

Strategic risks

Strategic delivery:	<input checked="" type="checkbox"/> Setting standards	<input checked="" type="checkbox"/> Increasing and informing choice	<input checked="" type="checkbox"/> Demonstrating efficiency economy and value
Details:			
Meeting	Audit and Governance Committee		
Agenda item	6		
Paper number	AGC (21/09/2016) 508		
Meeting date	21 September 2016		
Author	Helen Crutcher, Project Risk and Performance Manager		
Output:			
For information or decision?	Information and comment.		
Recommendation	AGC is asked to note the latest edition of the risk register, set out in the annex.		
Resource implications	In budget.		
Implementation date	Strategic risk register and operational risk monitoring: ongoing. CMG reviews risk quarterly in advance of each AGC meeting. AGC reviews the strategic risk register at every meeting. The Authority reviews the strategic risk register periodically.		
Organisational risk	<input type="checkbox"/> Low	<input checked="" type="checkbox"/> Medium	<input type="checkbox"/> High
Annexes	Annex 1: Strategic risk register		

1. Strategic risk register

Latest reviews

- 1.1. CMG reviewed the risk register on 7 September 2016. CMG discussed all risks, their controls, and scores. The Legal risk was reviewed in detail by risk owners at a separate meeting, to provide the current position. Three of the twelve risks are currently above tolerance.
- 1.2. The strategic risk register is attached at Annex A, and includes an overview of CMG's general discussions about the risk register. The annex includes the graphical overview of residual risks plotted against risk tolerances.
- 1.3. The Authority reviewed the risk register at its meeting on 6 July 2016. No amendments were proposed to the risks or the scores.

2. Recommendation

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

HFEA strategic risk register 2016/17

Risk summary: high to low residual risks

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

* This column tracks the four most recent reviews by AGC, CMG, or the Authority (eg, ↑ ↔ ↓ ↔).

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)

Recent review points are: CMG 18 May ⇒ AGC 15 June ⇒ Authority 6 July ⇒ CMG 7 September

CMG overview – summary from September risk meeting

CMG reviewed the risk register and risk scores at its meeting on 7 September. Detailed review of the legal (LC1) risk was undertaken offline with the risk owners.

CMG heard about the Department of Health risk audit recommendation that ALBs and the Department consider risk interdependencies across the health and care system, and heard that the HFEA would be seeking to embed this approach into future management of risk.

Three new inter-related strategic risk sources arising due to IfQ had been escalated to the register this month. These risks were the various impacts of Electronic Patient Record System (EPRS) providers not making the necessary changes to their systems to submit clinic treatment data to the new Register structure following IfQ release 2. The risk areas affected are firstly RM1 (the risk of a loss of regulatory authority), because any gaps in data could impact effective regulatory monitoring. Secondly, IfQ1 (the risk to improved information access), since any data that had not been provided would then not be available to provide to patients through Choose a Fertility Clinic. And finally, FV1 (financial viability - risk of overspend) could be impacted if the HFEA were not able to bill clinics for treatments that they had undertaken but not reported to us. CMG heard that this risk was not yet imminent since it would only apply following IfQ release 2, in 2017; however, the impact of the risk could potentially be wide-reaching if it were not managed effectively. CMG heard that the IfQ Programme Board had received proposals for a revised delivery plan and that this would positively affect the proximity of the risk. Work was also underway to develop further mitigation plans for these risks, alongside the finance and compliance departments where needed. CMG agreed that the HFEA was able to tolerate this situation at the current time, however, appropriate mitigation plans and risk monitoring would be essential.

Under item C1 (Knowledge and capability), CMG discussed the impact of the Head of Corporate Governance leaving the organisation in September. Although this would leave the HFEA with a Head level vacancy again, the residual risk level for this risk had previously been raised when there had been two Head vacancies at once, and had not been lowered since that point pending bedding in periods. Because of this, the risk would not increase as a result of having a vacancy again.

CMG reassessed the residual risk likelihood for IfQ3 (delivery of promised efficiencies), and agreed it should be reduced to a score of 2, since, with the mitigations currently in place it was unlikely that the HFEA would not be able to deliver these improvements. This brings this risk to within tolerance, with a score of 8.

All Finance related risks have been reassigned to the Head of Finance to reflect the interim period between the departure of the current Director of Finance and Resources and arrival of the new one at the beginning of November.

CMG also considered operational risks (under a different report) and noted that the main theme of each team's operational risks was resources. This has been the position for some time now and risks in this area were raised by all teams, though resource pressure was particularly being felt in the Legal team at the moment. Other teams have been made aware of these pressures on the Legal team and external support is being sought where useful.

An increase in the number of quality-related operational risks across teams was also noted. This was especially highlighted in a new business planning team risk, rated 'high', that 'unanticipated or uncontrolled risks could become live issues or cause internal incidents'. The importance of ongoing operational risk management with teams was highlighted to all Heads. The business planning team are also planning to implement further

measures to embed risk management in teams and upskill more junior team members, though this also requires the ongoing commitment of Heads.

A new finance risk was raised which was also the highest risk this month with a 'very high' rated residual risk of 20. This was the risk of non-payment of suppliers caused by technical issues with HFEA being migrated to Barclays internet banking, leaving the organisation with limited capability for paying suppliers. This had been escalated with the bank and meanwhile there is a workaround in place to use the existing system.

AGC feedback – June meeting (15/06/2016):

Some of the strategic risks were discussed in depth during the review of other agenda items, particularly IfQ risks. The committee was assured that the levels of risk were correctly recorded and that actions are being taken to mitigate the risks.

The committee discussed the data risk D2 – incorrect data being released – in particular detail and noted a recent upward trend in the number and complexity of Parliamentary Questions being raised, with challenging content and deadlines. The executive agreed to review the latest figures after the meeting, and consider the impact of this upon the risk level if it continued to be a trend. In summary, the committee noted they were encouraged by the consistency of risk levels and the management of the risks.

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 the 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.'

System-wide risk interdependencies

We also consider whether any HFEA strategic risks or controls have a potential impact for the Department or any other ALBs.

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner	
Regulatory model RM 1: Quality and safety of care	There is a risk of adverse effects on the quality and safety of care if the HFEA were to fail to deliver its duties under the HFE Act (1990) as amended.	Setting standards: improving the quality and safety of care through our regulatory activities.	Inherent risk level:			↔ ↔ ↔ ↔ Peter Thompson
			Likelihood	Impact	Inherent risk	
			3	5	15 High	
			Residual risk level:			
			Likelihood	Impact	Residual risk	
			2	4	8 Medium	
Tolerance threshold:			8 Medium			
Causes / sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary	
Inspection/reporting failure.		Inspections are scheduled for the whole year, using licence information held on Epicentre, and items are also scheduled to committees well in advance.	In place – Sharon Fensome-Rimmer		At tolerance. The Head of Corporate Governance and Chief Inspector started in their posts (in March and May 2016 respectively). While they are bedding into the organisation it is likely that some degree of ownership of controls will sit with both the respective Directors as well as the Heads themselves until they are fully trained. The Head of Corporate Governance will now be leaving the HFEA in September 2016 which leaves a head vacancy again. There will continue to be a period of bedding in for the Chief Inspector.	
		Audit of Epicentre conducted to reveal data errors. Queries now routed through Licensing, who hold a definitive list of all licensing details.	Completed October 2015 – Ian Brown			
		Inspector training, competency-based recruitment, induction process, SOPs, QMS, and quality assurance all robust.	In place – Sharon Fensome-Rimmer			
Regulatory monitoring processes may be disrupted as a result of the temporary inability of Electronic Patient Record System (EPRS) providers to submit data to the new register structure until their software has been updated. This could impact performance information used in inspection notebooks and RBAT alerts		Proposals on an updated IfQ delivery plan were made to August IfQ Programme Board, these should help address this risk by extending the release date for the EDI replacement by 3 months (IfQ release 2). Mitigation plans for this risk are in the process of being prepared and agreed with SMT as at September.	Mitigation planning in progress in September - Nick Jones			
Monitoring failure.		Outstanding recommendations from inspection reports are tracked and followed up by the team.	In place – Sharon Fensome-Rimmer			
Unresponsiveness to or mishandling of non-compliances or grade A incidents.		Update of compliance and enforcement policy.	Completed following Authority approval of new policy March 2016 - Nick Jones		The need to manage the imminent Head vacancy, the continuing training period and also the action plan being	
		Staffing model provides resilience in the inspection	In place – Sharon Fensome-Rimmer			

	team for such events – dealing with high-impact cases, additional incident inspections, etc.		implemented in connection with legal parenthood consent issues, has raised the residual risk likelihood from 1 (very unlikely) to 2 (unlikely) – from November through to at least November 2016.
Insufficient inspectors or licensing staff	Inspection team up to complement. The new Chief Inspector joined the HFEA in early May 2016.	In place – Nick Jones	
		Licensing team up to complement following earlier recruitment. The new Head of Corporate Governance joined the HFEA in March 2016.	In place – Ian Brown
Recruitment difficulties and/or high turnover/churn in various areas; resource gaps and resource diversion into recruitment and induction, with impacts felt across all teams.	So far recruitment rounds have yielded sufficient candidates, although this has required going beyond the initial ALB pool to external recruitment in some cases.	Managed as needed – Sharon Fensome-Rimmer	On legal parenthood, a strong set of actions is in place and continues to be implemented. The inspection team continue to work with colleagues in licensed centres where there are anomalies. The focus is on ensuring all affected patients are informed and appropriately supported.
	Additional temporary resources available during periods of vacancy and transition.	In place – Rachel Hopkins	
	Group induction sessions put in place where possible.	In place – Sharon Fensome-Rimmer	
Resource strain itself can lead to increased turnover, exacerbating the resource strain.	Operational performance, risk and resourcing oversight through CMG, with deprioritisation or rescheduling of work an option.	In place – Paula Robinson	
Unexpected fluctuations in workload (arising from eg, very high level of PGD applications received, including complex applications involving multiple types of a condition; high levels of non-compliances either generally or in relation to a particular issue).	Staffing model amended in May 2015, to release an extra inspector post out of the previous establishment. This increased general resilience, enabling more flex when there is an especially high inspection/report writing/application processing workload.	In place – Sharon Fensome-Rimmer	
	Greater sector insight into our PGD application handling processes and decision-making steps achieved in the past few years; coupled with our increased processing rate since efficiency improvements were made in 2013 (acknowledged by the sector).	In place – Sharon Fensome-Rimmer	
Some unanticipated event occurs that has a big diversionary impact on key resources, eg, legal parenthood consent issues, or several major Grade A	Resilient staffing model in place.	In place – Sharon Fensome-Rimmer	
	Update of compliance and enforcement policy and implementation of new policy and related procedures.	In place – revised policy agreed Spring 2016 – Nick Jones / Sharon Fensome-Rimmer	

incidents occur at once.

A detailed action plan in response to the legal parenthood judgment is in place.

There has been correspondence with clinics, who have completed full audits. PRs are responsible for the robustness of the audit.

The HFEA has required that clinics support affected patients – using Barts as a good example.

In working with clinics, the HFEA has experienced good cooperation. All clinics engaged and have provided assurances about current practice.

Through a detailed review of every clinic's responses, a summary list of all concerns is being produced.

Management review meetings took place for all clinics at which there are handling concerns or anomalies.

Plan of action in place to address all of the concerns identified, with direct follow up with centres who did not respond at all.

Where there are engagement concerns, we will do short-notice inspections, focused on parenthood consent.

The policy team will develop a range of tools to support licensed clinics in ensuring patients provide effective consent.

Range of lessons learned identified.

In progress – Nick Jones/Sharon Fensome-Rimmer

Policy team tools – development in 2017/18 business year – Joanne Anton

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Regulatory model RM 2: Loss of regulatory authority	There is a risk that the HFEA could lose authority as a regulator, jeopardising its regulatory effectiveness, owing to a loss of public / sector confidence.	Setting standards: improving the quality and safety of care through our regulatory activities.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Peter Thompson
			Likelihood	Impact	Inherent risk		
			3	5	15 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			2	4	8 Medium		
Tolerance threshold:			8 Medium				
Causes / sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Failures or weaknesses in decision making processes.		Keeping up to date the standard operating procedures (SOPs) for licensing, representations and appeals.	In place – Ian Brown		At tolerance.		
		Learning from past representations and Appeal Committee hearings incorporated into processes.	In place – Ian Brown		Although two additional risk sources exist at present (website outages until the new beta website is live and the plan of work to address legal parenthood consent issues), these are being well managed and/or tolerated, and the overall risk score has not increased.		
		Appeals Committee membership maintained. Ongoing process in place for regular appointments whenever vacancies occur or terms of office end.	In place – Ian Brown				
		Staffing structure for sufficient committee support.	In place – Ian Brown				
		Decision trees; legal advisers familiar.	In place – Ian Brown				
		Proactive management of quoracy for meetings.	In place – Ian Brown				
		New (ie, first application) T&S licences delegated to ELP. Delegations were revisited during 2016 review of Standing Orders. Licensing Officer role to take certain decisions from ELP –the documentation for recording Licensing Officer decisions is complete as at September 2016 and this process is ready for implementation.	In place – Ian Brown Licensing Officer role – ready for implementation September 2016 – Ian Brown Delegations in SOs were put in place - Spring 2016				
Failing to demonstrate competence as a regulator		Update of compliance and enforcement policy and implementation of new policy and related procedures.	In place – revised policy agreed Spring 2016 – Nick Jones / Sharon Fensome-Rimmer				

	Inspector training, competency-based recruitment, induction process, SOPs, quality management system (QMS) and quality assurance all robust.	In place – Sharon Fensome-Rimmer
Effect of publicised grade A incidents.	Staffing model provide resilience in inspection team for such events – dealing with high-impact cases, additional incident inspections, etc.	In place – Sharon Fensome-Rimmer
	SOPs and protocols with Communications team.	In place – Sharon Fensome-Rimmer
	Fairness and transparency in licensing committee information.	In place – Sharon Fensome-Rimmer
	Dedicated section on website, so that the public can openly see our activities in the broader context.	In place – Sharon Fensome-Rimmer
Administrative or information security failure, eg, document management, risk and incident management, data security.	Staff have annual information security training (and on induction).	In place – Dave Moysen
	TRIM training and guidance/induction in records management in place pending new work on records management to be commenced in autumn 2016 (see below).	New work in development as at September 2016
	Further work planned on records management in parallel with IT strategy. This piece of work is currently being scoped.	Linked to IT strategy work – in progress – Ian Brown / David Moysen
	Guidance/induction in handling FOI requests, available to all staff.	In place – Ian Brown
	The IfQ website management project has reviewed the retention schedule.	Completed – August 2015 – Juliet Tizzard
Until the IfQ website project has been completed, there is a continued risk of HFEA website outages, as well as difficulties in uploading updates to web pages.	Alternative mechanisms are in place for clinics to get information about materials such as the Code of Practice (eg, direct communications with inspectors, Clinic Focus).	In place – Sharon Fensome-Rimmer
	The IfQ work on the new website will completely mitigate this risk (the new content management system will remove the current instability we are experiencing from using RedDot). This risk has informed 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 sector in connection with legally disputed issues or major adverse events at clinics.	HFEA approach is only to go into cases on the basis of clarifying legal principles or upholding the standards of care by challenging poor practice. This is more likely to be perceived as proportionate, rational and necessary (and impersonal), and is in keeping with our strategic vision.	In place - Peter Thompson
HFEA process failings that create or contribute to legal challenges, or which weaken cases that are otherwise sound, or which generate additional regulatory sanctions activity (eg, legal parenthood consent).	Licensing SOPs, committee decision trees in place. Mitochondria donation application tools completed.	In place – Ian Brown
	Update of compliance and enforcement policy and implementation of new policy and related procedures.	In place – revised policy agreed Spring 2016 – Nick Jones / Sharon Fensome-Rimmer
	Seeking the most robust possible assurance from the sector with respect to legal parenthood consent issues, and detailed plan in operation to address identified cases and anomalies.	In progress – Nick Jones
	QMS and quality assurance in place in inspection team.	In place – Sharon Fensome-Rimmer

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
IfQ IfQ 1: Improved information access	If the information for Quality (IfQ) programme does not enable us to provide better information and data, and improved engagement channels, patients will not be able to access the improved information they need to assist them in making important choices.	Increasing and informing choice: ensuring that patients have access to high quality meaningful information.	Inherent risk level:			↔ ↔ ↔ ↔	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 and cleanse all of the data that will require correction before migration can be done. Decisions have been made about the degree of reliability required in each data field. For those fields where 100% reliability is needed, inaccurate or missing data is being addressed as part of project delivery.	All aspects – detailed project planning in place – Nick Jones		Above tolerance. The approval process has had to be tightly managed; a summary is set out below. The Department of Health gateway review took place in November 2015 and awarded a high score to the HFEA, but the formal decision on this was still not made by the Government Digital Service board until mid-January (a month later than expected). This meant that the beta (build) stage initially had to proceed at risk (subsequently resolved).		
Reduced ability to provide for patient choice based on CaFC information as a result of EPRS inability to submit/correct data in the new register structure if they do not update their systems in time to comply. This could impact the publication of CaFC data.		Proposals on an updated IfQ delivery plan were made to August IfQ Programme Board, these should help address this risk. Mitigation plans for this risk are in the process of being prepared and agreed with SMT as at September.	In progress - Nick Jones				

Stakeholders dislike or fail to accept the new model for CaFC. Stakeholders not on board with the changes.	In-depth stakeholder engagement and extensive user research completed to inform the programme's intended outcomes, products and benefits. This included, consultation, expert groups and Advisory Board and this continues to be an intrinsic part of programme approach.	In place and ongoing – Juliet Tizzard /Nick Jones	Approval also carried a number of requirements and conditions which need to be added to the delivery. Owing to these delays, it was necessary to extend the timeline for the private beta phase from March to June 2016.
Cost of delivering better information becomes too prohibitive, either because the work needed is larger than anticipated, or as a result of the approval periods associated with required DH/GDS gateway reviews.	Costs were taken into account as an important factor in consideration of contract tenders and negotiations. Following earlier long timelines and unsuccessful attempts to discuss with GDS, our experience at the Beta gateway has been much improved and feedback was almost immediate. Watching brief being kept.	In place – Nick Jones In place – Nick Jones	The live beta gateway approval in May was much more efficient, with approvals received within days of the assessment taking place. However, there were a number of requirements to address before implementing live beta.
Redeveloped website does not meet the needs and expectations of our various user types.	Programme approach and some dedicated resources in place to manage the complexities of specifying web needs, clarifying design requirements and costs, managing changeable Government delegation and permissions structures, etc. User research done, to properly understand needs and reasons. Tendering and selection process included clear articulation of needs and expectations. GDS Beta assessment was passed on all 18 points.	In progress – delivery of next stage of user research by end Oct 2016 – Juliet Tizzard	The move to public (live) beta was delayed by an injunction brought by a licensed clinic. We successfully managed to have the injunction lifted, but it meant that we could not issue the new website to public beta testing until August 2016.
Government and DH permissions structures are complex, lengthy, multi-stranded, and sometimes change mid-process.	Initial external business cases agreed and user research completed. Final business case for whole IfQ programme was submitted and eventually accepted. All GDS approvals sought so far have been granted, albeit with some delays to the earlier ones. Additional sprints of work were incorporated in beta, in an attempt to allow sufficient time (and resources) for the remaining GDS gateway review processes	In place – Juliet Tizzard In place – Nick Jones (decision received April 2015) In place – Nick Jones	

	and subsequent formal approval mechanisms. The beta timeline was extended by 3 months to compensate for previous and anticipated future delays.	
Resource conflicts between delivery of website and business as usual (BAU).	Backfilling where possible/affordable to free up the necessary staff time, eg, Websites and Publishing Project Manager post backfilled to free up core staff for IfQ work.	In place – Juliet Tizzard
Delivery quality is very supplier dependent. Contractor management could become very resource-intensive for staff, or the work delivered by one or more suppliers could be poor quality and/or overrun, causing knock-on problems.	Programme management resources and quality assurance mechanisms in place for IfQ to manage (among other things) contractor delivery. Agile project approach includes a 'one team' ethos and requires close joint working and communication among all involved contractors. Sound project management practices in place to monitor delivery. Previous lessons learned and knowledge exist in the organisation from managing some previous projects where poor supplier delivery was an issue requiring significant hands-on management. Ability to consider deprioritising other work, through CMG, if necessary. Regular contract meetings in place. This remains a challenge.	In place – Juliet Tizzard
New CMS (content management software) is ineffective or unreliable.	CMS options were scrutinised carefully as part of project. Appropriate new CMS chosen, and all involved teams happy with the selection.	In progress – implemented in beta phase, July 2016 – Juliet Tizzard
Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedded into new ways of working. Knowledge handover with the contractors will take place.	In place – Nick Jones

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
IfQ IfQ 2: Register data	HFEA Register data becomes lost, corrupted, or is otherwise adversely affected during IfQ programme delivery.	Increasing and informing choice: using the data in the Register of Treatments to improve outcomes and research.	Inherent risk level:			↔ ↔ ↔ ↔	Nick Jones
			Likelihood	Impact	Inherent risk		
			2	5	10 Medium		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			2	4	8 Medium		
Tolerance threshold:			8 Medium				
Causes / sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Risks associated with data migration to new structure, together with records accuracy and data integrity issues.		IfQ programme groundwork focused on current state of Register. Extensive planning in place, including detailed research and migration strategy.	In place – Nick Jones/Dave Moysen		At tolerance. This risk is being intensively managed – a major focus of IfQ detailed planning work, particularly around data migration.		
The firm (Avoca) which was scheduled to provide assurance on data migration has gone out of business.		The HFEA has considered other sources of assurance and have now sourced a supplier and is currently going through procurement processes to appoint them.	Pending a successful appointment process, we would expect the new company to begin providing assurance in September/October– Nick Jones				
Historic data cleansing is needed prior to migration.		A detailed migration strategy is in place, and data cleansing is in progress.	In place – Nick Jones/Dave Moysen				
Increased reporting needs mean we later discover a barrier to achieving this, or that an unanticipated level of accuracy is required, with data or fields which we do not currently focus on or deem critical for accuracy.		IfQ planning work incorporated consideration of fields and reporting needs were agreed. Decisions about the required data quality for each field were ‘future proofed’ as much as possible through engagement with stakeholders to anticipate future needs and build these into the design.	In place – Nick Jones				
Reliability of existing infrastructure systems – (eg, Register, EDI, network, backups).		Maintenance of desktop, network, backups, etc. core part of IT business as usual delivery.	In place – Dave Moysen				
System interdependencies change / are not recognised		Strong interdependency mapping done between IfQ and business as usual.	Done – Nick Jones				
Benefits not maximised and internalised into ways of working.		During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that	In place – Nick Jones				

	<p>the changes are culturally embraced and embedding into new ways of working. Knowledge handover with the contractors will take place.</p>		
--	---	--	--

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		
			2	4	8 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 phases of projects.	In place – Nick Jones/Juliet Tizzard		Below 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. Workshops were delivered with the sector regarding how information will be collected through the clinic portal. From beta live onwards we will receive feedback and iteratively develop the products.	In place – Nick Jones/Juliet Tizzard		September 2016 - Since, ultimately, we believe that the mitigations that are in place are working effectively and mean that we are on track to achieve the promised efficiencies, we have reduced the level of likelihood for this risk. This in turn brings the risk to below the tolerance threshold of 9.		
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		This risk is also affected by GDS approvals and associated requirements (see IfQ1).		
Efficiencies cannot, in the end, be delivered.		Detailed scoping phase included stakeholder input to identify clinic users' needs accurately. Specific focus in IfQ projects on efficiencies in data collected, submission and verification, etc.	In place – Nick Jones				
Cost of improvements becomes too prohibitive.		Contracts only awarded to bidders who made an affordable proposal. Detailed planning for release two (which includes the second iteration of the portal and the	In place (July 2015) – Nick Jones In progress (September 2016) – Nick Jones				

	introduction of the new EDI interface) is in progress and the HFEA will continue to work within agreed costs.	
Required GDS gateway approvals are delayed or approval is not given.	<p>All GDS approvals sought so far have been granted, albeit with some delays to earlier gateways. Our detailed planning includes addressing the requirements laid down by GDS as conditions of alpha and beta phase approval.</p> <p>Additional sprints of work were incorporated into beta, in an attempt to allow sufficient time (and resources) for the remaining GDS gateway review processes and subsequent formal approval mechanisms.</p> <p>The beta timeline was extended by 3 months to compensate for previous and anticipated future delays.</p>	In place – Nick Jones
Benefits not maximised and internalised into ways of working.	<p>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.</p> <p>Knowledge handover with the contractors will take place.</p>	In place (June 2015) – Nick Jones

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Legal challenge LC 1: Resource diversion	There is a risk that the HFEA is legally challenged in such a way that resources are diverted from strategic delivery.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			↓ ↔ ↔ ↔	Peter Thompson
			Likelihood	Impact	Inherent risk		
			4	5	20 Very high		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	4	12 High		
Tolerance threshold:			12 High				
Causes / sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Complex and controversial area.		Panel of legal advisors from various firms at our disposal for advice, as well as in-house Head of Legal.	In place – Peter Thompson		At tolerance. Current cases: The judgment in 2015 and subsequent cases on consents for parenthood have administrative and policy consequences for the HFEA. Further cases are going through court, although there have been no cases arising from new incidents post the 2015 judgment. The HFEA is unlikely to participate in most of these legal proceedings directly, though the court has required us to provide information and clarification in relation to six legal parenthood cases.		
		Evidence-based policy decision-making and horizon scanning for new techniques.	In place – Joanne Anton				
		Robust and transparent processes in place for seeking expert opinion – eg, external expert advisers, transparent process for gathering evidence, meetings minuted, papers available online.	In place – Joanne Anton/Juliet Tizzard				
HFE Act and regulations lead to the possibility of there being differing legal opinions from different legal advisers, that then have to be decided by a court.		Panel in place, as above, to get the best possible advice. Case by case decisions regarding what to argue in court cases, so as to clarify the position.	In place – Peter Thompson				
Decisions and actions of the HFEA and its committees may be contested. New guide to licensing and inspection rating (effective from go-live of new website) on CaFC may mean that more clinics make representations against		Panel in place, as above. Maintaining, keeping up to date and publishing licensing SOPs, committee decision trees etc. consistent decision making at licence committees supported by effective tools for committees Standard licensing pack completely refreshed and distributed to members/advisers (April 2015).	In place – Peter Thompson In place – Ian Brown		A judicial review hearing of one discrete element of the IfQ CaFC project has been set for December. Authority decisions in November may impact on the		

licensing decisions.	Well-evidenced recommendations in inspection reports.	In place – Sharon Fensome-Rimmer	<p>scope of the JR. We are advised that our case is strong; however, if it were lost then it may impact on aspects of the presentation of data.</p> <p>A patient has brought an application for a declaration seeking clarification about the continued storage of her embryos. The matter will be considered in court in September and we are hopeful that the agreed outcome can be reached.</p>
Subjectivity of judgments means the HFEA often cannot know in advance which way a ruling will go, and the extent to which costs and other resource demands may result from a case.	Scenario planning is undertaken at the initiation of any likely action.	In place – Peter Thompson	
HFEA could face unexpected high legal costs or damages which it could not fund.	If this risk was to become an issue then 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. This is therefore an accepted, rather than mitigated risk. It is also interdependent risk because DH would be involved in resolving it.	In place – Peter Thompson	
Legal proceedings can be lengthy and resource draining.	Panel in place, as above, enabling us to outsource some elements of the work.	In place – Peter Thompson	
	Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise work should this become necessary.	In place – Peter Thompson	
Adverse judgments requiring us to alter or intensify our processes, sometimes more than once.	Licensing SOPs, committee decision trees in place.	In place – Ian Brown	

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend		
Data D 1: Data loss or breach	There is a risk that HFEA data is lost, becomes inaccessible, is inadvertently released or is inappropriately accessed.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇔ ⇔ ⇔ ⇔
			Likelihood	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. 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 In place – Dave Moysen			
Cyber-attack and similar external risks.		Secure system in place as above, with regular penetration testing.	In place – Dave Moysen			
Infrastructure turns out to be insecure, or we lose connection and cannot access our data.		IT strategy agreed, including a thorough investigation of the Cloud option, security, and reliability.	In place – Dave Moysen			
		Deliberate internal damage to infrastructure, or data, is controlled through off-site back-ups and the fact that any malicious tampering would be a criminal act.	In place (March 2015) – Nick Jones			
Business continuity issue.		BCP in place and staff communication procedure tested. A new BCP is being produced by the Head of IT to reflect the changes to this following changes	In place – Morounke Akingbola Update being done by Dave Moysen – September 2016			

	to infrastructure and the office move.		
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	
Poor records management	TRIM training and guidance/induction in records management in place pending new work on records management to be commenced in autumn 2016 (see below). New work in development as at September 2016	New work in development as at September 2016	
	Further work planned on records management in parallel with IT strategy. This piece of work is currently being scoped. Linked to IT strategy work – in progress – Ian Brown / David Moysen	Linked to IT strategy work – in progress – Ian Brown / David 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.	In place – SMT		Above tolerance.		
		TRIM review and retention policy implementation work – part of records management project	To sync in with IT strategy. RM project to start autumn 2016– Dave Moysen/Ian Brown		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, complexity or deadlines.		
		Audit of Epicentre to reveal any data errors. All queries being routed through Licensing, who have a definitive list of all licensing details.	Completed October 2015 – Ian Brown Implementation of actions following Epicentre audit planned and to be completed by November 2016– Ian Brown		In September 2016 we have not yet registered an unusual spike in volumes following on from recess (during which time there were no PQs). However, with the current work on the mitochondria scientific review, due to be published in November, this situation is likely to change in future months. We continue to closely monitor volumes.		
Excessive demand on systems and over-reliance on a few key expert individuals – request overload – leading to errors		PQs, FOIs and OTRs have dedicated expert staff/teams to deal with them. If more time is needed for a complex PQ, it is occasionally necessary to take the issue out of the very tightly timed PQ process and replace this with a more detailed and considered letter back to the enquirer so as to provide the necessary level of detail and accuracy in the answer. We also refer back to previous answers so as to give a check, and to ensure consistent presentation of similar data.	In place – Juliet Tizzard / Nick Jones				

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

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Donor conception DC 1: OTR inaccuracy	There is a risk that an OTR applicant is given incorrect data.	Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.	Inherent risk level:			↔ ↔ ↔ ↔	Nick Jones
			Likelihood	Impact	Inherent risk		
			3	5	15 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			1	4	4 Low		
Tolerance threshold:			4 Low				
Causes / sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Data accuracy in Register submissions.		Continuous work with clinics on data quality, including current verification processes, steps in the OTR process, regular audit alongside inspections, and continued emphasis on the importance of life-long support for donors, donor-conceived people and parents.	In place – Nick Jones		At tolerance (which is very low for this risk).		
		Audit programme to check information provision and accuracy.	In place – Nick Jones				
		IfQ work will identify data accuracy requirements for different fields as part of the migration process, and will establish more efficient processes.	In place – Nick Jones				
		If subsequent work or data submissions reveal an unpreventable earlier inaccuracy (or an error), we explain this transparently to the recipient of the information, so it is clear to them what the position is and why this differs from the earlier provided data.	In place – Nick Jones				
Issuing of wrong person's data.		OTR process has an SOP that includes specific steps to check the information given and that it relates to the right person.	In place – Nick Jones				
Process error or human error.		As above.	In place – Nick Jones				

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Donor conception DC 2: Support for OTR applicants	There is a risk that inadequate support is provided for donor-conceived people or donors at the point of making an OTR request.	Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.	Inherent risk level:			↔ ↔ ↔ ↔	Nick Jones
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	3	9 Medium		
Tolerance threshold:			9 Medium				
Causes / sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Lack of counselling availability for applicants.		Counselling service established with external contractor in place.	In place (June 2015) – Nick Jones		At tolerance.		
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 returning to work from 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 ongoing team capacity issue under discussion – Nick Jones		The pilot counselling service has been in place since 1 June 2015, and we will make further assessments based on uptake and the delivery experience. Reporting to the Authority will occur annually during the pilot period, and the first such report was provided to the July Authority meeting.		
Risk of inadequate handling of a request.		Trained staff, SOPs and quality assurance in place.	In place – Nick Jones				
		SOPs reviewed by Register staff, CMG and PAC-UK, as part of the pilot set-up. Contract in place with PAC-UK for pilot delivery.	Done (May 2015) – ongoing management of the pilot by Rosetta Wotton.				

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Financial viability FV 1: Income and expenditure	There is a risk that the HFEA could significantly overspend (where significantly = 5% of budget, £250k)	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			↔ ↔ ↔ ↔	Morounke Akingbola
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	3	9 Medium		
Tolerance threshold:			9 Medium				
Causes / sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Fee regime makes us dependent on sector activity levels.		Activity levels are tracked and change is discussed at CMG, who would consider what work to deprioritise and reduce expenditure.	Monthly (on-going) – Morounke Akingbola		At tolerance. 2015/16 achieved a small under-spend but risk of additional legal costs remains.		
		Fees Group created enabling dialogue with sector about fee levels. Fee increase was agreed and approved by Treasury. This was implemented and the eSET discount ended (April 2016).	In place. Fees Group meeting in October, ongoing – Morounke Akingbola		The increase of per-cycle fees by £5 (to £80) and the end of the small 'eSET discount' for elective single embryo transfer has now been implemented following Treasury approval in February 2016. This should help secure sufficient funds going forward.		
EPRS suppliers may not make required changes to their systems in line with IfQ data submission mechanism (EDI, Register) changes. Clinics using these suppliers would be unable to provide treatment data leading to deferral of fee payment since we could not bill centres for treatments.		Proposals were made to August IfQ Programme Board for adjustments to the IfQ schedule which would impact when this risk is likely to be felt. Further discussions are needed with Finance to understand the scale of the potential impact of this risk and to plan for an effective mitigation to secure cash flow. These discussions will be ongoing while IfQ release 2 develops further.	Ongoing -Nick Jones		It is too early for us to tell whether this reduces this risk further. The situation will be clearer following IfQ implementation.		
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) – Morounke Akingbola		The potential impact of the IfQ risk here, related to EPRS suppliers and the impact on treatment fees, is not yet fully		
		Annual budget agreed with DH Finance team alongside draft business plan submission.	December annually – Morounke Akingbola				
		Detailed budgets for 2016/17 have been agreed with Directors. DH has previously agreed our resource envelope.	In place – Morounke Akingbola				

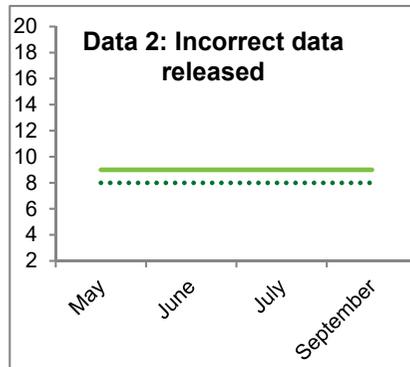
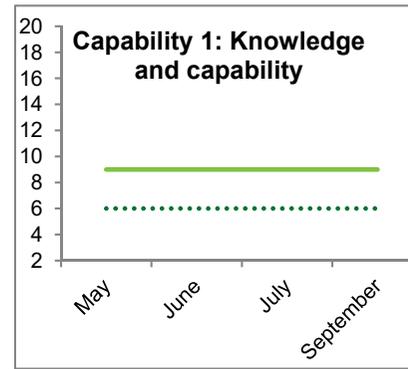
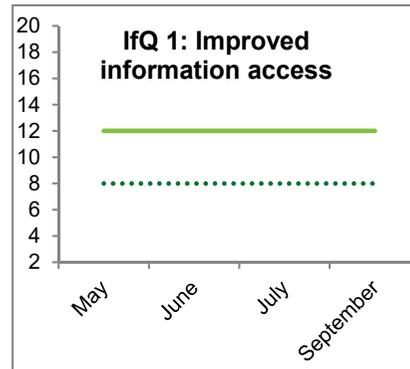
Budget setting process is poor due to lack of information from directorates	Quarterly meetings with directorates flags any shortfall or further funding requirements.	Quarterly meetings (on-going) – Morounke Akingbola	understood. It is also clear that this would not potentially impact the organisation until 2017, so the risk level is not affected at this time. Meanwhile, the IfQ team will work together closely with the finance team and the mitigation for this risk will be updated once more information is gathered and a plan agreed. We will keep this under review.
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 – Morounke Akingbola Monthly – IfQ Programme Board	
Upwards scope creep during projects, or emerging during early development of projects eg, IfQ.	Periodic review of actual and budgeted spend by IfQ project board and monthly budget meetings with finance. Cash flow forecast updated.	Ongoing – Wilhelmina Crown Monthly (on-going) – Morounke Akingbola	

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Capability C 1: Knowledge and capability	There is a risk that the HFEA experiences unforeseen knowledge and capability gaps, threatening delivery of the strategy.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Peter Thompson
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	3	9 Medium		
Tolerance threshold:			6 Medium				
Causes / sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
High turnover, sick leave etc. leading to temporary knowledge loss and capability gaps.		People strategy will partially mitigate. Mixed approach of retention, staff development, and effective management of vacancies and recruitment processes.	Done – May 2015 – Rachel Hopkins		Above tolerance. This risk and the set of controls remains focused on capability, rather than capacity. There are obviously some linkages, since managing turnover and churn also means managing fluctuations in capability and ensuring knowledge and skills are successfully nurtured and/or handed over. Since the HFEA is a small organisation, with little intrinsic resilience, it seems prudent to have a low tolerance level for this risk. Both Head vacancies were filled (in March and May 2016 respectively). The Head of Corporate Governance is now leaving in September 2016 which leaves a head vacancy again. There will continue to be a period of bedding in for the		
		Staff have access to civil service learning (CSL); organisational standard is five working days per year of learning and development for each member of staff.	In place – Rachel Hopkins				
		Organisational knowledge captured via records management (TRIM), case manager software, project records, handovers and induction notes, and manager engagement.	In place – Rachel Hopkins				
The new UK government may implement further cuts across all ALBs, resulting in further staffing reductions. This would lead to the HFEA having to reduce its workload in some way.		The HFEA was proactive in reducing its headcount and other costs to minimal levels over a number of years. We have also been reviewed extensively (including the McCracken review). Turnover is variable, and so this risk will be retained on the risk register, and will continue to receive ongoing management attention.	In place – Peter Thompson				
Poor morale leading to decreased effectiveness and performance failures.		Engagement with the issue by managers. Ensuring managers have team meetings and one-to-one meetings to obtain feedback and identify actions to be taken.	In place – Peter Thompson				

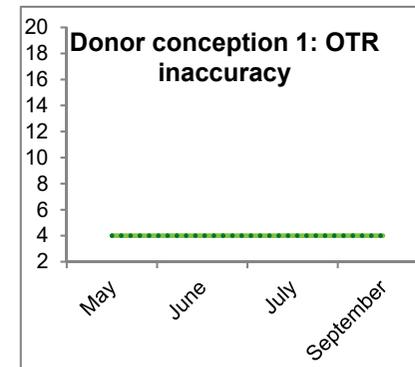
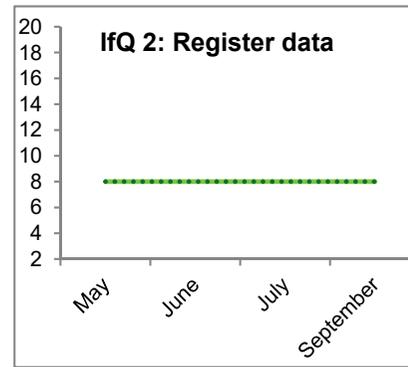
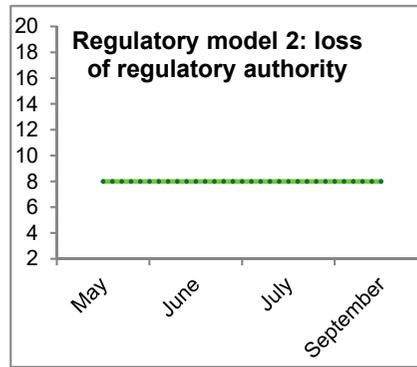
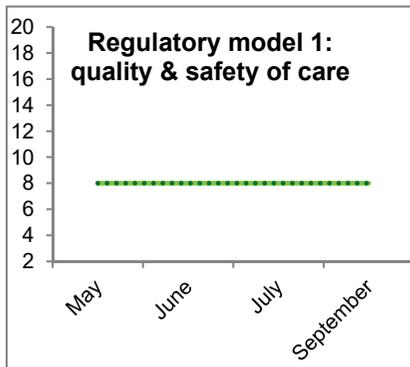
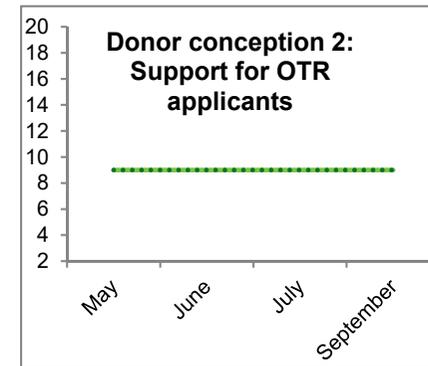
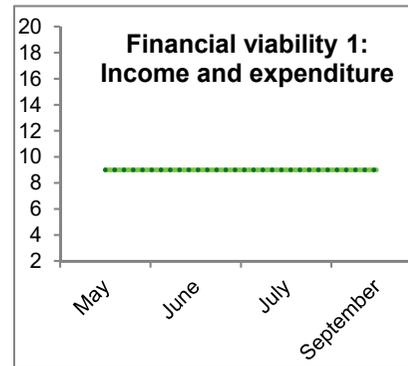
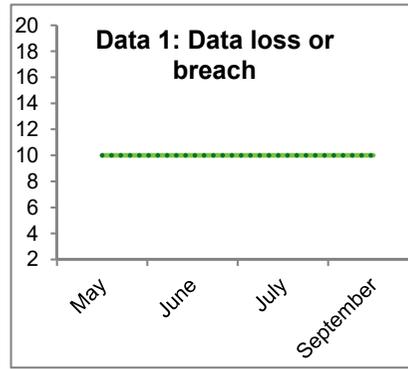
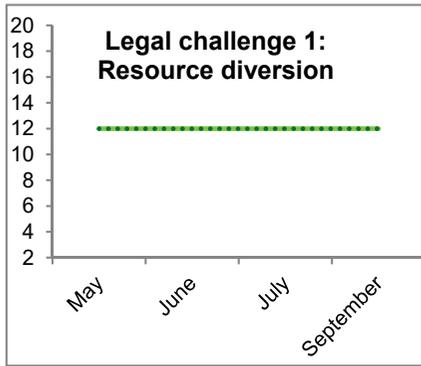
	Staff survey and implementation of outcomes, following up at December 2015 all staff conference.	Survey and staff conference done – Rachel Hopkins Follow-up communications in place (Staff Bulletin etc.) – Peter Thompson	Chief Inspector.
Differential impacts of IfQ-related change and other pressures for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

Tolerance vs Residual Risk:

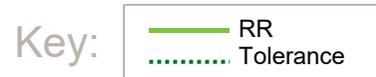
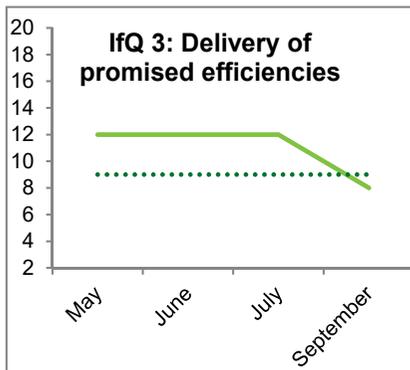
Risks above tolerance



Risks at tolerance



Risk below tolerance



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	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		1. Rare (≤10%)	2. Unlikely (11%-33%)	3. Possible (34%-67%)	4. Likely (68%-89%)	5. Almost Certain (≥90%)
		Likelihood				

Reserves Policy



Strategic delivery: Setting standards Increasing and informing choice Demonstrating efficiency economy and value

Details:

Meeting Audit and Governance Committee

Agenda item 11

Paper number AGC (21/09/2016) 510

Meeting date 21 September 2016

Author Morounke Akingbola - Finance Manager

Output:

For information or decision? Decision

Recommendation AGC is requested to consider, comment and approve the updated reserves policy. It will then be agreed with DH.

Resource implications Implementing and monitoring the policy is part of the role of the Finance directorate

Implementation date

Organisational risk Low Medium High

Annexes

Reserves Policy

Introduction

The purpose of this policy is to ensure that both the Executive and Authority of the HFEA are aware of the minimum level at which reserves are maintained and the reasons for doing so. The minimum level of reserves set out in this policy has been agreed with the Department of Health.

Principles

An organisation should maintain enough cash reserves to continue business operations on a day-to-day basis and in the event of unforeseen difficulty and commitments that arise. It is best practice to implement a reserves policy in order to guide key decision-makers.

Reserves Policy

1. The Authority has decided to maintain a reserves policy as this demonstrates:
 - Transparency and accountability to its licence fee payers and the Department of Health
 - Good financial management
 - Justification of the amount it has decided to keep as reserves
2. The following factors have been taken into account in setting this reserves policy:
 - Risks associated with its two main income streams - licence fees and Grant-in-aid - differing from the levels budgeted
 - Likely variations in regulatory and other activity both in the short term and in the future
 - HFEA's known, likely and potential commitments
3. The policy requires reserves to be maintained at least at a level that ensures the HFEA's core operational activities continue on a day-to-day basis and, in a period of unforeseen difficulty, for a suitable period. The level should also provide for potential commitments that arise.

Cashflow

4. To enable sufficient cover for day-to-day operations, a cash flow forecast is prepared at the start of the financial year which takes into account the timing of when receipts are expected and payments are to be made. Most receipts come from treatment fees -

invoices are raised monthly and on average take 60 days to be paid. Cash reserves are needed to ensure sufficient working capital is available to make payments when they become due throughout the year.

5. The HFEA experiences negative cashflow (more payments than receipts) in some months. £510k is needed to cover this cash shortage. Reserves should be maintained so that there is always a positive cash balance.

Unforeseen difficulty

6. The level of reserves required for unforeseen difficulty is based on two elements: salaries (including employer on-costs) and the cost of accommodation. These are deemed to be fixed costs that would have to be paid in times of unforeseen difficulty with all other of the HFEA's running costs being regarded as semi-variable or variable costs and thus excluded from this calculation. These two areas currently represent 77% of the HFEA's total annual budget.
7. The certainty and robustness of HFEA's key income streams and the predictability of fixed costs, as well as the relationship with the sponsor, the Department of Health, indicate that 2 months' salary and accommodation costs is a prudent, but sufficient, minimum level of reserves to hold.
8. Based on the HFEA's current revenue budget, the combined monthly cost of salaries and accommodation is around £336k. A prudent reserve of two months going forward would therefore be £672k.

Other potential commitments

9. The HFEA is also mindful of the financial risks it faces, in particular that it may be required to undertake additional activities not planned or make additional spend not included within budget or utilise its reserves for key pieces of work. While every effort would be made to cover costs within the budget allocated for the year, it may be necessary to use reserves to meet the cashflow needs arising from additional necessary spend.
10. A prudent reserve for other commitments would be £150k. If other exceptional spend was required, the HFEA would look to the Department of Health for support.

Minimum reserves

11. The HFEA's minimum level of reserves will be maintained at a level that enables positive cashflow (£510k), provides £672k for unforeseen difficulty and £150k for other potential commitments. The minimum level of cash reserves required is therefore £1.33m. These reserves will be in a readily realisable form at all times.
12. Each month the level of reserves will be reviewed by the Director of Finance and Resources as part of the HFEA's ongoing monitoring of its cash flow.

13. Each autumn as part of the HFEA's business planning and budget setting process, the required level of reserves for the following financial year will be reassessed.
14. In any assessment or reassessment of its reserves policy the following will be borne in mind.
- The level, reliability and source of future income streams.
 - Forecasts of future, planned expenditure.
 - Any change in future circumstances - needs, opportunities, contingencies, and risks – which are unlikely to be met out of operational income.
 - An identification of the likelihood of such changes in these circumstances and the risk that the HFEA would not be able to meet them.
15. HFEA's reserves policy will be reviewed annually by the Audit and Governance Committee.

Document name	Reserves Policy
Release date	October 2014
Author	Head of Finance
Approved by	CMG
Next review date	September 2017
Total pages	3

Version/revision control

Version	Changes	Updated by	Approved by	Release date
1.0	Created			Feb 2015
2.0	Branded/amended	HoF		August 2016