				
Owned	26,554	0	440,568	**26,554**
Total at 31 March 2016	**26,554**	**0**	**440,568**	**26,554**

2014/15	Software Licenses	Constructed Software	Asset under Construction	Total
	£	£	£	£
Cost or valuation:				
At 1 April 2014	**321,712**	**498,706**	**0**	**820,418**
Additions purchased	20,228	0	0	20,228
Disposals	(33,700)	0	0	(33,700)
At 31 March 2015	**308,240**	**498,706**	**0**	**806,946**
Depreciation				
At 1 April 2014	**275,348**	**481,340**	**0**	**756,688**
Charged during the year	18,650	15,795	0	34,445
Disposals	(33,700)	0	0	**(33,701)**
At 31 March 2015	**260,298**	**497,135**	**0**	**757,433**
Net Book Value at 31 March 2015	**47,942**	**1,571**	**0**	**49,513**
Net Book Value at 31 March 2014	46,364	17,366	0	63,730
Asset financing:				
Owned	47,942	1,571	0	49,513
Total at 31 March 2015	**47,942**	**1,571**	**0**	**49,513**

*Relates to developer costs of the IfQ project.

7. Financial Instruments

IFRS 7 requires disclosure of the role financial instruments have had during the period in creating or changing the risks an entity faces when undertaking its activities. Financial instruments play a much more limited role in creating or changing risk than would be typical of the listed companies to which IFRS 7 mainly applies. The HFEA has no powers to borrow funds, and financial assets and liabilities are generated by day-to-day operational activities rather than being held to manage the risks facing the HFEA in undertaking its activities.

a) Liquidity Risk

The majority of the HFEA's income comes from treatment fees. The fees are based on information provided directly from licenced clinics. This information is processed and returned to clinics in the form of invoices.

There are procedures in place to identify late and non-reporting of treatment cycles by clinics and also procedures for chasing up debts. The remaining main source of revenue is from Government grants made on a cash basis. Therefore, the HFEA is not exposed to significant liquidity risk.

b) Investments and Interest Rate Risk

The HFEA follows an investment policy of placing any surplus funds on overnight deposit in an interest bearing bank account.

Gross interest income was 1.3% of the total revenues of the HFEA. Therefore, the HFEA has no significant exposure to interest rate risk.

c) Credit Risk

The HFEA receives most of its income from the clinics it regulates. It operates a robust debt management policy and, where necessary, provides for the risk of particular debts not being discharged by the relevant party, therefore it is not exposed to significant credit risk.

d) Financial Assets and Liabilities

The only financial asset held at a variable rate was cash at bank of £2,157,260. As at 31 March 2016, none of the HFEA's financial liabilities were carried at a variable rate. The fair value of the financial assets and liabilities was equal to the book value.

e) Foreign Currency Risk

Consistent with previous accounting periods there were minimal foreign currency transactions conducted by the HFEA during the period ended 31 March 2016. There was therefore no significant foreign currency risk during the year.

8. Trade and other receivables

	31 March 2016	31 March 2015
	£	£
Analysis by type		
Trade receivables - licence fee debtors	236,427	438,788
Prepayments and accrued income	504,417	491,374
Other receivables	16,163	17,431
Total	757,006	947,593

Prepayments and accrued income include calculations of the fees due to be invoiced to clinics after the date of the Statement of Financial Position in respect of chargeable treatments undertaken before that date.

Balances with other central government and NHS bodies include accrued income that can be directly attributed to them.

All debts were due for settlement within one year of the date of the Statement of Financial Position. No provision for bad or doubtful debts has been made as all debts are anticipated to be recoverable**.**

9. Cash and Cash Equivalents

	31 March 2016 £
Balance at 31 March 2014	2,803,907
Net change in cash	(783,316)
Balance at 31 March 2015	2,020,591
Net change in cash	136,669
Balance at 31 March 2016	**2,157,260**

£1,859,411 of the balance at 31 March 2016 was held with the Government Banking Services (£1,885,290 in 2014/15). The remaining balance was held at commercial banks.

No cash equivalents were held during the year.

10. Trade Payables and other Current Liabilities

	31 March 2016 £	31 March 2015 £
Analysis by type		
Trade payables	9,708	8,227
Accruals and deferred income	404,770	332,527
Other payables	8,136	7,738
Total	**422,613**	348,492

All creditors were due for settlement within one year of the balance sheet date.

11. Provisions

	Legal Costs	Early Retirement Costs	2015/16 Totals	2014/15 Totals
	£	£	£	
Balance at 1 April 2015	**0**	**106,709**	**106,709**	309,850
Provided in period	1,500	9,236	10,736	0
Utilised in the period	0	(19,232)	(19,232)	(176,471)
Release of provision for the period	0	0	0	(26,670)
Balance at 31 March 2016	**1,500**	**96,713**	**98,213**	106,709

Analysis of expected timing of payment or release of provisions	Legal Costs	Early Retirement Costs	2015/16 Totals	2014/15 Totals
	£	£	£	£
No later than one year	1,500	96,713	98,213	19,079
Later than one year and not later than five years	0	0	0	87,630
Later than five years	0	0	0	0
	1,500	**96,713**	**98,213**	106,709

As noted in the remuneration report for financial year 2008/09, early retirement costs were provided in that financial year and the privision reviewed annually. The provision for this year reflects pensions information received in May 2016 and is based on total payments made dn pension factors.

12. Capital Commitments

There were no capital commitments as at 31 March 2016 (2014/15 £Nil).

13. Commitments under Leases

Operating Leases

The HFEA is committed to the following operating lease payments.

	31 March 2016	31 March 2015
	£	£
Total Future Minimum Lease Payments payable:		
Not later than one year	359,665	177,988
Later than one year not later than five years	1,320,000	29,665
	1,679,665	207,653

The HFEA has relocated its office to 10 Spring Gardens and is a sub-tennant of National Institute for Clinice Excellence (NICE). Our lease runs to 31 December 2020.

14. Contingent Liabilities

The HFEA regulates a sector that addresses some highly charged issues, of both a personal and clinical nature, which may generate close scrutiny. Some of the projects and work that the HFEA has undertaken, as well as certain decisions that the HFEA has made in 2015/16, may give rise to later challenge, including a risk of legal action.

At the date of finalising these accounts, there were two matters in litigation that may have financial consequences for the HFEA. For both, judgement is awaited and the liability will not be known until after then.

15. Related Party Transactions

a) The Department of Health is regarded as a related party. During the period the HFEA had various material transactions with the Department of Health and with some NHS Trusts for which the Department of Health is regarded as the parent Department.

During the period the HFEA received £1,120,000 (2014/15 £920,000) from the Department of Health in relation to operational Grant-in-aid and £100,00 (2014/15 £NIL) for capital Grant-in-aid. At the 31 March 2016 £Nil in grant-in-aid was due to the HFEA from the Department of Health and £Nil balances were due to the Deartment of Health from the HFEA.

The Department of Health invoiced the HFEA £31,337 in addition, we have accrued £2,660 in respect of internal audit work for the 2015/16 business year.

b) The Care Quality Commission (CQC) is regarded as a related party. During the period the HFEA had various material transactions with the CQC.

The CQC invoiced the HFEA £289,969 in relation to rent, rates and other facility costs . At 31 March 2015 we have accrued £82,818 representing rent and rates for the last quarter of 2015/16 . £Nil was due to the HFEA from the CQC.

c) The Human Tissue Authority (HTA) is regarded as a related party. During the period the HFEA had transactions with the HTA to the value of £128,172.

16. Losses and Special payments

No losses or special payments arose during the period (£nil 2014/15).

17.IFRSs, Amendments and interpretations in issue but not yet effective

The Treasury FReM does not require the following standards and interpretations to be applied in 2015/16.
IFRS 9 Financial Instruments
IFRS 16 Leases

18.Events after the Reporting Period

The Accounting Officer authorised these financial statements for issue on the date on which the accounts are certified by the Comptroller and Auditor General

Audit and Governance Committee Forward Plan

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Audit & Governance Committee Forward Plan		
Agenda item	14		
Paper number	AGC (15/06/2016) 504		
Meeting date	15 June 2016		
Author	Sue Gallone, Director of Finance & Resources		
Output:			
For information or decision?	Decision		
Recommendation	The Committee is asked to review and make any further suggestions and comments and agree the plan.		
Resource implications	None		
Implementation date	N/A		
Organisational risk	☒ Low	☐ Medium	☐ High
	Not to have a plan risks incomplete assurance, inadequate coverage or unavailability key officers or information		
Annexes	N/A		

Audit & Governance Committee Forward Plan

AGC Items Date:	21 Sept 2016	7 December 2016	Mar 2017	June 2017
Following Authority Date:	16 November 2016	January 2017	May 2017	July 2017
Meeting 'Theme/s'	Strategy & Corporate Affairs, AGC review	Register and Compliance, Business Continuity	Finance and Resources	Annual Reports, Information Governance, People
Reporting Officers	Juliet Tizzard	Nick Jones	Sue Gallone	Peter Thompson
High Level Risk Register	Yes	Yes	Yes	Yes
Information for Quality (IfQ) Programme	Yes			
Annual Report & Accounts (inc Annual Governance Statement)				Approval
External audit (NAO) strategy & work	Audit Planning Report	Update	Interim Feedback	Audit Completion Report
Information Assurance & Security				Yes
Internal Audit Recommendations Follow-up	Yes	Yes	Yes	Yes
Internal Audit	Update	Update	Early Results, approve draft plan	Plan, Results, annual opinion
Whistle Blowing, fraud (report of any incidents)	Update as necessary	Update as necessary	Update as necessary	Update as necessary
Contracts & Procurement including SLA management	Update as necessary	Update as necessary	Update as necessary	Update as necessary
HR, People Planning & Processes				Yes

AGC Items Date:	21 Sept 2016	7 December 2016	Mar 2017	June 2017
Strategy & Corporate Affairs management	Yes			
Regulatory & Register management		Yes		
Resilience & Business Continuity Management		Yes		
Finance and Resources management			Yes	
Reserves policy	Yes			
Review of AGC activities & effectiveness, terms of reference		Yes		
Legal Risks			Yes	
AGC Forward Plan	Yes	Yes	Yes	Yes
Session for Members and auditors	Yes	Yes	Yes	Yes
Other one-off items				