

Authority paper

Strategic delivery	Setting standards	<input type="checkbox"/>	Increasing and informing choice	<input type="checkbox"/>	Demonstrating efficiency, economy and value	<input checked="" type="checkbox"/>
Paper title	Strategic Risk Register					
Agenda item	7					
Paper number	HFEA (08/07/2015) 759					
Meeting date	11 March 2015					
Author	Paula Robinson, Head of Business Planning					
For information or decision?	Information					
Recommendation	The Authority is asked to note and comment on the latest edition of the strategic risk register.					
Resource implications	In budget					
Implementation	Throughout 2015/16.					
Communication	AGC reviewed the risk register at its meeting on 10 June.					
Organisational risk	Low.					
Annexes	A: Strategic Risk Register					

1. Strategic Risk Register – CMG review May 2015

- 1.1. CMG reviewed the new Strategic Risk Register (SRR) on 20 May at its quarterly risk meeting. Five of the twelve risks are currently above tolerance. CMG reviewed all risks, controls and scores. CMG's specific comments are contained in the SRR at Annex A.
- 1.2. The risk register was also discussed at AGC on 10 June. No changes were proposed. AGC also discussed progress with developing our approach to risk assurance (a new activity), coupled with recent work to refresh the way in which we identify and record operational risks.

2. Recommendations

- 2.1. The Authority is invited to note the June edition of the strategic risk register.

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*
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	↔ ↔ ↔ ↔
Data	D2: Incorrect data released	Efficiency, economy and value	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	↔ ↔ ↔ ↔
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	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	↔ ↔ ↔ ↔
Regulatory model	RM1: Quality and safety of care	Setting standards: quality and safety	4 – Low	Below tolerance	↔ ↔ ↓ ↔

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

Recent review points: CMG February 2015 ⇒ AGC and Authority March 2015 ⇒ CMG 20 May 2015 ⇒ AGC 10 June 2015 (latest review).

¹ Strategic objectives 2014-2017:

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

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

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

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

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

CMG and AGC Overview**20 May CMG Risk meeting:**

- CMG updated the controls and the scores throughout.
- CMG noted AGC's discussion in March about the capability risk (C1) and its interaction with capacity (in the context of turnover and induction/probation periods for new staff members). CMG agreed that although the current period of high turnover seems to be coming to an end, this risk could recur, and should therefore be retained. AGC had specifically requested that the tolerance level for this risk (set low, at 6) should be reviewed by CMG. The reduction in overall staffing numbers over the past few years has left us with little resilience, particularly in specialist and small functions, and so turnover could affect capability more in some instances, with possible impacts on strategic delivery. Therefore, CMG agreed that our tolerance for the capability risk needs to remain low, even though the risk level is now reducing.

10 June AGC meeting:

- AGC noted that some risks are controlled by good records management practices including occasional TRIM refresher (or induction) training. The Senior Management Team (SMT) has begun to discuss how best to maintain good records management practices and learning in the organisation.
- Members of AGC were supportive of our intention to ensure that records management remains of good quality, especially in light of the fact that we expect clinics to perform well on records management, and inspect them on that basis. They also accepted that good practice is already largely in place, and that it is not straightforward to assign such duties in an organisation with few staff. SMT will give this further thought in the near future.
- AGC also heard (under other substantive items) about current risks/controls with respect to the new people strategy and current IfQ developments. It was acknowledged that the IfQ risks would need a thorough update once sprint zero was under way (July). It was also agreed that the risks relating to IfQ needed to include reference to maximising the benefits at the end of the programme of work, ie, culturally embracing and embedding the changes and new ways of working. Another risk factor was identified relating to the probable office move in or around April 2016, in that this could potentially coincide with a critical delivery period. There is general awareness of this issue across IfQ, and work-arounds will be decided well ahead of time, as soon as a firm date is announced for the HFEA's move.

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, CMG would like to define 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		
			1	4	4 Low		
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	Below tolerance for the time being, following recent recruitment and new staffing model.			
		Audit of Epicentre to reveal any data errors.	Due for completion June 2015 – Sam Hartley				
		Inspector training, competency-based recruitment, induction process, SOPs, QMS, and quality assurance all robust.	In place – Debra Bloor				
Monitoring failure.		Outstanding recommendations from inspection reports are tracked and followed up by the team.	In place – Debra Bloor				
Unresponsiveness to or mishandling of non-compliances or grade A incidents.		Update planned to compliance and enforcement policy. Authority workshop took place in March 2015. More work to follow, including input from Committee Chairs and revised policy to September Authority alongside a set of other related Compliance team updates.	Partly complete – revision will go to September 2015 Authority – Debra Bloor				
		Staffing model changed to increase resilience in inspection team for such events – dealing with high-impact cases, additional incident inspections, etc..	In place – Debra Bloor – May 2015				

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Insufficient inspectors or licensing staff	Inspection team up to complement following several recruitments.	In place – Debra Bloor	
	Licensing team up to complement following recruitment.	In place – Sam Hartley	
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 the situation evolves – Debra Bloor	
	NHS Jobs account changed in May 2015 so that vacancies now appear under an HFEA identity rather than a CQC identity (with CQC continuing to administer), so as to address the cause of misunderstandings by many job candidates.	In place – Rachel Hopkins	
	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	
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 developed (May 2015), to release an extra inspector post out of the previous establishment. This increased general resilience so as to enable more flex when there is an especially high inspection/report writing/application processing workload (as there is, in 2015).	In place – Debra Bloor	
	PGD workshop annually with the sector to increase their insight into our PGD application handling processes and decision-making steps; coupled with our increased processing times from efficiency improvements made in 2013 (acknowledged by the sector).	In place and annual – Debra Bloor	
Some unanticipated event occurs that has a big diversionary impact on key resources, eg, several major Grade A incidents occur at once.	Addressed by revised staffing model.	In place – Debra Bloor	
	Compliance and enforcement policy review (see above) will improve handling processes for incidents and non-compliance.	Partly complete – revision will go to September 2015 Authority – Debra Bloor	

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	At tolerance.				
	Learning from recent representations experience incorporated into processes.	In place – Sam Hartley					
	Appeals Committee membership maintained – vacancy filled.	In place – Sam Hartley					
	Staffing structure for sufficient committee support.	In place – Sam Hartley					
	Decision trees; legal advisers familiar.	In place – Sam Hartley					
	Proactive management of quoracy for meetings.	In place – Sam Hartley					
	New T&S licences delegated to ELP and now in place. Licensing Officer due to become live.	Delegation to be returned to, in 2016 review of SOs. Licensing Officer role to take decisions from ELP – implementation due end June 2015.					
Failing to demonstrate competence as a regulator	Review of compliance and enforcement policy (in progress).	Partly complete – revision will go to September 2015 Authority – Debra Bloor					
	Inspector training, competency-based recruitment, induction process, SOPs, quality management system (QMS) and quality assurance all robust.	In place – Debra Bloor					

Effect of publicised grade A incidents.	Staffing model changed (May 2015) to build resilience in inspection team for such events – dealing with high-impact cases, additional incident inspections, etc.	In place – Debra Bloor
	SOPs and protocols with Communications team.	In place – Debra Bloor
	Fairness and transparency in licensing committee information.	In place – Debra Bloor
	Dedicated section on website, so that the public can openly see our activities in the broader context.	In place – Debra Bloor
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 (next round is due in Q1 of 2015/16)
	TRIM training and guidance/induction in records management in place.	Internal ownership of this function will be decided by SMT in the near future – end July 2015
	The IfQ website management project will be reviewing the retention schedule.	By December 2015 – Juliet Tizzard
	Guidance/induction in handling FOI requests, available to all staff.	In place – Sam Hartley
	Further work to be planned on records management in parallel with IT strategy	Linked to IT strategy work – in progress – Dave Moysen/Sam Hartley
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.	Licensing SOPs, committee decision trees in place. Mitochondria tools in development.	Existing tools in place; mitochondria tools due by October 2015 – Sam Hartley
	Review of compliance and enforcement policy (in progress).	Partly complete – revision will go to September 2015 Authority – Debra Bloor
	QMS and quality assurance in place in inspection team.	In place – Debra Bloor

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					
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. 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 progress – Nick Jones (IfQ sprint zero in July 2015 will lead to more elaboration of work sequencing; migration will be done later rather than sooner, and will only be done when we are sure associated risks are thoroughly managed.)	Above tolerance. Managing these risks has formed an intrinsic and essential part of the detailed project planning and tendering. Following a lengthy delay, we received formal approval for both the data and digital elements of IfQ in late April 2015.				
Unable to work out how best to improve CaFC, and/or failure to find out what data/information patients really need.	Stakeholder engagement and user research is in place as intrinsic part of programme approach.	In place and ongoing – Dec 2014 onwards – Nick Jones	The digital side of the programme has received only partial approval; full delivery will still require additional approvals after the first phase of work. There is a risk that this could lead to further long delays which would have a further				
Stakeholders not on board with the changes.	In-depth stakeholder engagement 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 taken into account as an important factor in consideration of contract tenders and negotiations.	In place – Dec 2014 to June 2015 – Nick Jones					

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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. Tendering and selection process includes clear articulation of needs and expectations.	In progress – delivery by end Mar 2016 – Juliet Tizzard	negative impact. This would adversely affect the quality of the final product (rather than the existence of a final product).
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 submitted.	In place (Nov 2014) – Juliet Tizzard In place (Dec 2014) – Nick Jones (decision received April 2015)	
Resource conflicts between delivery of website and business as usual (BAU).	Backfilling 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 will be very supplier dependent. It is also likely to involve multiple different suppliers and 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 for other suppliers.	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 during the Sprint Zero start-up phase. 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 being scrutinised as part of project.	In progress – Jan/Feb 2015 (depending on approval) – Juliet Tizzard	
Communications infrastructure incapable of supporting the planned changes.	Needs to be updated as part of IfQ in order to support the changes.	In place – set out in business case – Juliet Tizzard (Dec 2014)	

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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 (June 2015) – Nick Jones	
Potential risks associated with the HFEA's likely office move in April 2015, 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.	For further thought once there is certainty about the timetable for the move (July/August 2015) – Nick Jones/Sue Gallone	

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. Intensive 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 (the migration itself will occur much later).	In place – Nick Jones/Dave Moysen				
Increased reporting needs mean we later discover a problem, 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 – April 2015				
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 (June 2015) – Nick Jones				

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Potential risks associated with the HFEA's likely office move in April 2015, 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.	For further thought once there is certainty about the timetable for the move (July/August 2015) – Nick Jones/Sue Gallone	
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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					
Causes/ sources			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 coming to an end, but a new stakeholder group for implementation phase is planned.	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 are a critical part of the decision in awarding the contract.	In place and contract awards in progress – Nick Jones – May 2015				
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 will only be awarded to bidders who make an affordable proposal.	In progress – Nick Jones – May 2015				

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<p>Benefits not maximised and internalised into ways of working.</p>	<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 embedding into new ways of working.</p>	<p>In place (June 2015) – Nick Jones</p>	
<p>Potential risks associated with the HFEA’s likely office move in April 2015, in that this will coincide with the delivery period for some IfQ milestones.</p>	<p>Early awareness of the potential for disruption means that this can be managed through careful planning.</p>	<p>For further thought once there is certainty about the timetable for the move (July/August 2015) – Nick Jones/Sue Gallone</p>	

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 is awaiting judgment as at the end of June 2015. We hope that this can be resolved shortly.			
		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				
		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				

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	More work planned on enhancing committee tools to incorporate recent lessons learned.	In progress as at May 2015 – Catherine Drennan / Sam Hartley	
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 likely action.	In place – Peter Thompson	
HFEA could face unexpected high legal costs or damages which it could not fund.	Discussion with the Department of Health would need to take place regarding possible cover for any extraordinary costs, since it is not possible for the HFEA to insure itself against such an eventuality, and not reasonable for the HFEA's small budget to include a large legal contingency.	In place – Peter Thompson	
Legal proceedings can be lengthy and resource draining.	Panel in place, as above, enabling us to outsource some elements of the work.	In place – Peter Thompson	
	Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise work should this become necessary.	In place – Peter Thompson	
Adverse judgments requiring us to alter or intensify our processes, sometimes more than once.	Licensing SOPs, committee decision trees in place.	In place – Sam Hartley.	
	Work planned to explore other relevant processes in light of lessons learned following a recent judicial review judgment.	In progress as at May 2015 – Catherine Drennan / Sam Hartley	

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. 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. 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 – Dave Moysen In place (March 2015) – Nick Jones	Above tolerance.			

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Business continuity issue.	BCP in place and staff communication procedure tested. A period of embedding the policies is now in progress.	In place (January 2015) – Sue Gallone	
Register data becomes corrupted or lost somehow.	Back-ups and warehouse in place to ensure data cannot be lost.	In place – Nick Jones/Dave Moysen	
Other HFEA data (system or paper) is lost or corrupted.	As above. Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality.	In place – Dave Moysen	

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Data D 2: Incorrect data released	There is a risk that incorrect data is released in response to a Parliamentary question (PQ), or a Freedom of Information (FOI) or data protection request.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:		↔ ↔ ↔ ↔	Juliet Tizzard	
			Likelihood	Impact			Inherent risk
			5	4			20 Very high
			Residual risk level:				
			Likelihood	Impact			Residual risk
3	4	12 High					
Causes/ sources			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.	Ownership of this function will be decided by SMT in the near future – end June 2015		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 were among the highest we have ever experienced. It is not yet possible to tell if further high volumes will occur during the mitochondria project and the subsequent start-up of applications processing.		
		TRIM review and retention policy implementation work – subsumed by IT strategy.	To sync in with IT strategy – Dave Moysen/Sam Hartley				
		Audit of Epicentre information	In progress – for completion June 2015 – Sam Hartley				
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				

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<p>Answers in Hansard may not always reflect advice from HFEA.</p>	<p>The PQ team attempts to catch any changes to drafted wording that may unwittingly have changed the meaning. This, and ongoing issues with the very high volume being received at present, will be raised with DH when the framework agreement is next reviewed. HFEA's suggested answer and DH's final submission both to be captured in new PQ log.</p>	<p>In place – Sam Hartley / Peter Thompson Date of next review to be confirmed shortly – Peter Thompson</p>	
<p>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.</p>	<p>As above – expert staff with the appropriate knowledge and understanding in place.</p>	<p>In place – Juliet Tizzard / Nick Jones</p>	

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 progress – June 2015 – 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 being established with external contractor.	Set-up in progress – Nick Jones – Jun 2015		At tolerance. The pilot counselling service will be in place from June onwards, and we will make a further assessment shortly based on early uptake and the delivery experience.		
Insufficient Register team resource to deal properly with OTR enquiries and associated conversations.		Additional member of staff dedicated to handling such enquiries.	In place – Nick Jones				
Risk of inadequate handling of a request.		Trained staff, SOPs and quality assurance in place. SOPs being reviewed by Register staff, CMG and PAC-UK, as part of the pilot set-up. Contract signed with PAC-UK for pilot delivery.	In place – Nick Jones Done (May 2015) – In June the management of the Pilot will transfer 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.		
		Fees Group created enabling dialogue with sector about fee levels.	In place. First meeting 29-10-14; and Apr and Oct each year, 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 confirmation for 2015/16 obtained. Capital allocation is outstanding as at 27 May 2015.	In place – Sue Gallone Being actively sought from DH – 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.	Monthly – Sue Gallone				
		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 – IfQ Programme Board				

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Upwards scope creep during projects, or emerging during early development of projects eg, IfQ.	Finance presence at Programme Board (PB) level. Periodic review of actual and budgeted spend by PB.	Ongoing – Wilhelmina Crown	
	Cash flow forecast updated.	Monthly (on-going) – Morounke Akingbola	

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Capability C 1: Knowledge and capability	There is a risk that the HFEA experiences unforeseen knowledge and capability gaps, threatening delivery of the strategy.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:		⇔ ⇔ ↓ ⇔	Peter Thompson	
			Likelihood	Impact			Inherent risk
			4	4			16 High
			Residual risk level:				
			Likelihood	Impact			Residual risk
3	3	9 Medium					
Tolerance threshold:			6 Medium				
Causes/ sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
High turnover, sick leave etc. leading to temporary knowledge loss and capability gaps.		People strategy will partially mitigate. Mixed approach of retention, staff development, and effective management of vacancies and recruitment processes.	Done – May 2015 – Rachel Hopkins		Above tolerance. This risk and the set of controls currently focuses 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. Now that the period of highest turnover appears to be ending, CMG has reduced (slightly) the likelihood of this risk, but still decided to retain it, given that high turnover could recur. CMG also reviewed the tolerance level for this risk, and agreed it should remain at 6. Since the HFEA has become a much smaller organisation over the past few years, leaving less		
		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				

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<p>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.</p>	<p>The HFEA has already 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). Although turnover is currently reducing to more normal levels, this risk will be retained on the risk register, and will continue to receive ongoing management attention.</p>	<p>In place – Peter Thompson</p>	<p>intrinsic resilience, it seems prudent to have a low tolerance for this risk.</p>
<p>Poor morale leading to decreased effectiveness and performance failures.</p>	<p>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.</p>	<p>In place – Peter Thompson</p>	
	<p>Staff survey and implementation of outcomes, following up on Oct 2014 all staff conference.</p>	<p>Survey done (Jan 2015) – Rachel Hopkins Follow-up communications and implementation in place (Staff Bulletin etc.) – Peter Thompson</p>	
<p>Differential impacts of IfQ-related change and other pressures for particular teams could lead to specific areas of knowledge loss and low performance.</p>	<p>Staff kept informed of likely developments and next steps, and when applicable of personal role impacts and choices.</p>	<p>In place – Nick Jones</p>	
	<p>Policies and processes to treat staff fairly and consistently, particularly if people are 'at risk'.</p>	<p>In place – Peter Thompson</p>	
<p>Additional avenues of work open up, or reactive diversions arise, and need to be accommodated alongside the major IfQ programme.</p>	<p>Careful planning and prioritisation of both business plan work and business flow through our Committees. Regular oversight by CMG.</p>	<p>In place – Paula Robinson</p>	
	<p>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.</p>	<p>In place (Jan 2015) – Paula Robinson</p>	
	<p>IfQ has some of its own dedicated resources.</p>	<p>In place – Nick Jones</p>	

	<p>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.</p>	<p>In place – Peter Thompson</p>	
<p>Regarding the current work on licensing mitochondrial replacement techniques, there is a possible future risk, beyond October 2015, that we will need to increase both capability and capacity in this area, depending on uptake (this is not yet certain).</p>	<p>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.</p>	<p>New issue for consideration – Juliet Tizzard</p>	

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 MANAGEMENT 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						