Strategic risks

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Audit and Governance Committee		
Agenda item	6		
Paper number	AGC (09/12/2015) 478		
Meeting date	9 December 2015		
Author	Paula Robinson, Head of Business Planning		
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 November 2015. CMG discussed all risks, their controls, and scores. A new risk relating to the forthcoming office move has been added. Six of the 13 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 Authority also received the risk register at its meeting on 11 November 2015. There were no comments on the details of the risks or the scores.

2. Risk assurance mapping

2.1. A risk assurance workshop (our first) has now been scheduled for 10 February 2016. The workshop will be run by DH Internal Audit.

2.2. As agreed previously, based on recent analyses of our operational risks, the workshop will focus on capacity and resilience. We believe this is the highest value area for us to start with. Current operational risks include turnover and recruitment, next year's office move, general resource and timescale pressures (eg, IfQ), team interdependencies and role-related bottlenecks.

3. Recommendation

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

Annex A

HFEA strategic risk register 2015/16

Risk summary: high to low residual risks

Risk area	Risk title	Strategic linkage[1]	Residual risk	Current status	Trend
Office move	OM1: Office move	Efficiency, economy and value	**16 – High**	Above tolerance	⊙ (New)
Legal challenge	LC1: Resource diversion	Efficiency, economy and value	**15 – High**	Above tolerance	⇔⇔⇔⇔
Information for Quality	IfQ1: Improved information access	Increasing and informing choice: information	**12 – High**	Above tolerance	⇔⇔⇔⇔
Financial viability	FV1: Income and expenditure	Efficiency, economy and value	**12 – High**	Above tolerance	⇔⇔⇔⇔
Data	D1: Data loss or breach	Efficiency, economy and value	**10 – Medium**	At tolerance	⇔⇔⇔⇔
Data	D2: Incorrect data released	Efficiency, economy and value	**9 – Medium**	Above tolerance	⇔⇔⇔⇩
Information for Quality	IfQ3: Delivery of promised efficiencies	Efficiency, economy and value	**9 – Medium**	At tolerance	⇔⇔⇔⇔
Donor conception	DC2: Support for OTR applicants	Setting standards: donor conception	**9 – Medium**	At tolerance	⇔⇔⇔⇔
Capability	C1: Knowledge and capability	Efficiency, economy and value	**9 – Medium**	Above tolerance	⇔⇔⇔⇔
Regulatory model	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	⇔⇔⇔⇔

[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)

The ‘trend’ column in the above table tracks the four most recent reviews by AGC, CMG, or the Authority (e.g. ⇧⇔⇩⇔).

Recent review points are:

AGC 10 June 2015 ⇨ CMG 2 September 2015 ⇨ AGC 7 October ⇨ CMG 18 November.

The Authority also recently received the risk register, at its 11 November meeting. No changes were proposed.

CMG overview

CMG reviewed the risk register and discussed each risk in detail at its meeting on 18 November.

CMG agreed that the office move, confirmed for April 2016, should now be added as a separate risk. The project plan and project risk log are being formulated now and the project was discussed at the monthly CMG meeting on 19 November. Since we are still in the early planning stages and no contract is yet in place, this comes in as our highest risk, but we expect this to decrease shortly (see the risk itself for details). The tolerance has been set quite low, at 6 (medium), since any major disruption as a result of the move could be costly to us in terms of strategic delivery.

CMG agreed that the recent judgment relating to legal parenthood, and the ensuing extensive work on consent issues, should be recognised in the two regulatory model risks. The judgment may have administrative consequences for the HFEA, and a range of additional work has already been needed. Further cases are expected over the coming months, although the HFEA is unlikely to participate in legal proceedings directly.

CMG also recognised that there are other factors which also affect the two regulatory model risks. Under the first regulatory model risk (RM1: adverse effects on the quality and safety of care if the HFEA were to fail to deliver its duties under the Act), the team Heads for both inspection and licensing are both leaving the HFEA in the next couple of months, and both are significant control owners for this risk. The controls will need to be assigned upwards pending recruitment, once they have left (in late November and January respectively). In light of this and legal parenthood considerations, we have raised the residual risk level for RM1 from 4 to 8 for the time being.

Under the second regulatory model risk (RM2: loss of regulatory authority), CMG discussed information provision risks. The HFEA’s current website is old, and based on a content management system that is error prone and difficult to manage. The IfQ work on the new website will completely mitigate this risk, but not until February 2016, when the beta phase of the project is reached. Meanwhile, we continue to tolerate the issue of regular website outages and frequent inability to publish data successfully at the first attempt, and a low risk that the old website could fail completely, preventing us from publishing any information for a period of time. This risk is informing our decisions about which content to move first to the new site, when we enter the beta phase of IfQ in February 2016. CMG did not however feel that any change in the residual risk score was merited at the moment, since good mitigations are in place.

CMG heard that indicative approval has now been received for the remaining IfQ work on the website, in that the recent Department of Health gateway review awarded excellent scores to the HFEA’s plans for delivering the remainder of the work. However, the approval decision still needs to be made formal by the GDS board, and so the final outcome will not be confirmed for a few more weeks (possibly around the time of the AGC meeting). Therefore, it is prudent to keep scores at the same level until at least that point.

The Authority also discussed the risk register, at its meeting on 11 November, and commented on issues including data security and staff turnover. No changes to scores were proposed.

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 – Debra Bloor/Nick Jones	At tolerance. The Head of Governance and Licensing and the Chief Inspector are both leaving the HFEA (in late November and mid January, respectively). While recruitment is pending, ownership of controls will move upwards to the relevant Director. This, 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).
	Audit of Epicentre to reveal data errors. Queries being routed through Licensing, who have a definitive list of all licensing details.	Completed October 2015 – Sam Hartley/Juliet Tizzard	
	Inspector training, competency-based recruitment, induction process, SOPs, QMS, and quality assurance all robust.	In place – Debra Bloor/Nick Jones	
Monitoring failure.	Outstanding recommendations from inspection reports are tracked and followed up by the team.	In place – Debra Bloor/Nick Jones	
Unresponsiveness to or mishandling of non-compliances or grade A incidents.	Update of compliance and enforcement policy.	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - Debra Bloor/Nick Jones	
	Staffing model provides resilience in the inspection team for such events – dealing with high-impact cases, additional incident inspections, etc..	In place – Debra Bloor/Nick Jones	
Insufficient inspectors or licensing staff	Inspection team up to complement following earlier recruitment. (The Chief Inspector is leaving the HFEA in January, and will be replaced on a like-for-like basis.)	In place – Debra Bloor/Nick Jones	

	Licensing team up to complement following earlier recruitment. (The Head of Governance and Licensing is leaving the HFEA in November, but will be replaced on a like-for-like basis.)	In place – Sam Hartley/Juliet Tizzard
Recruitment difficulties and/or high turnover/churn in various areas; resource gaps and resource diversion into recruitment and induction, with impacts felt across all teams.	So far recruitment rounds for inspectors and support staff have yielded sufficient candidates, although this has required going beyond the initial ALB pool to external recruitment in some cases.	Managed as needed – Debra Bloor/Nick Jones
	Additional temporary resources available during periods of vacancy and transition.	In place – Rachel Hopkins
	Group induction sessions put in place where possible.	In place – Debra Bloor/Nick Jones
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 – Debra Bloor/Nick Jones
	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 from efficiency improvements made in 2013 (acknowledged by the sector).	In place – Debra Bloor/Nick Jones
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 – Debra Bloor/Nick Jones
	Update of compliance and enforcement policy (and application of existing policy, meanwhile).	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - Debra Bloor/Nick Jones

	A detailed action plan in response to the legal parenthood judgement is being worked up. There has been correspondence with clinics, who are doing detailed audits. Through a detailed review of every clinic's responses, a summary list of all concerns is in progress. Management review meetings are taking place for all clinics at which there are handling concerns or anomalies. Plan of action being decided to address all of the concerns identified, with direct follow up with centres who have not responded at all. Where there are engagement concerns, we will do short-notice inspections, focused on parenthood consent.	In progress – Debra Bloor/Nick Jones	

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

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Failures or weaknesses in decision making processes.	Keeping up to date the standard operating procedures (SOPs) for licensing, representations and appeals.	In place – Sam Hartley/Juliet Tizzard	At tolerance. Although two additional risk sources have been identified (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 – Sam Hartley/Juliet Tizzard	
	Appeals Committee membership maintained. Ongoing process in place for regular appointments whenever vacancies occur or terms of office end.	In place – Sam Hartley/Juliet Tizzard	
	Staffing structure for sufficient committee support.	In place – Sam Hartley/Juliet Tizzard	
	Decision trees; legal advisers familiar.	In place – Sam Hartley/Juliet Tizzard	
	Proactive management of quoracy for meetings.	In place – Sam Hartley/Juliet Tizzard	
	New (ie, first application) T&S licences delegated to ELP. Delegations to be revisited during 2016 review of Standing Orders. Licensing Officer role to take certain decisions from ELP – implementation due end of 2015.	To be put in place – Sam Hartley/Juliet Tizzard Licensing Officer role – December 2015 (postponed from June 2015) Delegations in SOs – April 2016	
Failing to demonstrate competence as a regulator	Update of compliance and enforcement policy (and application of existing policy, meanwhile).	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - Debra Bloor/Nick Jones	
	Inspector training, competency-based recruitment, induction process, SOPs, quality management	In place – Debra Bloor/Nick Jones	

	system (QMS) and quality assurance all robust.	
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 – Debra Bloor/Nick Jones
	SOPs and protocols with Communications team.	In place – Debra Bloor/Nick Jones
	Fairness and transparency in licensing committee information.	In place – Debra Bloor/Nick Jones
	Dedicated section on website, so that the public can openly see our activities in the broader context.	In place – Debra Bloor/Nick Jones
Administrative or information security failure, eg, document management, risk and incident management, data security.	Staff have annual information security training (and on induction).	In place – Dave Moysen
	TRIM training and guidance/induction in records management in place. Head level 6 month contract recruited to manage the office move and review records management.	In place – SMT
	The IfQ website management project has reviewed the retention schedule.	Completed – August 2015 – Juliet Tizzard
	Guidance/induction in handling FOI requests, available to all staff.	In place – Sam Hartley/Juliet Tizzard
	Further work planned on records management in parallel with IT strategy.	Linked to IT strategy work – in progress – Jamie Munro/David Moysen
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 – Debra Bloor/Nick Jones
	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 Red-Dot). This risk is informing our decisions about which content to move first to the beta version of the new site.	In progress – beta phase February 2016 – Juliet Tizzard
Negative media or criticism from the	HFEA approach is only to go into cases on the basis	In place - Peter Thompson

sector in connection with legally disputed issues or major adverse events at clinics.	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.	
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 – Sam Hartley/Juliet Tizzard
	Update of compliance and enforcement policy (and application of existing policy meanwhile).	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - Debra Bloor/Nick Jones
	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 – Debra Bloor/Nick Jones
	QMS and quality assurance in place in inspection team.	In place – Debra Bloor/Nick Jones

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

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

Redeveloped website does not meet the needs and expectations of our various user types.	Programme approach and dedicated resources in place to manage the complexities of specifying web needs, clarifying design requirements and costs, managing changeable Government delegation and permissions structures, etc. User research done, to properly understand needs and reasons. Tendering and selection process included clear articulation of needs and expectations.	In progress – delivery by end Mar 2016 – Juliet Tizzard	HFEA, but we still need to await the formal decision on this by the Government Digital Service board (expected mid December). At this stage, therefore, there remains a risk of negative impact, although this risk now feels much lower.
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.	In place – Juliet Tizzard In place – Nick Jones (decision received April 2015)	
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 required close joint working and communication among all involved contractors during the Sprint Zero start-up phase and beyond. 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.	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 now chosen, and all involved teams happy with the selection.	In progress – implemented in beta phase, February 2016 – Juliet Tizzard	
Communications infrastructure incapable	Needs to be updated as part of IfQ in order to	In place – set out in business case –	

of supporting the planned changes.	support the changes.	Juliet Tizzard (Dec 2014)
Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedded into new ways of working.	In place – Nick Jones
Potential risks associated with the HFEA's likely office move in April 2016, in that this will coincide with the delivery period for some IfQ milestones.	Early awareness of the potential for disruption means that this can be managed through careful planning.	Being considered – Nick Jones/Sue Gallone/Jamie Munro

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

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Risks associated with data migration to new structure, together with records accuracy and data integrity issues.	IfQ programme groundwork focusing on current state of Register. Extensive planning in progress, including detailed research and migration strategy.	In place – Nick Jones/Dave Moysen	At tolerance. This risk is being intensively managed – a major focus of IfQ detailed planning work, particularly around data migration.
Historic data cleansing is needed prior to migration.	A detailed migration strategy is in place, and a data cleansing step forms part of this.	In place – Nick Jones/Dave Moysen	
Increased reporting needs mean we later discover a barrier to achieving this, or that an unanticipated level of accuracy is required, with data or fields which we do not currently focus on or deem critical for accuracy.	IfQ planning work incorporates consideration of fields and reporting needs are agreed. Decisions about the required data quality for each field were 'future proofed' as much as possible through engagement with stakeholders to anticipate future needs and build these into the design.	In place – Nick Jones	
Reliability of existing infrastructure systems – (eg, Register, EDI, network, backups).	Maintenance of desktop, network, backups, etc. core part of IT business as usual delivery.	In place – Dave Moysen	
System interdependencies change / are not recognised	Strong interdependency mapping being done between IfQ and business as usual.	Done – Nick Jones	
Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedding into new ways of working.	In place – Nick Jones	
Potential risks associated with the HFEA's likely office move in April 2016, in	Early awareness of the potential for disruption means that this can be managed through careful	Being considered – Nick Jones/Sue Gallone/Jamie Munro	

that this will coincide with the delivery period for some IfQ milestones.	planning.		

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

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Poor user acceptance of changes, or expectations not managed.	Stakeholder involvement strategy in place and user testing being incorporated into implementation phase of projects.	In place – Nick Jones/Juliet Tizzard	At tolerance.
Clinics not consulted/involved enough.	Working with stakeholders has been central to the development of IfQ, and will continue to be. Advisory Group and expert groups have ended, but a stakeholder group for the implementation phase is in place.	In place – Nick Jones/Juliet Tizzard	
Scoping and specification are insufficient for realistic resourcing and on-time delivery of changes.	Scoping and specification were elaborated with stakeholder input, so as to inform the tender. Resourcing and timely delivery were a critical part of the decision in awarding the contract.	In place and contracts awarded (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.	In place (July 2015) – Nick Jones	
Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedded into new ways of working.	In place (June 2015) – Nick Jones	

Potential risks associated with the HFEA's likely office move in April 2016, in that this will coincide with the delivery period for some IfQ milestones.	Early awareness of the potential for disruption means that this can be managed through careful planning.	Being considered – Nick Jones/Sue Gallone/Jamie Munro	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Legal challenge LC 1: Resource diversion	There is a risk that the HFEA is legally challenged in such a way that resources are diverted from strategic delivery.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Peter Thompson
			Likelihood	Impact	Inherent risk		
			4	5	20 Very high		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	**5**	**15 High**		
			Tolerance threshold:		12 High		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Complex and controversial area.	Panel of legal advisors from various firms at our disposal for advice, as well as in-house Head of Legal.	In place – Peter Thompson	Above tolerance. One case decided in the HFEA's favour at summary judgement, but is now to be appealed (in February 2016). A recent judgement on consents for parenthood may have administrative consequences for the HFEA. Further court cases are also likely, although the HFEA is unlikely to participate in legal proceedings directly. The 'M' case regarding the export of gametes for treatment abroad will also go to a final appeal in the next few months.
	Evidence-based policy decision-making and horizon scanning for new techniques.	In place – Hannah Verdin	
	Robust and transparent processes in place for seeking expert opinion – eg, external expert advisers, transparent process for gathering evidence, meetings minuted, papers available online.	In place – Hannah Verdin/Sam Hartley/Juliet Tizzard	
Lack of clarity in HFE Act and regulations, leading to the possibility of there being differing legal opinions from different legal advisers, that then have to be decided by a court.	Panel in place, as above, to get the best possible advice.	In place – Peter Thompson	
Decisions and actions of the HFEA and its committees may be contested.	Panel in place, as above.	In place – Peter Thompson	
	Maintaining, keeping up to date and publishing licensing SOPs, committee decision trees etc. Standard licensing pack completely refreshed and distributed to members/advisers (April 2015).	In place – Sam Hartley/Juliet Tizzard	
Subjectivity of judgments means the	Scenario planning is undertaken at the initiation of	In place – Peter Thompson	

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

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

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

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

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

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Poor record keeping	Refresher training and reminders about good records management practice. Head level 6 month contract to be recruited to manage the office move and review records management.	In place – SMT Head post recruitment in progress September 2015 - SMT	Above tolerance. Although we have some good controls in place for dealing with PQs and other externally generated requests, it should be noted that we cannot control incoming volumes, which in January 2015 (for example) were among the highest we have ever experienced. Volumes have decreased recently. However, at the same time, the number of FOI requests (on other subjects) has increased. FOIs, however, are less impactful owing to the longer timeframes available for responding, so we have lowered the impact score from 4 (major) to 3 (moderate) to reflect this change.
	TRIM review and retention policy implementation work – subsumed by IT strategy.	To sync in with IT strategy – Dave Moysen/Sam Hartley/Juliet Tizzard	
	Audit of Epicentre to reveal any data errors. All queries being routed through Licensing, who have a definitive list of all licensing details.	Completed October 2015 – Sam Hartley/Juliet Tizzard	
Excessive demand on systems and over-reliance on a few key expert individuals – request overload – leading to errors	PQs, FOIs and OTRs have dedicated expert staff/teams to deal with them. If more time is needed for a complex PQ, attempts are made to take the issue out of the very tightly timed PQ process and replace this with a more detailed and considered letter back to the enquirer so as to provide the necessary level of detail and accuracy in the answer. We also refer back to previous answers so as to give a check, and to ensure consistent presentation of similar data.	In place – Juliet Tizzard / Nick Jones	
	PQ SOP revised and log created, to be maintained by new Committee and Information Officer/Scientific Policy Manager.	In place - Sam Hartley/Juliet Tizzard	

Answers in Hansard may not always reflect advice from HFEA.	The PQ team attempts to catch any changes to drafted wording that may unwittingly have changed the meaning. HFEA's suggested answer and DH's final submission both to be captured in new PQ log.	In place – Sam Hartley/Juliet Tizzard / Peter Thompson	
Insufficient understanding of underlying system abilities and limitations, and/or of the topic or question, leading to data being misinterpreted or wrong data being elicited.	As above – expert staff with the appropriate knowledge and understanding in place.	In place – Juliet Tizzard / Nick Jones	
Servicing data requests for researchers - poor quality of consents obtained by clinics for disclosure of data to researchers.	There is a recognised risk of centres reporting research consents inaccurately. Work to address consent reporting issues is being planned.	Actions to be confirmed – end of November 2015 – 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 pilot 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, and we will make further assessments based on early uptake and the delivery experience. Reporting to the Authority will occur annually during the pilot period.
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) – In June the ongoing management of the Pilot transferred to Rosetta Wotton.	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Financial viability FV 1: Income and expenditure	There is a risk that the HFEA could significantly overspend (where significantly = 5% of budget, £250k)	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Sue Gallone
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			4	**3**	**12 High**		
			Tolerance threshold:		9 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Fee regime makes us dependent on sector activity levels.	Activity levels are tracked and change is discussed at CMG, who would consider what work to deprioritise and reduce expenditure.	Monthly (on-going) – Sue Gallone	Above tolerance, but 2014/15 overspend was able to be met from reserves. 2015/16 on course for small under-spend but risk of legal costs remains. In November 2015, the Authority approved a proposal to increase per-cycle fees by £5 (to £80) and to end the small 'eSET discount' for elective single embryo transfer, which has been in place for a few years to assist with the introduction of the Authority's multiple births policy (now firmly established and in place). This should help secure sufficient funds going forward.
	Fees Group created enabling dialogue with sector about fee levels. Fee increase agreed (November 2015), and eSET discount to end, subject to Treasury agreement.	In place. Fees Group meetings in April and 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	
	Budget discussions with DH finance to set out needs in context of spending review.	November and December 2015 – Sue Gallone	
Budget setting process is poor due to lack of information from directorates	Quarterly meetings with directorates flags any short-fall or further funding requirements.	Quarterly meetings (on-going) – Morounke Akingbola	
Unforeseen increase in costs eg, legal, IfQ or extra in-year work required	Use of reserves, up to contingency level available. DH kept abreast of current situation and are a final source of additional funding if required. 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	Periodic review of actual and budgeted spend by IfQ project board and monthly budget meetings with	Ongoing – Wilhelmina Crown	

projects eg, IfQ.	finance.		
	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: Likelihood: 4 / Impact: 4 / Inherent risk: 16 High Residual risk level: Likelihood: **3** / Impact: **3** / Residual risk: **9 Medium** Tolerance threshold: 6 Medium	⇩ ⇔ ⇔ ⇔	Peter Thompson

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
High turnover, sick leave etc. leading to temporary knowledge loss and capability gaps.	People strategy will partially mitigate. Mixed approach of retention, staff development, and effective management of vacancies and recruitment processes.	Done – May 2015 – Rachel Hopkins	Above tolerance. This risk and the set of controls remains focused on capability, rather than capacity. There are obviously some linkages, since managing turnover and churn also means managing fluctuations in capability and ensuring knowledge and skills are successfully nurtured and/or handed over. When the period of highest turnover appeared to be ending (May 2015), CMG slightly reduced the likelihood of this risk, but still decided to retain it, given that high turnover could recur. Indeed this may now be starting to happen. Since the HFEA is a small organisation, with little intrinsic resilience, it seems prudent to have a low tolerance level for this risk.
	A programme of development work is planned to ensure staff have the skills needed, so as to ensure they and the organisation are equipped under any future model, maximising our resilience and flexibility as much as possible. Staff can access civil service learning (CSL); organisational standard is five working days per year of learning and development for each member of staff.	In place – Rachel Hopkins	
	Organisational knowledge captured via records management (TRIM), case manager software, project records, handovers and induction notes, and manager engagement.	In place – Rachel Hopkins	
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 has been proactive in reducing its headcount and other costs to minimal levels over a number of years. We have also already been reviewed extensively (including the McCracken review). 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 on Oct 2014 all staff conference.	Survey done (Jan 2015) – 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.	In place – Paula Robinson
	Early emphasis given to team-level service delivery planning for 2015, with active involvement of team members. Delivery (and resources) in Q1 to date were also considered at monthly CMG in May, and delivery is currently on track. CMG will continue to review this.	In place (Jan 2015) – Paula Robinson
	Moratorium on new project work under consideration in planning for remainder of 2015/16 and for 2016/17, so as to prioritise IfQ delivery and therefore strategy delivery) within our limited resources.	Ongoing dialogue about this in place as part of business planning (August 2015 onwards) – Paula Robinson
	IfQ has some of its own dedicated resources.	In place – Nick Jones
	There is a degree of flexibility within our resources, and increasing resilience is a key consideration whenever a post becomes vacant. Staff are encouraged to identify personal development opportunities with their manager, through the PDP process, making good use of Civil Service Learning.	In place – Peter Thompson

Regarding the 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.	New issue for consideration – Juliet Tizzard	

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner
Office move OM 1: Office move	There is a risk that the office move could compromise our capability and capacity to deliver our strategy.	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: **4** / Impact: **4** / Residual risk: **16 High** Tolerance threshold: 6 Medium	New ⊙	Sue Gallone

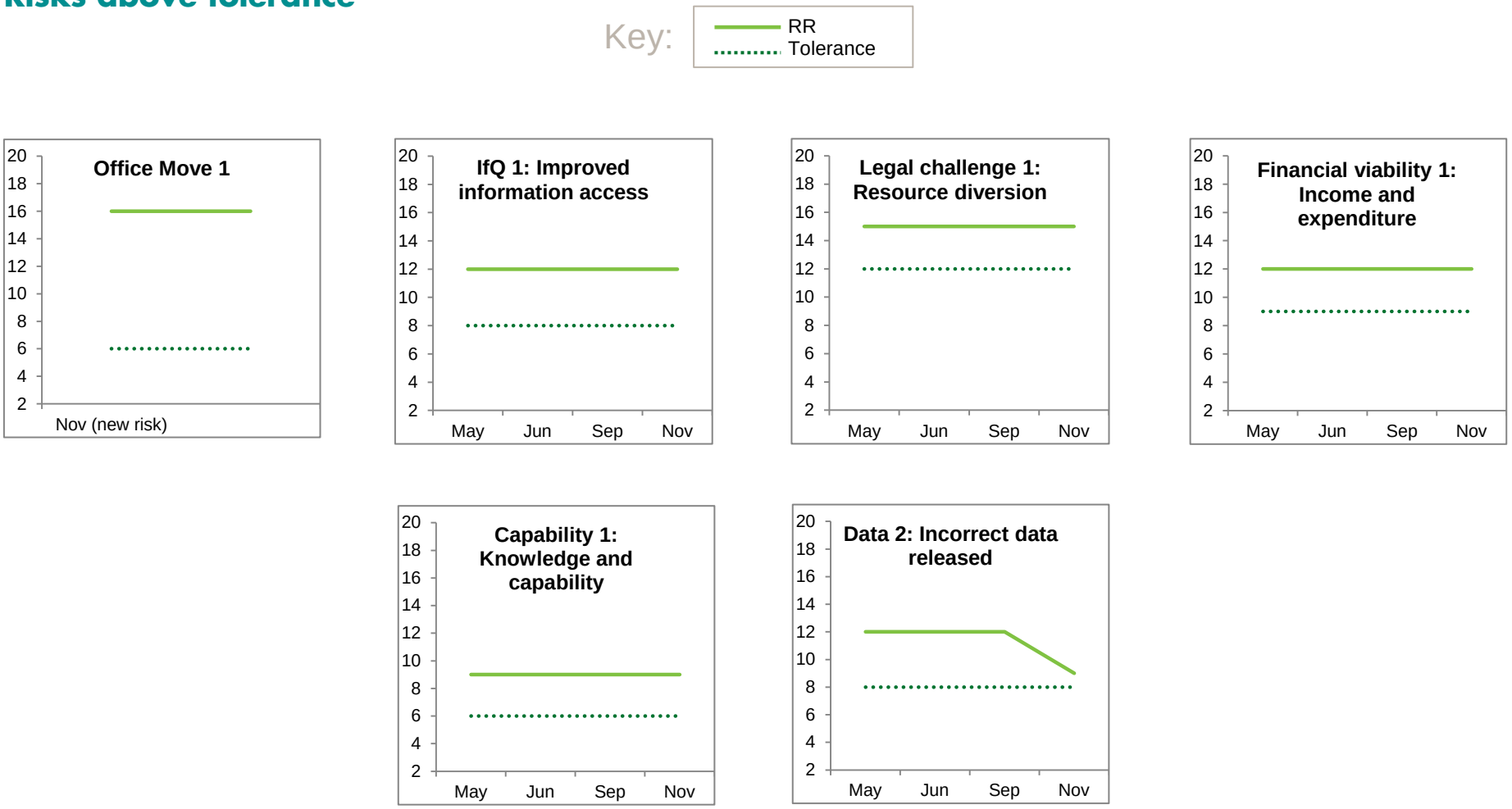
Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Contractual risks.	Contract being drafted by NICE. Signing should follow shortly.	By early December 2015 - Sue Gallone	Above tolerance for now, until more detailed planning and assurance work has been done. This is underway. We feel that the likelihood should be able to be reduced as soon as certain things have been resolved, eg, contract signed, staff engagement group fully started up, Office 365 implications and timing of any data migration clearer. All these things are being actively worked on now.
Preparation and space planning risks, including establishing clarity about the facilities available in the building (eg, lockers).	Project manager in place. Staff engagement group being established. Detailed information becoming available about the new office space. Visits started, building relationship with NICE facilities team.	From now until the move – Jamie Munro	
Storage availability will be limited. The HFEA has some unavoidable paper records in Register team, Legal, Finance.	Planning work being done to identify unavoidable paper records, and to determine whether any of these can be scanned to reduce storage needs.	For resolution by end of January 2016 – Jamie Munro	
The office will be shared, and there will be generally less space, and limited meeting room availability.	The meeting room risk mainly applies to smaller meetings such as one to ones. Larger meeting room availability in the building is manageable. Meeting rooms are being secured in advance from April/May onwards (on a like-for-like basis). Staff engagement group to consider cultural and ways of working impact of having less ‘free space’ in which to have impromptu or small meetings. Trips to the new office will be planned so that staff can see the space. Our IT kit will be replaced with laptops/tablets before the move, so that smaller desks will not be an issue. There will be preparation planned in before the move, to deal with the reality of reduced storage (eg, ‘Tidy Fridays’ etc. - but staff capacity for this will be very limited owing to IfQ and other high workloads).	From now until the move and slightly beyond – Jamie Munro	

The actual move – practical risks.	We will be moving minimal kit and no desks, reducing both risk and cost. Detailed planning and communications will take place with all involved, including contractors, NICE and HFEA staff. Following procurement framework to select contractors, and selecting carefully.	From now until the move – Jamie Munro
Cabling risks – ensuring communications lines are available to HFEA in new office.	Establish needs and place orders as necessary.	From now until the move – David Moysen
IT risks (information security, business continuity, introduction of new equipment and Office 365 upgrade in advance of move).	Office 365 upgrade project in place to include issuing of new laptops. Register safeguards will be put in place; security of new Comms Room will be considered with NICE. Business continuity plan already in place, and arrangements will continue for now – to be reviewed after move. Planned timing of surrounding tasks (eg, IfQ milestone delivery) will need to allow for some down-time. Back-ups will continue and will be stored off site as now.	From now until the move and slightly beyond – David Moysen
People risks: resources to participate in planning, packing etc., turnover and/or extra management work resulting from change of location, engagement on ways of working, willingness to adapt etc.	Staff engagement, communications and HR contractual considerations built into project plan. Staff engagement group being established and first meeting being planned. Staff being issued with new, smarter IT kit, including tablets/laptops replacing PCs, a better access method for secure HFEA login, and Office 365 available.	In place and ongoing – Jo Triggs
Diversion from business. Coincides with the delivery period for some IfQ milestones, which are key to delivering	Early awareness of the potential for disruption means that this can be managed through careful	Detailed planning and awareness raising beginning in November – Paula Robinson (and all managers)

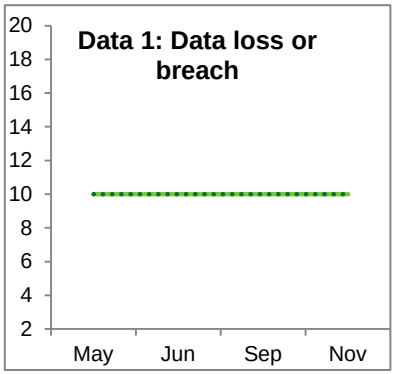
our strategy to publicly announced timescales. Some other work will also coincide because of year-end considerations.	planning and prioritisation.		
Cost increase compared to current rent.	Unavoidable, but in keeping with DH requirements which will reduce costs overall for the health ALBs as a whole group. Costs factored into to funding required from 2016/17. Business case includes ensuring the HFEA is in line with Government Estates Strategy.	In place – Sue Gallone	
Project failure - The move could fail to take place if unforeseen issues arise, or the timetable could be jeopardised by factors outside the HFEA's control.	Contract will shortly be secured and planning is in place. Should the new building become unavailable for some reason, at any point, (eg, fire, flood), business continuity arrangements would apply while a new plan was put in place. (There is no option to stay on in Finsbury Tower beyond April.)	Detailed risk-based planning in place – Jamie Munro	

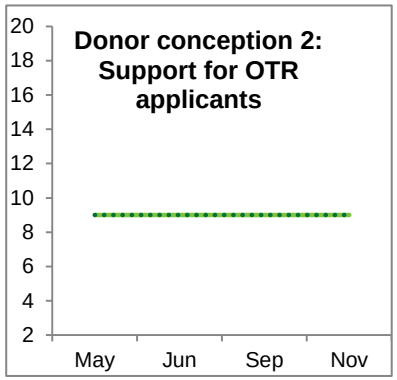
Tolerance vs Residual Risk:

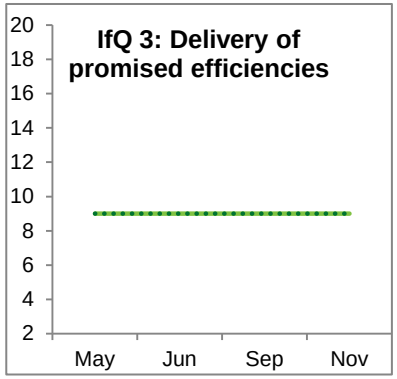
Risks above tolerance

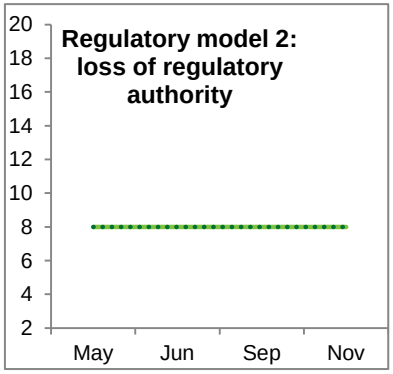


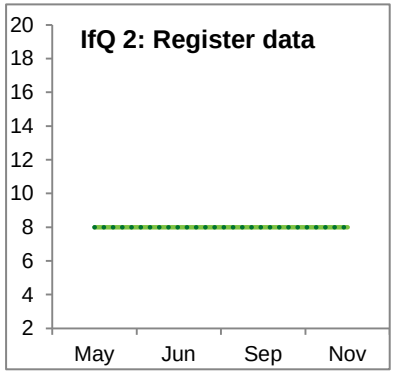
Risks at tolerance

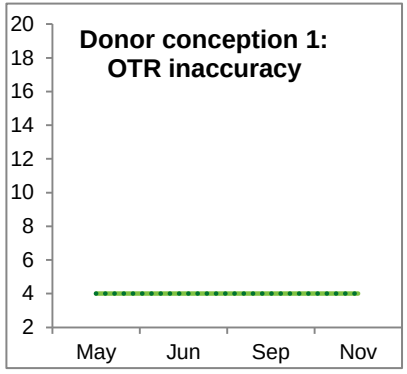












Risk below tolerance

None.

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

HFEA Internal Audit Progress Report

1) Purpose of paper

This paper sets out the progress to against the 2015/16 Audit Plan since the last Audit and Governance Committee in October 2015.

2) Progress against 2015/16 Internal Audit Plan

2.1 Status of agreed plan:

The table below summarises the progress against each of the review areas in the 2015/16 Audit Plan.

Reviews per 2015/16 IA plan	Audit scope per 2015/16 plan	Status	Findings			Overall report rating	Audit days per plan	Revised audit days	Actual audit days
			High	Medium	Low				
Requests for Information	The HFEA may be required to release information as a result of: • Parliamentary Questions (PQs); • Freedom of Information (FOI) requests; and • Data Protection (DP) requests. We will examine current policies and procedures for the release of information under these circumstances and consider whether: • Current policies and procedures cover all relevant information held by the HFEA to which PQs, FOI and DP requests might relate; • Authorisation for the release of information is restricted to the appropriate committees and/or individuals; and • Risks in relation to the release of sensitive information have been identified, are regularly monitored, and are aligned to mitigating	Final report issued 26/10/15	0	2	2	**Moderate**	15	10.5	10.5

Reviews per 2015/16 IA plan	Audit scope per 2015/16 plan	Status	Findings			Overall report rating	Audit days per plan	Revised audit days	Actual audit days
			High	Medium	Low				
	controls.								
Incident Handling	It is a requirement of licensed centres to report adverse incidents to the HFEA, where adverse incidents are described as 'any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos and/or gametes, or to staff or a licensed centre.' NOTE: there are circa 500 incidents raised in each year in relation to circa 50,000 activities undertaken by the clinics. These incidents must be notified to the HFEA within 24 hours of their taking place. Once these reports are received, the HFEA must investigate the incident and respond in line with its Compliance and Enforcement Policy. In addition, HFEA has a responsibility to review and respond to complaints made against clinics. Circa 10 complaints are received each year. We will review current policies and procedures relating to incident and complaints reporting and responses and consider whether: • The HFEA's responses to reported incidents and complaints in the 12 months to the date of fieldwork have been conducted in line with agreed procedures; • The HFEA produces and retains sufficient documentation to support its response to incident and complaint reports; • Clear and sufficient information is available to all licensed centres to encourage the timely and	Final report issued 24/11/15	0	0	6	**Moderate**	12	10	10

Reviews per 2015/16 IA plan	Audit scope per 2015/16 plan	Status	Findings			Overall report rating	Audit days per plan	Revised audit days	Actual audit days
			High	Medium	Low				
	appropriate reporting of adverse incidents and complaints; • HFEA has appropriate performance reporting of all incidents and complaints in order to make appropriate management decisions on their relationships with the clinics.								
Data Migration – Register of Treatments	Building on the 2014/15 'Register of Treatments' review, we will: • Provide 'critical friend' input into the work performed by the HFEA to migrate data to the new Register of Treatments database; • Test a sample of data between the old and new Registers to verify the accuracy and completeness of data.	First update memo issued September 2015	N/A – No ratings provided			N/A	12	10.5	3
Assurance mapping	The focus of assurance mapping of 'capacity and resilience' has been agreed with the Director of Finance and Resources and the Head of Business Planning.	Final ToR issued 27/11/15. Workshop agreed for 10/02/15	N/A – No ratings provided			N/A	0	3	1
Audit Management	All aspects of audit management to include: • Attendance at liaison meetings and HFEA Audit and Governance committees; • Drafting committee papers/progress reports; • Follow-up work; • Drafting 2016/17 audit plan; • Resourcing and risk management; and • Contingency.	Ongoing	N/A – No ratings provided			N/A	8.4 (inc. 2.4 days c/f from 14/15)	8.9	7
		Total Findings:	**0**	**2**	**8**				
						Total days	**47.4**	**42.9**	**31.5**

2.2 Summary of reports issued since the last Audit and Governance Committee:

Since the last Audit and Governance Committee in October 2015 we have issued:

- The final Request for Information report; and
- The final Incident Handling report.

A summary of the findings from these reports are set out overleaf.

Requests for information (*Overall report rating: MODERATE*):

- **Policies and Procedures are overdue for review (*No rating)***
  It was noted that the Information Access Policy (last updated October 2010) and Information Access SOP (last updated in June 2012) were overdue for review at the date of the audit, and the PQ SOP was under review at the audit date (previously reviewed in October 2011). However, given that an overall finding around outdated policies was raised as part of the Internal Policies review in 2014/15 (Ref: HFEA201415003, Finding #2), we have not raised this as a detailed finding in Section 2 of the report.

- **Formal written authorisation is currently not required prior to submission of responses to PQs and FOI requests *(Medium)***
  The PQ SOP states that the Chief Executive is required to sign-off all PQs prior to submission of responses. However, formal written authorisation is currently not required and therefore it was not possible to see evidence of this authorisation taking place during our audit testing. In addition, whilst responses to FOI requests are signed off by the Information Access and Policy Manager, again no formal written authorisation was available to demonstrate this.

- **Failure to meet the 48 hour deadline for PQs in two cases since 1st January 2015 was at least in part due to staff availability *(Medium)***
  HFEA have missed the 48 hour deadline for PQs in two out of 75 cases since the start of the calendar year. In both cases, the reason was in part staff availability, where the staff members required to respond to the request were not available to prepare the response. This suggests that there may be a business resilience risk that requires addressing, to ensure that KPIs are not breached, and prevent damage to HFEA's reputation.

- **The audit trail held on TRIM (the Authority's Information Management system) for PQs is not currently sufficient to show how policies and procedures have been adhered to *(Low)***
  Currently the only information held on TRIM to show the PQ response process for each request is the draft response prepared to send back to parliament. Information on the date the initial request was received, and the date that the initial response was sent back to the Department of

Health, however, is not stored on TRIM. Whilst this information was made available from staff members' email inboxes for the purposes of the audit testing, there is a risk that key audit trail evidence is lost if not held on TRIM.

- **There is scope to improve the PQ log to allow for easier access to groups of similar requests, and access rights to the PQ log are not currently restricted *(Low)***
  As noted above, a new PQ log was introduced prior to the 2015 summer parliamentary recess, with the aim of ensuring accessibility to previous similar PQs and therefore the consistency of responses provided. Whilst the log is not yet fully operational, the aim going forward is that it will list all PQs received, and responses given. It was noted that currently any staff member at HFEA can access and edit the PQ log. Access to edit the log should be restricted to the appropriate individuals.

Incident Handling (*Overall report rating: MODERATE*):

- **The Risk Matrix in the policy is not entirely reflective of the incident severity grading in practice *(Low)***
  There is a Risk Matrix that has been developed which is designed to show how incidents will be assessed according to the severity of incidents and near misses, and the likelihood of recurrence. However, as drawn it is not entirely reflective of incident severity grades in practice and therefore should be reviewed.

- **Policies and Procedures are overdue for review *(Low)***
  At the time of our review a number of policies and procedures were under review. The SOP for managing patient complaints and SOP for management of Grade A adverse incidents were both last updated in August 2012, the SOP for management of the Grade B and C adverse incidents was last updated in November 2011, and the Compliance and Enforcement Policy in October 2011. Management need to complete the process of updating the policies and procedures.

- **Rationale for closure of a complaint is not documented within the Epicentre system *(Low)***
  We identified one complaint from our sample of five where the complainant had indicated that they were not satisfied with the response to the complaint. In such circumstances the SOP indicates that there would be further follow up. In this particular instance we understand that it was felt that further correspondence would not change the outcome and might be unhelpful, so no further actions were taken but this rationale was not formally documented.

- **Performance reporting of incidents and complaints is not formalised *(Low)***
  We understand that the number of incidents and complaints are reported to, and discussed within, management and trends monitored. However, there are no formal reports or evidence of discussion in meetings to demonstrate that this is taking place.

- **Some documents on the Epicentre system cannot be opened *(Low)***
  We noted that some Word documents (six that we found) cannot be opened from Epicentre due to IT issues. The documents can, if required, be found and opened on TRIM.

2.3 Follow-up work:

The HFEA performs its own follow-up work where it reviews the status of agreed audit actions prior to each Audit and Governance Committee.

As such, Internal Audit has been asked to provide independent assurance only over those agreed actions which relate to high priority recommendations. This approach was agreed with the Director of Finance and Resources.

No high risk issues have been raised as part of the 2015/16 plan. However, two high risk issues from the 2014/15 Internal Policies review were outstanding at date of our last IA progress report in October 2015, and are therefore reviewed below.

Below is the current status for both of the two high risk issues:

	Complete
	In progress (within agreed timescale)
	In progress (original timescale elapsed)
	No action yet taken

Name of Audit	Issue	Management Action	Responsible Officer and Timescale	Current Status
Internal Policies Review	Completeness of register and allocation of ownership of register and policies. The register is not complete, with policies currently available to staff not being included within the register. We understand that a staff member from the Governance and Licensing team has been allocated from January 2015 with responsibility for keeping the register up to date going forward and liaising with individual departments to ensure that policies are current and reflect best practice.	Complete list to be compiled, to specification outlined in recommendation. Proposals for priority of update/ streamlining of policies to be considered by SMT.	Complete list to be in place by end April 2015. Priorities/streamlining of policies to be considered by SMT by end August 2015 Both actions owned by Head of Governance and Licensing (HoGL)	SMT have reviewed and approved the proposed SOP for the maintenance of policies, including the register and timetable for completion of the outstanding policies.
Internal Policies Review	The majority of policies evidenced on the register are past their revision date and are not subject to version control. From review of 46 HFEA policies on the Register, we found that only two were up to date as at the date of this review.	SMT to give consideration to process to be used to introduce/	Set process for introduction/revision/ monitoring of policies to be in place by end	As above.

Name of Audit	Issue	Management Action	Responsible Officer and Timescale	Current Status
	There are also no set procedures for documentation standards for policy creation or the subsequent monitoring of policies. We note from discussion with Heads of departments that the organisation had gone through a period of uncertainty in previous years insofar as its main responsibilities were considered for transfer to the Care Quality Commission, and that this may have delayed the proactive update of policies. Subsequent to the decision by Government to not progress this transfer further in January 2013, and also to not pursue a further proposal to merge the Human Tissue Authority and HFEA, as announced by the Department of Health in July 2013, Heads of departments have begun to re-engage with the process of ensuring that policies are reviewed and up to date. We note the uniform and positive view from all Heads of departments to ensure that this is now addressed as a matter of urgency.	revise/monitor policies, proportionate to size of HFEA and number of functions	June 2015 Owner: HoGL	

2.4 Impact on Annual Governance Statement:

All reports issued with a high risk rating or report findings that are individually rated high risk will have an impact on the Authority's Annual Governance Statement (AGS). To date, no high risk issues have been raised as a result of work undertaken during 2015/16. However, if the high risk issues remain outstanding by the end of 2015/16, they should again be referenced in the AGS.

Internal Audit coverage 2013/14 - 15/16:

Review area	High-level scope	2013/14	2014/15	2015/16
Strategy/Compliance				
Francis and McCracken	Robust arrangements are in place to respond to the recommendations of the Francis and McCracken reports.	4		
Corporate Governance	An assessment of the efficacy of key HFEA committees	4		
Risk Management	Review and testing of the arrangements in place for managing risk at all levels across HFEA, including monitoring, filtering and escalation processes.	4		
Internal Policies	Review of the HFEA's arrangements to monitor, review and refresh key policies, procedures and terms of reference.		4	
Operational				
Requests for information	Review of policies and procedures in relation to Parliamentary Questions (PQs), Freedom of Information (FOI) requests and Data Protection (DP) requests.			4
Incident Handling	Review of current policies and procedures relating to incident and complaints reporting and responses			4
Financial				
Payroll and expenses	Accuracy and completeness of payments payroll and expense payments. Compliance with HMRC rules of payments for expenses and emoluments made to committee members	4		
Standing Financial Instructions	Assurance over current standing financial instructions, including a comparison with HFEA's existing arrangement versus good/best practice.		4	
Information Technology				
Information for Quality	Assurance over the IfQ programme using PwC's 'Twelve Elements Top Down Project Assurance Model'.		4	
Register of treatments	'Critical friend' input into key project meetings in relation to the migration of data to the new register of treatments.		4	
Data migration – Register of treatments	'Critical friend' input into the work performed by the HFEA to migrate data to the new Register of Treatments database. Testing a sample of data between the old and new Registers to verify the accuracy and completeness of data.			4

Appendix A – Report Rating Definitions

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.

Appendix B - Limitations and responsibilities

Internal control

Internal control systems, no matter how well designed and operated, are affected by inherent limitations. These include the possibility of poor judgment in decision-making, human error, control processes being deliberately circumvented by employees and others, management overriding controls and the occurrence of unforeseeable circumstances.

Future periods

Historic evaluation of effectiveness is not relevant to future periods due to the risk that:

- the design of controls may become inadequate because of changes in operating environment, law, regulation or other; or
- the degree of compliance with policies and procedures may deteriorate.

Responsibilities of management and internal auditors

It is management's responsibility to develop and maintain sound systems of risk management, internal control and governance and for the prevention and detection of irregularities and fraud. Internal audit work should not be seen as a substitute for management's responsibilities for the design and operation of these systems.

We endeavour to plan our work so that we have a reasonable expectation of detecting significant control weaknesses and, if detected, we shall carry out additional work directed towards identification of consequent fraud or other irregularities. However, internal audit procedures alone, even when carried out with due professional care, do not guarantee that fraud will be detected.

Accordingly, our examinations as internal auditors should not be relied upon solely to disclose fraud, defalcations or other irregularities which may exist.

This report has been prepared solely for the Human Fertilisation & Embryology Authority in accordance with the terms and conditions set out in our engagement letter with the Department of Health. We do not accept or assume any liability or duty of care for any other purpose or to any other party. This report should not be disclosed to any third party, quoted or referred to without our prior written consent.

Our Internal audit work has been performed in accordance with Public Sector Internal Auditing Standards (PSIAS). As a result, our work and deliverables are not designed or intended to comply with the International Auditing and Assurance Standards Board (IAASB) and International Framework for Assurance Engagements (IFAE).

Health Group Internal Audit

REFERENCE NUMBER: DHX215008002
FINAL REPORT
HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY
NOVEMBER 2015

Health Group Internal Audit provides an objective and independent assurance, analysis and consulting service to the Department of Health and its arms length bodies, bringing a disciplined approach to evaluating and improving the effectiveness of risk management, control and governance processes.

Health Group Internal Audit focuses on business priorities and key risks, delivering its service through three core approaches across all corporate and programme activity:

- Review and evaluation of internal controls and processes;
- Advice to support management in making improvements in risk management, control and governance; and
- Analysis of policies, procedures and operations against good practice.

Health Group Internal Audit findings and recommendations:

- Form the basis of an independent opinion to the Accounting Officers and Audit Committees of the Department of Health and its arms length bodies on the degree to which risk management, control and governance support the achievement of objectives; and
- Add value to management by providing a basis and catalyst for improving operations.

For further information please contact:

Bronwyn Baker

01132 54 5515 – 1N16 Quarry House, Quarry Hill, Leeds, LS2 7UE

INCIDENT HANDLING

Overall report rating: Moderate

Our work has been conducted and our report prepared solely for the benefit of the Department of Health and its arms length bodies and in accordance with a defined and agreed terms of reference. In doing so, we have not taken into account the considerations of any third parties. Accordingly, as our report may not consider issues relevant to such third parties, any use they may choose to make of our report is entirely at their own risk and we accept no responsibility whatsoever in relation to such use. Any third parties requiring access to the report may be required to sign 'hold harmless' letters.

CONTENTS **PAGE**

Date fieldwork completed:	**05 October 2015**
Staff survey results available	**22 October 2015**
Staff survey results assessed	**28 October 2015**
1st draft report issued:	**28 October 2015**
Management responses received:	**19 November 2015**
Final report issued	**24 November 2015**

Report Author:	Umair Khan
Version №:	2
Date:	24/11/2015

Health Group
Internal Audit

Distribution List – Draft Report

Main recipient

Sue Gallone

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Distribution List – Final Report

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1. Introduction

1.1 This review has been undertaken as part of the 2015/16 Internal Audit Plan which was approved by the Audit and Governance Committee.

1.2 It is a requirement for licensed centres to report adverse incidents to the HFEA, with adverse incidents defined as 'any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos and/or gametes, or to staff or a licensed centre'. There are approximately 500 incidents reported each year from around 50,000 activities undertaken by clinics.

1.3 All incidents must be notified to the HFEA within 24 hours of them taking place. Once reports are received, the HFEA must consider the issue, investigate (if appropriate) and respond in line with its adverse incident management protocols. Incidents reported to HFEA are graded A, B and C according to their severity and likelihood of recurrence, with A being the most severe. Category A and more severe Category B incidents would lead to an investigation. In the 12 months to September 2015, there were 434 incidents reported which included one Grade A, 185 Grade B and 251 Grade C.

1.4 We have reviewed procedures relating to incident handling and complaints management. This included whether:

- The HFEA's responses to reported incidents and complaints in the 12 months to the date of fieldwork has been in line with agreed procedures;
- The HFEA produces and retains sufficient documentation to support its response to incident and complaints received;
- Clear and sufficient information is available to all licensed centres to encourage the timely and appropriate reporting of adverse incidents and complaints; and
- HFEA has appropriate performance reporting of all incidents and complaints in order to make appropriate management decisions on their relationships with the clinics.

1.5 In addition, within this review we have considered HFEA's management of complaints. HFEA has a limited responsibility to review and respond to complaints made against clinics where the matter indicates that a clinic may not have complied with the terms of its licence, including if a clinic has not followed its own complaints process in dealing with a complaint. We understand that approximately 60 patient "queries" are received annually, of which perhaps 10 might represent formal complaints that warrant further investigation. Queries will typically relate to matters that centres should respond to under their own complaints process, but will be deemed formal complaints if it is established that the matter concerns either non-compliance with the licence or if a

centre has failed to follow its complaints process. In the year from 1 October 2014, HFEA had received 73 queries, of which 13 had been deemed formal complaints.

1.6 As part of our work we tested a sample of 25 incidents, including the Grade A, 10 Grade B and 14 Grade C incidents. We also reviewed a sample of five formal complaints from the total of 13 in the last 12 months to ensure that matters have been handled by HFEA in line with the Standard Operating Procedures ('SOPs').

1.7 In addition, as a further part of our review we worked with management to develop a survey to clinics to assess the level of awareness of their responsibility for raising incidents with the HFEA and to collate views on the effectiveness of the process. The survey was issued with the Clinic Focus paper in September 2015 which is sent to all clinics (approximately 130) and has a total of around 500 subscribers. The results of the survey have been included in the appendix to this report, although unfortunately there were only eight responses which means the results must be treated with caution.

2. Review conclusion

2.1 The overall rating for the report is **Moderate** - some improvements are required to enhance the adequacy and effectiveness of the framework of governance, risk management and control.

3. Summary of Findings

3.1 **The Risk Matrix in the policy is not entirely reflective of the incident severity grading in practice**
There is a Risk Matrix that has been developed which is designed to show how incidents will be assessed according to the severity of incidents and near misses, and the likelihood of recurrence. However, as drawn it is not entirely reflective of incident severity grades in practice and therefore should be reviewed.

3.2 **Policies and Procedures are overdue for review**
At the time of our review a number of policies and procedures were under review. The SOP for managing patient complaints and SOP for management of Grade A adverse incidents were both last updated in August 2012, the SOP for management of the Grade B and C adverse incidents was last updated in November 2011, and the Compliance and Enforcement Policy in October 2011. Management need to complete the process of updating the policies and procedures.

3.3 **Rationale for closure of a complaint is not documented within the Epicentre system**
We identified one complaint from our sample of five where the complainant had indicated that they were not satisfied with the response to the complaint. In such circumstances the SOP indicates that there would be further follow up. In this particular instance we understand that it was felt that further correspondence

would not change the outcome and might be unhelpful, so no further actions were taken but this rationale was not formally documented.

3.4 **Performance reporting of incidents and complaints is not formalised.**
We understand that the number of incidents and complaints are reported to, and discussed within, management and trends monitored. However, there are no formal reports or evidence of discussion in meetings to demonstrate that this is taking place.

3.5 **Some documents on the Epicentre system cannot be opened.**
We noted that some Word documents (six that we found) cannot be opened from Epicentre due to IT issues. The documents can, if required, be found and opened on TRIM.

Survey results

3.6 As explained, the number of responses to the Survey means that results need to be treated with caution. However, it is positive that respondents had read the Annual Complaints Report, regularly read Clinic Focus and had used articles and the report on incidents to review local practices. One outcome of note is that two of the respondents stated that they did feel inhibited in reporting incidents, citing the culture at a clinic and job safety, that a report would be scrutinised at a subsequent inspection and HFEA's focus on seeing a reduction in the level of B and C rated incidents as factors This tension will exist as a result of the nature of regulation, but the comments should be taken to highlight the need to continually monitor the balance of communications.

Summary of Findings

3.7 The table below summaries the number of findings by rating:

	High	Medium	Low
Policies and Procedures	0	0	1
Risk Management	0	0	1
Incidents and complaints handling	0	0	2
Documentation	0	0	1
Survey	0	0	1
Total	**0**	**0**	**6**

3.8 Section 2 of this report includes specific and detailed recommendations against observations and findings.

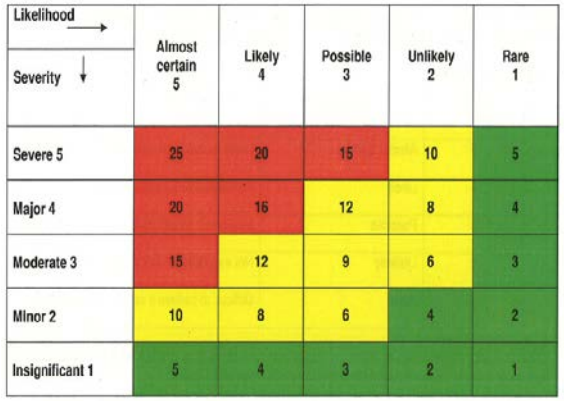
4. Action Required

4.1 Public Sector Internal Audit Standards require you to consider the recommendations made in Section 2; and complete section 3 (Agreed Action Plan) detailing what

action you are intending to take to address the individual recommendations, the owner of the planned actions and the planned implementation date. The agreed action plan will then form the basis of subsequent audit activity to verify that the recommendations have been implemented effectively.

4.2 Finally, we would like to thank management for their help and assistance during this review.

Detailed Findings

<table>
<tr><th>IMPORTANCE</th><th>NO</th><th>FINDING/OBSERVATION</th><th>RISK/IMPLICATION</th><th>RECOMMENDATION</th></tr>
<tr><td>Low</td><td>1</td><td colspan="3"><u>Risk Management</u>
The Risk Matrix in the policy is not entirely reflective of the incident grading in practice</td></tr>
<tr><td></td><td></td><td>Incidents reported to HFEA are graded A (red), B (yellow) and C (green) according to their severity and likelihood of recurrence. This is depicted in the policy by way of the following Risk Matrix:
 
<table>
<tr><th>Likelihood →
Severity ↓</th><th>Almost certain 5</th><th>Likely 4</th><th>Possible 3</th><th>Unlikely 2</th><th>Rare 1</th></tr>
<tr><td>Severe 5</td><td>25</td><td>20</td><td>15</td><td>10</td><td>5</td></tr>
<tr><td>Major 4</td><td>20</td><td>16</td><td>12</td><td>8</td><td>4</td></tr>
<tr><td>Moderate 3</td><td>15</td><td>12</td><td>9</td><td>6</td><td>3</td></tr>
<tr><td>Minor 2</td><td>10</td><td>8</td><td>6</td><td>4</td><td>2</td></tr>
<tr><td>Insignificant 1</td><td>5</td><td>4</td><td>3</td><td>2</td><td>1</td></tr>
</table>
When we reviewed the grading of our sample of 25 incidents, the gradings applied appeared reasonable to us under the framework but in some cases did not fully align with the matrix. For instance, a severe incident is usually rare and might rightly be graded A, but per the matrix rare incidents are all coloured green regardless of their severity. Similarly, mild to moderate OHSS (Ovarian Hyper stimulation Syndrome) is a known and fairly common side effect of fertility treatment and is graded C in practice, but per the matrix it might be</td><td>There may be uncertainty as to the grading of incidents, which could lead to an inconsistent response and potential for challenge.

In practice, the limited number of staff involved in the process means coding is likely to be consistent, but could be open to question by someone referring to the matrix.</td><td>The risk matrix should be reviewed to see whether it can be updated to better reflect the balance between severity and likelihood of recurrence.</td></tr>
</table>

Detailed Findings

IMPORTANCE	NO	FINDING/OBSERVATION	RISK/IMPLICATION	RECOMMENDATION
		argued to be Grade B as whilst the severity is minor the likelihood is likely or possible.		
Low	**2**	**<u>Policies and Procedures</u>** **Key Policies and Procedures are overdue for review**		
		We noted that a number of key policies and procedures are under review having not been updated for some time: • The SOP for Managing Patient Complaints and that for Managing A grade Adverse Incidents have not been updated since August 2012; • The SOP for Managing B and C grade Incidents has not been updated since November 2011; and • The Compliance and Enforcement Policy has not been updated since October 2011. The version published on the HFEA website states that it is due for review in April 2013. We noted that within the existing policies there are some references to certain systems and processes that are no longer applicable or relevant. However, we recognise that this has been identified by management and that these policies and procedures are already undergoing review. We also noted that the narrative for the Grade A category states that an inspection is required for these	Staff may not be fully aware of the required process for managing incidents and complaints. This could lead to HFEA's response being inappropriate or ineffective. Lapses in process may be more likely to arise if there is staff turnover or if roles have to be reassigned during a period of absence of a key individual. There could be uncertainty as to whether investigation by the HFEA is required in circumstances where there is a severe incident but other bodies are undertaking their own investigations.	Management should ensure that the ongoing review of policies and procedures is completed and revised versions formalised and issued. The updates should take account of the findings from this review. The wording around when an investigation should be undertaken should be reviewed to better describe when HFEA would undertake its own investigation and when it might rely on the results of investigations by others.

IMPORTANCE	NO	FINDING/OBSERVATION	RISK/IMPLICATION	RECOMMENDATION
		incidents but we understand that HFEA does not always need to undertake an investigation itself, for instance if it can obtain assurance from external investigations.		
Low	3	**Closure of formal complaints** **Rationale for closure of one complaint in our sample was not formally documented.**		
		We reviewed a sample of five formal complaints and in one instance there was evidence that the complainant was not wholly satisfied with the final correspondence. The SOP indicates that where the complainant is not satisfied, HFEA should advise them that they may request a review by the Head of Clinical Governance within 10 working days of notification of the outcome of the initial consideration. However, in this instance the complaint was closed on the system without any further follow up. The final correspondence from the complainant noted that they did understand that there was nothing further the HFEA could do, but that they remained dissatisfied with their treatment and the service at the particular clinic. The Clinical Governance Lead/Inspector stated that HFEA could have written another letter re-iterating that there is nothing further they could do, but in this case it was felt that it would have only induced further unnecessary correspondence. This rationale for closing the complaint, however, was not documented.	There is a risk of inconsistency, which could lead to challenge and reputational harm if complaints are not fully dealt with in line with the SOP. HFEA may find it harder to demonstrate full compliance with the SOP if the rationale for decisions is not formally recorded on the system.	As best practice, when closing complaints on the system, a rationale should to be documented for closure if it is noted that the complainant is fully satisfied with the response.

Detailed Findings

IMPORTANCE	NO	FINDING/OBSERVATION	RISK/IMPLICATION	RECOMMENDATION
Low	4	**Performance reporting** **Performance reporting of incidents and complaints to management is not documented.**		
		It was confirmed by the Clinical Governance Lead/Inspector that the number of incidents and complaints are reported to, and discussed within, management. This is usually done within her monthly one to one meetings with the Chief Inspector. The numbers and trends are also discussed with Director of Compliance from time to time. However, these meetings are not documented and there are no formal reports so there is limited evidence that management has considered the number and type of incidents and complaints and assessed whether any particular response may be required. In due course, the numbers are summarised within the Annual Report, which states the number and trends of the reported incidents and details any Grade A incidents along with the key learning outcomes are published on the HFEA website.	If the numbers and the resulting trends of incidents and complaints are not appropriately analysed and monitored on a timely basis management may fail to identify potential issues that may have warranted action. If action is not taken where required, then there is increased risk of issues recurring or of policies and procedures not being developed to improve services.	Some formalisation of brief reporting of the number of incidents and complaints and of any relevant trends or other matters should be considered. formalised. This could perhaps be done on a quarterly basis.
Low	5	**Documents accessibility due to IT issue** **Certain documents are not accessible from the Epicentre System**		
		Epicentre is the core system used by HFEA for the management of the incidents and complaints. The incidents are reported via the dedicated outlook mailbox which is accessible to all Clinics' on the HFEA website and these reports along with any	Speed of accessing information may be reduced if staff attempt to find information in Epicentre and then have to go to other systems.	IT Services should identify and seek to remedy the issue causing certain documents not to be openable from Epicentre.

Detailed Findings

IMPORTANCE	NO	FINDING/OBSERVATION	RISK/IMPLICATION	RECOMMENDATION
		documentation are then uploaded onto TRIM (Record Management System) and Epicentre. We noted that due to an IT issue certain documents uploaded onto Epicentre cannot be opened. In our testing we identified six attachments in a specific version of Microsoft Word that we could not open. In all cases the documents were also available on TRIM and within the outlook mailbox, and were accessible.		
	6	**Survey Results**		
Low		While the response rate to the survey was low there are some comments that HFEA management may wish to reflect on in terms of enhancements to incident reporting. Please refer to Section 5 of this report for the full survey results. As mentioned in section 1.7 above, the survey was issued with the Clinic Focus paper in September 2015 which is sent to all clinics (approximately 130) and has a total of around 500 subscribers. Unfortunately there were only eight responses which means the results must be treated with caution	Where stakeholders do not see any change a as a result of comments made from such surveys, engagement levels may fall. Not acknowledging appreciation to those who responded to the wider population of subscribers might miss an opportunity to encourage more people to respond to any future surveys.	Send out a thank you communication regarding the survey to the full population and a brief summary of any changes that are planned to be taken as a result of the comments made.

3 Action Plan

Customer to provide details of planned action; owner and implementation date. Action taken will later be assessed by Health Group Internal Audit, and therefore the level of detail provided needs to be sufficient to allow for the assessment of the adequacy of action taken to implement the recommendation to take place.

To be completed by Health Group Internal Audit as part of the recommendation follow-up process

№	RECOMMENDATION	RATING	AGREED ACTION	OWNER & PLANNED IMPLEMENTATION DATE	OBSERVATIONS: RECOMMENDATION / AGREED ACTION IMPLEMENTED?	FURTHER ACTION REQUIRED?
1	The risk matrix should be reviewed to see whether it can be updated to better reflect the balance between severity and likelihood of recurrence.	**Low**	Review risk matrix	Accepted by the Clinical Governance Lead who has reviewed the Risk Matrix. It has been revised to reflect the balance between severity and likelihood of recurrence. Waiting for sign off by the Chief Inspector to be completed by 31 December 2015.		
2	Management should ensure that the ongoing review of policies and procedures is completed and revised versions formalised and issued. The updates should take account of the findings from this review. The wording around when an investigation should be undertaken should be reviewed	**Low**	SOP review	Accepted by the Clinical Governance Lead. In process for completion 31 December 2015.		

3 Action Plan

Customer to provide details of planned action; owner and implementation date. Action taken will later be assessed by Health Group Internal Audit, and therefore the level of detail provided needs to be sufficient to allow for the assessment of the adequacy of action taken to implement the recommendation to take place.

To be completed by Health Group Internal Audit as part of the recommendation follow-up process

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4	to better describe when HFEA would undertake its own investigation and when it might rely on the results of investigations by others.					
3	As best practice, when closing complaints on the system, a rationale should to be documented for closure if it is not that the complainant is fully satisfied with the response.	**Low**	Further information on how to handle an unhappy complainant now added to the complaint handling SOP.	Accepted by the Clinical Governance Lead. Rolled into the SOP update to be completed by the end of December 2015.		
4	Some formalisation of brief reporting of the number of incidents and complaints and of any relevant trends or other matters should be considered. formalised. This could perhaps be done on a quarterly basis.	**Low**	Quarterly meetings now in calendrer	Accepted by the Clinical Governance Lead. The Clinical Governance Lead and the Chief Inspector will meet in December to set the standing agenda and use this first meeting as a “look back” over 2014.		

3 Action Plan

Customer to provide details of planned action; owner and implementation date. Action taken will later be assessed by Health Group Internal Audit, and therefore the level of detail provided needs to be sufficient to allow for the assessment of the adequacy of action taken to implement the recommendation to take place.

To be completed by Health Group Internal Audit as part of the recommendation follow-up process

№	RECOMMENDATION	RATING	AGREED ACTION	OWNER & PLANNED IMPLEMENTATION DATE	OBSERVATIONS: RECOMMENDATION / AGREED ACTION IMPLEMENTED?	FURTHER ACTION REQUIRED?
5	IT Services should identify and seek to remedy the issue causing certain documents not to be openable from Epicentre.	**Low**	Liaised with IT regarding this issue	Accepted by the Clinical Governance Lead. There was an issue on our document management server (HP Trim) It seems the service that enables this functionality was offline and after some troubleshooting we have resolved this issue.The Clinical Governance Lead checked the six items that could not be opened via Epicentre at the time of the audit. All six items can now be opened via Epicentre.		
6	Send out a thank you communication regarding the survey to the full population and a brief summary of any changes that are planned to be taken as a result of the comments made.	**Low**	A brief thank you will be sent out in the December edition of Clinic Focus	Accepted by the Clinical Governance Lead. Clinic Focus is sent to over 120 clinics and 500 individual subscribers. Due to the very low volume of responses (8) – no meaningful information was gleaned to make any changes to the current system. Therefore a brief thank you to those that		

Action Plan

Customer to provide details of planned action; owner and implementation date. Action taken will later be assessed by Health Group Internal Audit, and therefore the level of detail provided needs to be sufficient to allow for the assessment of the adequacy of action taken to implement the recommendation to take place.

To be completed by Health Group Internal Audit as part of the recommendation follow-up process

№	RECOMMENDATION	RATING	AGREED ACTION	OWNER & PLANNED IMPLEMENTATION DATE	OBSERVATIONS: RECOMMENDATION / AGREED ACTION IMPLEMENTED?	FURTHER ACTION REQUIRED?
				participated will be mentioned in Clinic Focus.		

Report Rating - Definitions

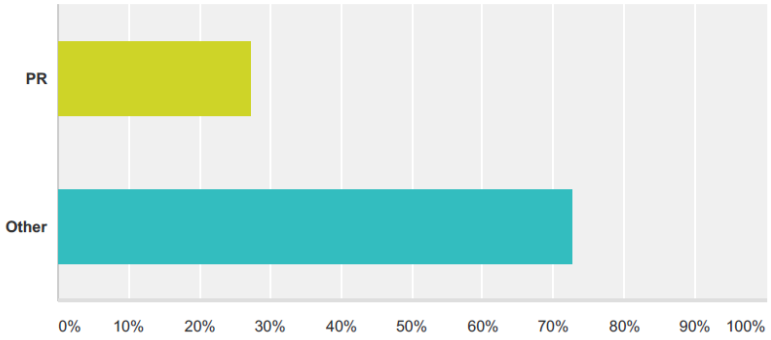
Substantial	In my opinion, the framework of governance, risk management and control is adequate and effective.
Moderate	In my opinion, some improvements are required to enhance the adequacy and effectiveness of the framework of governance, risk management and control.
Limited	In my opinion, there are 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.

5 Appendix

Appendix – Survey Results

Q1 Please indicate whether you are a PR (Person Responsible) or other clinic staff member.

Answered: 11 Skipped: 0



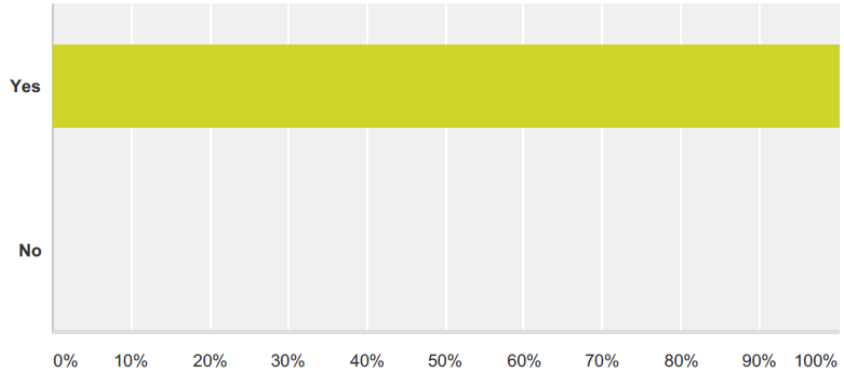
Answer Choices	Responses	
PR	27.27%	3
Other	72.73%	8
Total		11

5 Appendix

Appendix – Survey Results

Q2 Did you read the annual incident report ('Adverse incidents in fertility clinics: lessons to learn')?

Answered: 8 Skipped: 3



Answer Choices	Responses	
Yes	100.00%	8
No	0.00%	0
Total		8

Comments were added by respondents as follows;

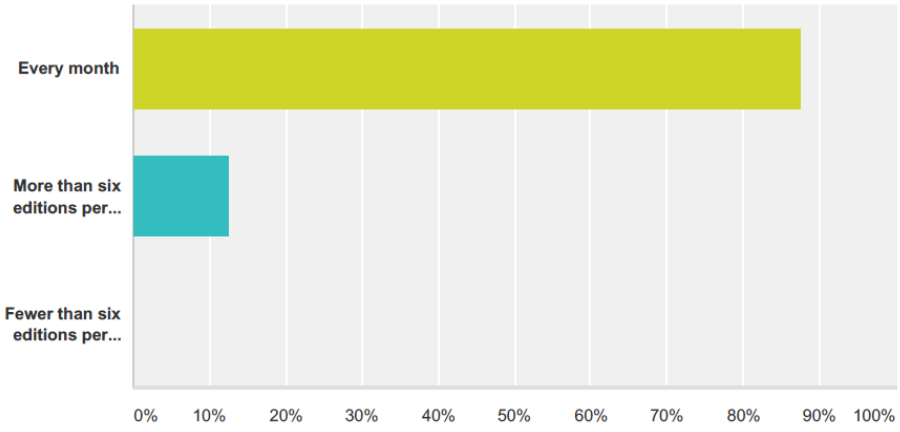
- Yes, admin services have been reviewed.
- Clinic practices have not been changed so far, but we will discuss key learning points at upcoming management meeting to ensure we are following best practice.
- Yes we now produce quarterly incident reports and also an annual report.

5 Appendix

Appendix – Survey Results

Q3 How often do you read the Clinic Focus newsletter?

Answered: 8 Skipped: 3



Answer Choices	Responses	
Every month	87.50%	7
More than six editions per year	12.50%	1
Fewer than six editions per year	0.00%	0
Total		8

Appendix – Survey Results

Q4 Have you reviewed any of your clinic's practices as a result of the articles in Clinic Focus?

Answered: 8 Skipped: 3

7 of 8 respondents who answered this question said that they had reviewed clinic practices in response to articles.

Appendix – Survey Results

Q5 Is there anything you would change about the annual report or Clinic Focus to make them more helpful to your work?

Answered: 7 Skipped: 4

6 of 8 respondents said that there would not change anything. Other comments were:

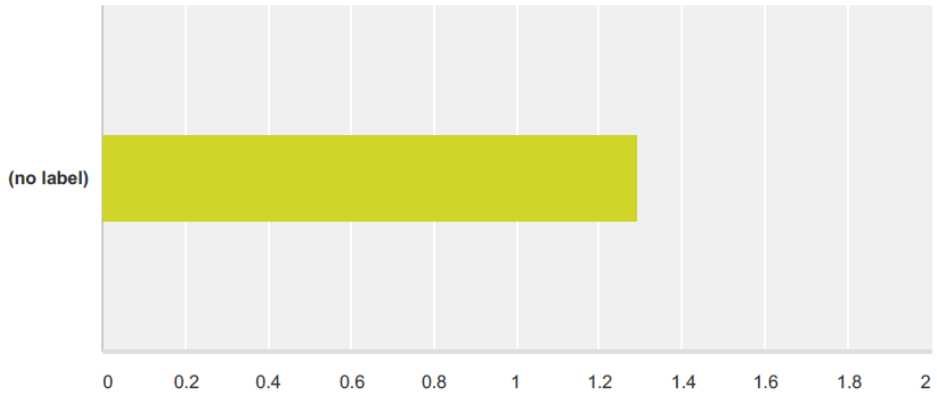
- Annual report could look at trends in lower grade incidents and recommendations from those, and include shared learning from RCAs carried out by clinics.
- In the annual report list more the minor incidents i.e. a brief title for each such as 'wrong sticker put on patient notes'. Some clinics report things that others don't.

5 Appendix

Appendix – Survey Results

Q6 Do you understand your incident reporting responsibilities? Please rate on a scale of 1 (understand completely) to 5 (no understanding).

Answered: 7 Skipped: 4



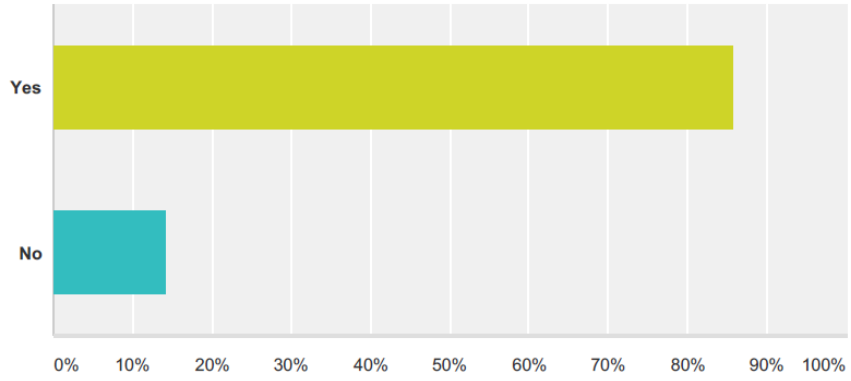
	1	2	3	4	5	Total	Weighted Average
(no label)	85.71% 6	0.00% 0	14.29% 1	0.00% 0	0.00% 0	7	1.29

5 Appendix

Appendix – Survey Results

Q7 Do you think that incident reporting helps you improve the safety and quality of services offered to your patients? If 'No', what could we do to help you achieve this?

Answered: 7 Skipped: 4



Answer Choices	Responses	
Yes	85.71%	6
No	14.29%	1
Total		7

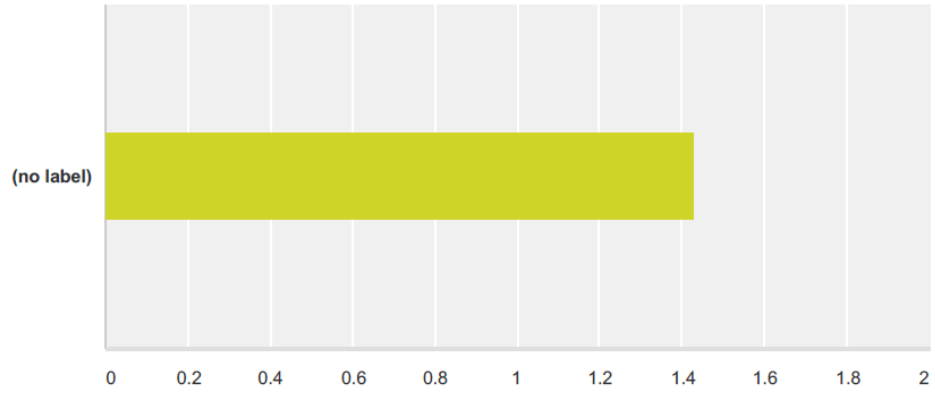
One comment was made explaining the no response: “If we didn’t report incidents we would still do a root cause analysis.

5 Appendix

Appendix – Survey Results

Q8 Is the incident reporting system straightforward to use? If you find it difficult to use, what improvements could you suggest? Please answer on a scale of 1 (very straightforward) to 5 (difficult to use.

Answered: 7 Skipped: 4



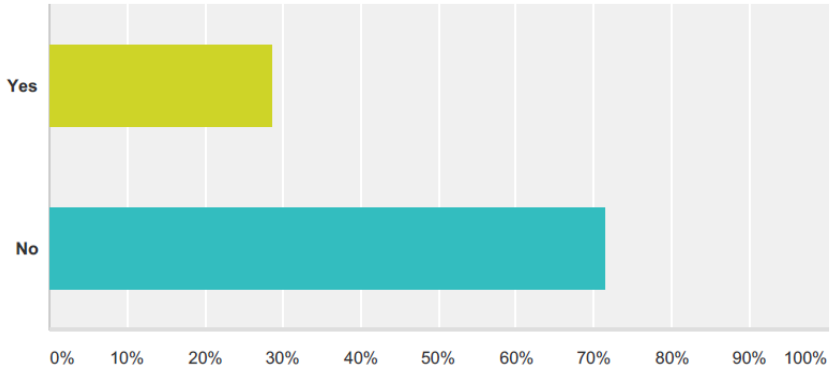
	1	2	3	4	5	Total	Weighted Average
(no label)	71.43% 5	14.29% 1	14.29% 1	0.00% 0	0.00% 0	7	1.43

5 Appendix

Appendix – Survey Results

Q9 Have you ever felt inhibited from reporting an incident?

Answered: 7 Skipped: 4



Answer Choices	Responses	
Yes	28.57%	2
No	71.43%	5
Total		7

The two respondents who commented yes to this question provided further explanation as follows:

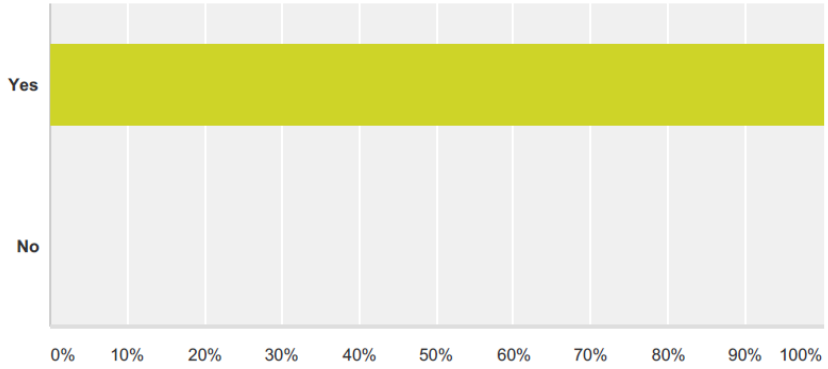
- By culture of clinic, and safety of job. Whistleblowing versus incident reporting can be a very difficult dilemma.
- As a PR any report is expected to be scrutinized at a subsequent inspection as a result consideration for reporting an event can be seen as giving ammunition to the inspection team / making a noose for your own neck.

5 Appendix

Appendix – Survey Results

Q10 Do you think the root cause analyses completed by your clinic are useful in helping you identify how to stop incidents recurring?

Answered: 7 Skipped: 4



Answer Choices	Responses	
Yes	100.00%	7
No	0.00%	0
Total		7

Appendix – Survey Results

Q11 Please provide any other comments you have that will help the HFEA improve your experience of the incident management process.

Answered: 3 Skipped: 8

Clarity from the HFEA, particularly around clinical incident reporting as is currently very vague, would improve meaningful reporting and create a level playing field for clinics.

I feel it is important to encourage an open culture surrounding incidents and the 'no blame' culture is extremely important to encourage openness. I also feel it is important that learning is shared with the entire clinic to prevent re-occurrence and enable learning. I feel the reporting of incidents to the HFEA is simple and straightforward.

HFEA commentary such as "...reducing their grade B and C incidents. Such mistakes are often distressing to patients, largely avoidable and frankly shouldn’t happen..." are frankly not particularly helpful since they themselves can create underreporting. IVF clinics have comparable incident rates to other clinical fields around the world (published evidence!) and as such grade B and C incidents while frustrating are going to happen while humans are involved in the processes. The HFEA ask us to reduce B and C's but in the same breath to ensure we are reporting all incidents. If you want us to report everything then don’t expect the B's and C's to reduce significantly. I can only conclude from the statement above that the HFEA is an error free authority? I've personally seen evidence to the contrary. We are all in this together surely?

Health Group Internal Audit

REFERENCE NUMBER: DHX215010001
FINAL REPORT
HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY
OCTOBER 2015

Health Group Internal Audit provides an objective and independent assurance, analysis and consulting service to the Department of Health and its arms length bodies, bringing a disciplined approach to evaluating and improving the effectiveness of risk management, control and governance processes.

Health Group Internal Audit focuses on business priorities and key risks, delivering its service through three core approaches across all corporate and programme activity:

- Review and evaluation of internal controls and processes;
- Advice to support management in making improvements in risk management, control and governance; and
- Analysis of policies, procedures and operations against good practice.

Health Group Internal Audit findings and recommendations:

- Form the basis of an independent opinion to the Accounting Officers and Audit Committees of the Department of Health and its arms length bodies on the degree to which risk management, control and governance support the achievement of objectives; and
- Add value to management by providing a basis and catalyst for improving operations.

For further information please contact:

Bronwyn Baker

01132 54 5515 – 1N16 Quarry House, Quarry Hill, Leeds, LS2 7UE

REQUESTS FOR INFORMATION

Overall report rating: MODERATE

Our work has been conducted and our report prepared solely for the benefit of the Department of Health and its arms length bodies and in accordance with a defined and agreed terms of reference. In doing so, we have not taken into account the considerations of any third parties. Accordingly, as our report may not consider issues relevant to such third parties, any use they may choose to make of our report is entirely at their own risk and we accept no responsibility whatsoever in relation to such use. Any third parties requiring access to the report may be required to sign 'hold harmless' letters.

CONTENTS **PAGE**

Date fieldwork completed:	**11 September 2015**
1st draft report issued:	**22 September 2015**
Management responses received:	**19 October 2015**
Final report issued	**26 October 2015**

Report Author:	Aimee Gibson
Version №:	3
Date:	26/10/2015

Health Group
Internal Audit

Distribution List – Draft Report

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Lynn Yallop (Head of Audit)

Distribution List – Final Report

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Sam Hartley
Charlotte Keen

Cc:

Lynn Yallop (Head of Audit)

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1. Introduction

1.1 This review has been undertaken as part of the 2015/16 Internal Audit Plan which was approved by the Audit and Governance Committee.

The HFEA may be required to release information as a result of:

- Parliamentary Questions (PQs);
- Freedom of Information (FOI) requests; and
- Data Protection (DP) requests.

This review has focussed on the policies and procedures in place to respond to the above types of request, and processes in place to mitigate key risks associated with information access. To put the report findings into context please note the following statistics in terms of requests HFEA have had since January 2015:

- PQs – 75;
- FOIs – 73; and
- DPAs – none within the last two years.

Following discussion with management we have also reviewed, and provided advice where appropriate, on the following areas:

- The introduction, by HFEA, of a new log which has been designed to improve the accessibility of previous responses to PQs. It is clear that this log will serve as a very useful tool for ensuring consistency of responses to PQs, and recommendations for further improvement of this log are provided in Finding #4 below
- The process to review those responses which relate to small numbers of individuals, to ensure that the confidentiality of these individuals is protected. The Authority now have a policy of substituting the number of individuals for '<5' if a response involves less than five individuals, and we have confirmed through our sample testing that this is being consistently applied. Another key element of this new process, due to be rolled out in the months following the audit, is the introduction of a panel of HFEA management who will meet to consider the response to requests that involve small numbers of individuals. This will further decrease the risk of disclosure of identities; and
- We have also reviewed whether the current Key Performance Indicators (KPIs) regime effectively promotes the quality of services in relation to requests for information, beyond meeting minimum statutory requirements.

2. Review conclusion

2.1 The overall rating for the report is **Moderate** - some improvements are required to enhance the adequacy and effectiveness of the framework of governance, risk management and control.

3. Summary of Key Findings

3.1 **Policies and Procedures are overdue for review**

It was noted that the Information Access Policy (last updated October 2010) and Information Access SOP (last updated in June 2012) were overdue for review at the date of the audit, and the PQ SOP was under review at the audit date (previously reviewed in October 2011). However, given that an overall finding around outdated policies was raised as part of the Internal Policies review in 2014/15 (Ref: HFEA201415003, Finding #2), we have not raised this as a detailed finding in Section 2 of the report.

3.2 **Formal written authorisation is currently not required prior to submission of responses to PQs and FOI requests**

The PQ SOP states that the Chief Executive is required to sign-off all PQs prior to submission of responses. However, formal written authorisation is currently not required and therefore it was not possible to see evidence of this authorisation taking place during our audit testing.

In addition, whilst responses to FOI requests are signed off by the Information Access and Policy Manager, again no formal written authorisation was available to demonstrate this.

3.3 **Failure to meet the 48 hour deadline for PQs in two cases since 1st January 2015 was at least in part due to staff availability**

HFEA have missed the 48 hour deadline for PQs in two out of 75 cases since the start of the calendar year. In both cases, the reason was in part staff availability, where the staff members required to respond to the request were not available to prepare the response. This suggests that there may be a business resilience risk that requires addressing, to ensure that KPIs are not breached, and prevent damage to HFEA's reputation.

3.4 **The audit trail held on TRIM (the Authority's Information Management system) for PQs is not currently sufficient to show how policies and procedures have been adhered to**

Currently the only information held on TRIM to show the PQ response process for each request is the draft response prepared to send back to parliament. Information on the date the initial request was received, and the date that the initial response was sent back to the Department of Health, however, is

not stored on TRIM. Whilst this information was made available from staff members' email inboxes for the purposes of the audit testing, there is a risk that key audit trail evidence is lost if not held on TRIM.

3.5 **There is scope to improve the PQ log to allow for easier access to groups of similar requests, and access rights to the PQ log are not currently restricted**

As noted above, a new PQ log was introduced prior to the 2015 summer parliamentary recess, with the aim of ensuring accessibility to previous similar PQs and therefore the consistency of responses provided. Whilst the log is not yet fully operational, the aim going forward is that it will list all PQs received, and responses given. It was noted that currently any staff member at HFEA can access and edit the PQ log. Access to edit the log should be restricted to the appropriate individuals.

Summary of Findings

3.6 The table below summaries the number of findings by rating:

	Total recs	High	Medium	Low
Policies and Procedures	3	0	2	1
PQ response log	1	0	0	1
Requests involving small numbers	0	0	0	0
KPIs	0	0	0	0

3.7 Section 2 of this report includes specific and detailed recommendations against observations and findings.

4. Action Required

4.1 Public Sector Internal Audit Standards require you to consider the recommendations made in Section 2; and complete section 3 (Agreed Action Plan) detailing what action you are intending to take to address the individual recommendations, the owner of the planned actions and the planned implementation date. The agreed action plan will then form the basis of subsequent audit activity to verify that the recommendations have been implemented effectively.

4.2 Finally, we would like to thank management for their help and assistance during this review.

Detailed Findings

IMPORTANCE	NO	FINDING/OBSERVATION	RISK/IMPLICATION	RECOMMENDATION
Medium	**1**	**Policies and Procedures** **Formal written authorisation is currently not required prior to submission of responses to PQs and FOI requests**		
		All PQs are required to be signed off by HFEA's Chief Executive, as outlined in the PQ SOP. However, discussion with management, and detailed testing of 20 PQs confirmed that a written record of this authorisation is currently not required. On the morning that the response must be submitted, a meeting will be held with the Chief Executive, Information Access and Policy Manager and other relevant staff and the Chief Executive will sign off the response. However minutes are not taken in these meetings and there is no formal written record of sign-off, due to the quick turnaround time for PQs. In addition, responses to FOI requests are reviewed by the Information Access and Policy Manager prior to submission. Again, this is currently done via a verbal meeting held between the Information Access and Policy Manager and the staff member(s) who have prepared the response. However there is no formal requirement for written authorisation to be obtained and held on file prior to the response being submitted. Whilst the Information Access SOP does	Without formal written authorisation of final responses to PQs or FOI requests before they are sent out, there is not a sufficient audit trail on file to show that the requests have been responded to in line with HFEA's policies and procedures. Were HFEA to receive a complaint or enquiry on a particular request, it may be important for HFEA to be able to demonstrate that it has followed its own internal procedures, and that the response was prepared and authorised appropriately.	A written record of authorisation of PQ and FOI responses should be required in all cases, and held on TRIM. This written record could be in the form of minutes taken during meetings held with the authoriser or via an email or other form of written authorisation.

Detailed Findings

IMPORTANCE	NO	FINDING/OBSERVATION	RISK/IMPLICATION	RECOMMENDATION
		not explicitly state that the Information Access and Policy Manager must sign off all FOI responses, as best practice a written record of sign-off should be available on file.		
Medium	**2**	**Policies and Procedures** **Failure to meet the 48 hour deadline for PQs in two out of 75 cases since 1st January 2015 was at least in part due to staff availability**		
		As part of the audit testing for this review, 20 PQs were sampled, and supporting evidence viewed, in order to validate that the 48 hour deadline had been met. In two out of these 20 cases, the 48 hour deadline was missed. In one instance (PQ ref HL5228) the response was late because the staff member required to deal with the request was not available. In the second instance (PQ ref HL4885), the late response was in part due to the complexity of the question and data, but again in part due to staff availability. Given that both of these instances were at least in part due to staff availability, this suggests that there may be a business resilience risk that requires addressing.	HFEA fail to meet their KPIs due to staff availability issues. This could cause significant reputational damage and affect the timing of parliamentary decisions.	Whilst it is understood that the nature of having a small team means staff availability will often be a key constraint, HFEA should ensure, where possible, that there are always at least two staff members at the Authority who can respond to each type of request. HFEA should carry out an analysis into the types of requests received, and staff members who are able to respond to these requests, in order to identify request types where responses are currently reliant on one individual.

Detailed Findings

IMPORTANCE	NO	FINDING/OBSERVATION	RISK/IMPLICATION	RECOMMENDATION
Low	3	**Policies and Procedures** **The audit trail held on TRIM for PQs is not currently sufficient to show how policies and procedures have been adhered to**		
		HFEA is notified of PQs via a daily email from the Department of Health (DoH), and upon receipt of this email HFEA have 48 working hours to respond to the request. Compliance with the 48 hour timeframe is measured by when HFEA sends its initial response back to DoH. Following this, there will often be a number of email exchanges between DoH and HFEA in order to ensure DoH are also happy with the response. Information on the date the initial request was received, and evidence to show that the request was responded to within the 48 hour deadline, is not stored on TRIM. Currently, only a copy of the draft response is held on TRIM (Note: As part of our testing of 20 PQs, the above information was made available, as whilst not on TRIM it is currently stored in staff email inboxes). Discussion with management confirmed that due to the volume of email exchanges that can occur between the DoH and HFEA before the final response is sent, it is not deemed efficient to store all of this	Without a clear audit trail on TRIM, there is a risk that key audit trail information relating to PQs may be lost, as it is currently stored in email inboxes. As a result, HFEA may be unable to demonstrate how it followed its policies and procedures as well as compliance with the 48 hour response deadline.	Sufficient information should be stored on TRIM for HFEA to be able to demonstrate that it has followed its internal policies and procedures, as well as meeting the 48 hour deadline for PQ responses. Information held on TRIM should therefore include as a minimum: • Details of the date that the request was initially received from DoH. • Written evidence of authorisation of the initial response (as noted in Finding #1) sent to DoH. • Email evidence showing the initial response sent out to DoH request was responded to within the 48 hour deadline, to show that the KPI has been met. • Details of the final response agreed between the DoH and HFEA (in the form of email exchanges), once email

Detailed Findings

IMPORTANCE	NO	FINDING/OBSERVATION	RISK/IMPLICATION	RECOMMENDATION
		information on TRIM. Going forward, HFEA plan to include information relating to PQ responses on the new PQ log that is now in place which will list all PQs that are received, and the responses provided to these PQs. However, there is still scope to include key information on TRIM. It is noted that for FOI requests, the information currently included on TRIM includes details of the initial request received and the date received, as well as the final response sent out to the requestor, allowing HFEA to show that they complied with the 20 working day response timeframe for FOI requests.		exchanges have taken place.
Low	**4**	**PQ Response log** **There is scope to improve the PQ log to allow for easier access to groups of similar requests, and access rights to the PQ log are not currently restricted**		
		Shortly prior to the summer parliamentary recess, a PQ response log was introduced. Whilst the log is not yet fully operational, going forward the PQ log will list all PQs received, and responses given, and the log is designed to allow for easy searching of similar requests, so that HFEA ensures its responses are consistent with that of previous requests. It was noted that the log can currently be	If access to the PQ log is not sufficiently restricted, there is a risk that edits may be made to the log that are inaccurate, and that the log therefore does not accurately reflect PQs that HFEA have received and responded to.	Access to edit the PQ log should be restricted to those staff members who are responsible for keeping the log updated.

Detailed Findings

IMPORTANCE	NO	FINDING/OBSERVATION	RISK/IMPLICATION	RECOMMENDATION
		viewed and edited by any staff member in HFEA. The log is currently held in the Security and Access Policy folder on TRIM. Whilst it may be appropriate for the majority of staff to be able to view this log, editing of this log should be restricted to those who are responsible for maintaining the log.		

Action Plan

Customer to provide details of planned action; owner and implementation date. Action taken will later be assessed by Health Group Internal Audit, and therefore the level of detail provided needs to be sufficient to allow for the assessment of the adequacy of action taken to implement the recommendation to take place.

To be completed by Health Group Internal Audit as part of the recommendation follow-up process

№	RECOMMENDATION	RATING	AGREED ACTION	OWNER & PLANNED IMPLEMENTATION DATE	OBSERVATIONS: RECOMMENDATION / AGREED ACTION IMPLEMENTED?	FURTHER ACTION REQUIRED?
1	A written record of authorisation of PQ and FOI responses should be required in all cases, and held on TRIM. This written record could be in the form of minutes taken during meetings held with the authoriser or via an email or other form of written authorisation.	**Medium**	As confirmed in the key findings, formal written authorisation is not required within the HFEA SOPs. A written record of authorisation is not sustainable for either FOI or PQs (which are signed off by the Chief Executive) and would only serve to delay submission of responses. This is a particular risk with PQs given the short timeframe between the sign off meeting with the Chief Executive and the deadline for submission.	n/a		
2	Whilst it is understood that the nature of having a small team means staff availability will often be a key constraint, HFEA should ensure, where	**Medium**	The HFEA has missed the deadline twice in 75 cases for PQs. Given the size of the organisation and the small number of staff with	The requirement for resilience on data queries is covered under the Information for Quality programme.		

Action Plan

Customer to provide details of planned action; owner and implementation date. Action taken will later be assessed by Health Group Internal Audit, and therefore the level of detail provided needs to be sufficient to allow for the assessment of the adequacy of action taken to implement the recommendation to take place.

To be completed by Health Group Internal Audit as part of the recommendation follow-up process

№	RECOMMENDATION	RATING	AGREED ACTION	OWNER & PLANNED IMPLEMENTATION DATE	OBSERVATIONS: RECOMMENDATION / AGREED ACTION IMPLEMENTED?	FURTHER ACTION REQUIRED?
	possible, that there are always at least two staff members at the Authority who can respond to each type of request. HFEA should carry out an analysis into the types of requests received, and staff members who are able to respond to these requests, in order to identify request types where responses are currently reliant on one individual.		the knowledge and expertise in order to respond to PQs, this is an excellent record of meeting deadlines, as acknowledged by the Department of Health. With the resources available, it is therefore simply not currently possible to ensure there are always two staff members available to respond to each type of request. We can assure, however, that the IfQ programme will address this and enable more members of staff to have access in future to the relevant data in order to respond. It is also worth noting that the HFEA's reputation would be much			

Action Plan

Customer to provide details of planned action; owner and implementation date. Action taken will later be assessed by Health Group Internal Audit, and therefore the level of detail provided needs to be sufficient to allow for the assessment of the adequacy of action taken to implement the recommendation to take place.

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			more at risk by providing less accurate responses simply to meet the deadline than failing to meet the deadline itself.			
3	Sufficient information should be stored on TRIM for HFEA to be able to demonstrate that it has followed its internal policies and procedures, as well as meeting the 48 hour deadline for PQ responses. Information held on TRIM should therefore include as a minimum: • Details of the date that the request was initially received from DoH. • Written evidence of authorisation of the initial response (as noted in Finding #1) sent to DoH.	**Low**	The details of the date that the request is initially received from the Department is captured in the PQ log, and saving the initial commissioning email would therefore duplicate issues and serve little purpose in the whole process. Written evidence of authorisation has been addressed in Finding#1. As part of the process it is agreed the email sent to the Department with the proposed response will be saved to Trim as	Information Access and Policy Manager; Log to be updated with TRIM refs for saved final returns; By 30/10/15		

Action Plan

Customer to provide details of planned action; owner and implementation date. Action taken will later be assessed by Health Group Internal Audit, and therefore the level of detail provided needs to be sufficient to allow for the assessment of the adequacy of action taken to implement the recommendation to take place.

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	• Email evidence showing the initial response sent out to DoH (as it is this email that is used to demonstrate HFEA's compliance with the 48 hour deadline). • Details of the final response agreed between the DoH and HFEA (in the form of email exchanges), once email exchanges have taken place.		recommended. There would be little point, however in saving email exchanges with details of the final response. This would be labour intensive and could potentially confuse the issue with later, linked PQs. In any event, the only substantive, final response is that which is published in Hansard.			
4	Access to edit the PQ log should be restricted to those staff members who are responsible for keeping the log updated.	**Low**	. It is agreed that any editing rights for the PQ log should be restricted to those members of staff who are responsible for	Head of IT – editing rights to be changed by 30/10/15		

Health Group Internal Audit

Action Plan

Customer to provide details of planned action; owner and implementation date. Action taken will later be assessed by Health Group Internal Audit, and therefore the level of detail provided needs to be sufficient to allow for the assessment of the adequacy of action taken to implement the recommendation to take place.

To be completed by Health Group Internal Audit as part of the recommendation follow-up process

№	RECOMMENDATION	RATING	AGREED ACTION	OWNER & PLANNED IMPLEMENTATION DATE	OBSERVATIONS: RECOMMENDATION / AGREED ACTION IMPLEMENTED?	FURTHER ACTION REQUIRED?
			keeping the log updated.			

Report rating - Definitions

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.

Implementation of Audit Recommendations – Progress Report

Strategic delivery	**Setting standards**	☐	**Increasing and informing choice**	☐	**Demonstrating efficiency economy and value**	☒	
Meeting	Audit and Governance Committee						
Agenda item	09						
Paper number	[AGC (09/12/2015) 482 WEC]						
Meeting date	Wednesday, 9 December 2015						
Author	Wilhelmina Crown						
For information or decision?	Decision						
Recommendation	AGC is requested to review the enclosed progress updates and to comment as appropriate.						
Resource implications	As noted in the enclosed summary of outstanding audit recommendations						
Implementation	N/A						
Communication	CMG						
Organisational risk	As noted in the enclosed summary						
Annexes	Annex 1: Summary of Recommendations						

Annex 1: Summary of Recommendations

Recommendation Source	Status / Actions	2015/16	Total
Internal – *DH Internal Audit*	*Complete*	*2*	***2***
External Auditor – *NAO*	*Complete*	*-*	***-***
COUNT		***2***	***2***

1. Report

1.1. This report presents an update to the audit recommendations paper presented to this committee in October 2015.

1.2. The recommendations agreed as completed by this committee in October have been removed.

1.3. The final report and recommendations from the latest audits (Requests for information and Incident handling) will be presented to this meeting. Recommendations from the Requests for information audit are included in this report – Incident handling will be added next time.

1.4. Recommendations are classified as high (red), medium (amber) or low (green).

1.5. Four new recommendations were received with two each noted as medium and low.

1.6. One of the two recommendations classified as medium was noted as requiring no further action with the second forming part of the IFQ project. These have not been included as part of this document.

1.7. Two recommendations classified as low have been added to our progress report.

1.8. Recent updates received from Action Managers are recorded under a November 2015 heading in this document.

1.9. Both recommendations are noted as completed and there are no outstanding recommendations.

2. Recommendation

AGC is requested to review the enclosed summary of recommendations and updated management responses.

FINDING/*RISK*	Recommendation	Agreed actions / Progress Made	Action Owner/ completion date
2015/16 – INTERNAL AUDIT CYCLE			
1. Requests for Information - Policies and Procedures	**The audit trail held on TRIM for PQs is not currently sufficient to show how policies and procedures have been adhered to**		
Discussion with management confirmed that due to the volume of email exchanges that can occur between the DoH and HFEA before the final response is sent, it is not deemed efficient to store all of this information on TRIM. Going forward, HFEA plan to include information relating to PQ responses on the new PQ log that is now in place which will list all PQs that are received, and the responses provided to these PQs. However, there is still scope to include key information on TRIM. It is noted that for FOI requests, the information currently included on TRIM includes details of the initial request received and the date received, as well as the final response sent out to the requestor, allowing HFEA to show that they complied with the 20 working day response timeframe for FOI requests *Without a clear audit trail on TRIM, there is a risk that key audit trail information relating to PQs may be lost, as it is currently stored in email inboxes. As a result, HFEA may be unable to demonstrate how it followed its policies and procedures as well as compliance with the 48 hour response deadline.*	Sufficient information should be stored on TRIM for HFEA to be able to demonstrate that it has followed its internal policies and procedures, as well as meeting the 48 hour deadline for PQ responses. Information held on TRIM should therefore include as a minimum: • Details of the date that the request was initially received from DoH. • Written evidence of authorisation of the initial response (as noted in Finding #1) sent to DoH. • Email evidence showing the initial response sent out to DoH request was responded to within the 48 hour deadline, to show that the KPI has been met. • Details of the final response agreed between the DoH and HFEA (in the form of email exchanges), once email exchanges have taken place.	***The details of the date that the request is initially received from the Department is captured in the PQ log, and saving the initial commissioning email would therefore duplicate issues and serve little purpose in the whole process. Written evidence of authorisation has been addressed in Finding#1. As part of the process it is agreed the email sent to the Department with the proposed response will be saved to Trim as recommended. There would be little point, however in saving email exchanges with details of the final response. This would be labour intensive and could potentially confuse the issue with later, linked PQs. In any event, the only substantive, final response is that which is published in Hansard.*** **November 2015 update**: Action completed – closed. **Recommendation completed**	Information Access and Policy Manager; Log to be updated with TRIM refs for saved final returns; By **30/10/15** **COMPLETE**

FINDING/*RISK*	Recommendation	Agreed actions / Progress Made	Action Owner/ completion date
2. Requests for Information - PQ Response log	**There is scope to improve the PQ log to allow for easier access to groups of similar requests, and access rights to the PQ log are not currently restricted**		
Shortly prior to the summer parliamentary recess, a PQ response log was introduced. Whilst the log is not yet fully operational, going forward the PQ log will list all PQs received, and responses given, and the log is designed to allow for easy searching of similar requests, so that HFEA ensures its responses are consistent with that of previous requests. It was noted that the log can currently be viewed and edited by any staff member in HFEA. The log is currently held in the Security and Access Policy folder on TRIM. Whilst it may be appropriate for the majority of staff to be able to view this log, editing of this log should be restricted to those who are responsible for maintaining the log. *If access to the PQ log is not sufficiently restricted, there is a risk that edits may be made to the log that are inaccurate, and that the log therefore does not accurately reflect PQs that HFEA have received and responded to.*	Access to edit the PQ log should be restricted to those staff members who are responsible for keeping the log updated.	***It is agreed that any editing rights for the PQ log should be restricted to those members of staff who are responsible for keeping the log updated.*** **November 2015 update:** Action completed – closed. **Recommendation completed**	Head of IT – editing rights to be changed by **30/10/15** **COMPLETE**