

# Strategic risk register

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

## Details:

Meeting      Authority

Agenda item      8

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## Output:

For information or decision?      For information

Recommendation      The Authority is asked to note and comment on the latest edition of the strategic risk register.

Resource implications      In budget

Implementation date      Ongoing

Communication(s)      The risk register is reviewed quarterly by the Corporate Management Group (CMG), and presented at every Audit and Governance Committee (AGC) meeting. AGC reviewed the risk register at its meeting on 7 October.

Organisational risk       Low       Medium       High

Annexes      Annex 1: Strategic risk register

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## 1. Latest reviews

- 1.1. CMG reviewed the risk register at its meeting on 2 September. Five of the twelve risks remain above tolerance. CMG reviewed all risks, controls and scores. CMG's specific comments are contained in the risk register at Annex A.
- 1.2. The risk register was also discussed at AGC on 7 October. No changes were proposed. AGC also noted progress towards implementing risk assurance mapping in the HFEA, which will be taken forward early next year as part of the internal audit programme, with the support of the Department of Health internal audit team.

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## 2. Recommendation

- 2.1. The Authority is asked to note and comment on the latest edition of the strategic risk register.

## Annex A - HFEA strategic risk register 2015/16

### Risk summary: high to low residual risks

Risk area	Risk title	Strategic linkage <sup>1</sup>	Residual risk	Current status	Trend*
Legal challenge	LC1: Resource diversion	Efficiency, economy and value	<b>15 – High</b>	Above tolerance	↔↔↔↔
Information for Quality	IfQ1: Improved information access	Increasing and informing choice: information	<b>12 – High</b>	Above tolerance	↔↔↔↔
Data	D2: Incorrect data released	Efficiency, economy and value	<b>12 – High</b>	Above tolerance	↔↔↔↔
Financial viability	FV1: Income and expenditure	Efficiency, economy and value	<b>12 – High</b>	Above tolerance	↔↔↔↔
Data	D1: Data loss or breach	Efficiency, economy and value	<b>10 – Medium</b>	At tolerance	↔↔↔↔
Information for Quality	IfQ3: Delivery of promised efficiencies	Efficiency, economy and value	<b>9 – Medium</b>	At tolerance	↔↔↔↔
Donor conception	DC2: Support for OTR applicants	Setting standards: donor conception	<b>9 – Medium</b>	At tolerance	↔↔↔↔
Capability	C1: Knowledge and capability	Efficiency, economy and value	<b>9 – Medium</b>	Above tolerance	↓↔↔↔
Regulatory model	RM2: Loss of regulatory authority	Setting standards: quality and safety	<b>8 – Medium</b>	At tolerance	↔↔↔↔
Information for Quality	IfQ2: Register data	Increasing and informing choice: Register data	<b>8 – Medium</b>	At tolerance	↔↔↔↔
Donor conception	DC1: OTR inaccuracy	Setting standards: donor conception	<b>4 – Low</b>	At tolerance	↔↔↔↔
Regulatory model	RM1: Quality and safety of care	Setting standards: quality and safety	<b>4 – Low</b>	Below tolerance	↓↔↔↔

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

#### Recent review points:

CMG 20 May 2015 ⇒ AGC 10 June 2015 ⇒ CMG 2 September 2015 ⇒ AGC 7 October

<sup>1</sup> Strategic objectives 2014-2017:

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

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

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

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

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

## CMG overview

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CMG reviewed the risk register and discussed each risk in detail at its meeting on 2 September.

In addition, CMG recognised that the office move, which will most likely occur in April 2016, will present certain risks, and may interact with risks and controls already listed. As soon as we have confirmation of the move date and location, the move will be explicitly added to the risk register, either as a separate risk, or as a specific source/cause of risk in relation to several of our existing strategic risks. It is already mentioned in several places, but not yet in any detail.

Since CMG met, the Family Court has passed judgement on several cases where consents to legal parenthood were in doubt. That judgement may have administrative consequences for the HFEA. Further cases can be expected over the coming months, although the HFEA is unlikely to participate in legal proceedings directly. Nonetheless, a decision has been taken that the impact of this work ought to be reflected in the legal challenge risk (LC1), and accordingly the risk score for the likelihood component of the residual risk has been increased to 3 (having been briefly reduced to 2 following the conclusion of another outstanding case). This means that this risk, which briefly dipped within tolerance, is now above tolerance.

AGC noted the above information at its meeting on 7 October. Controls and risk management for IfQ were discussed briefly, following an earlier item covering latest IfQ developments in greater depth. No changes were proposed to scores and tolerances.

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## Criteria for inclusion of risks:

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

### Rank

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

### Risk trend

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

### Risk scoring system

See last page.

### Assessing inherent risk

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

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

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
<b>Regulatory model</b>  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				
<b>Causes/sources</b>		<b>Mitigations</b>	<b>Timescale and ownership of mitigations</b>		<b>Effectiveness – commentary</b>		
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.		
		Audit of Epicentre to reveal any data errors. All queries being routed through Licensing, who have a definitive list of all licensing details.	Due for completion October 2015 – Sam Hartley (report and recommendations to October CMG)				
		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 of compliance and enforcement policy.	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - 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				
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 needed – Debra Bloor
	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, so far in 2015).	In place – Debra Bloor
	PGD workshop annually (or biannually, as appropriate) 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 – 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
	Update of compliance and enforcement policy.	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - Debra Bloor

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
<b>Regulatory model</b>  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 and Appeal Committee experience incorporated into processes.	In place – Sam Hartley				
		Appeals Committee membership maintained – vacancy filled earlier in year; 4 new members recruited in September. Ongoing process in place for regular appointments whenever vacancies occur or terms of office end.	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 (ie, first application) T&S licences delegated to ELP. Delegations to be revisited during 2016 review of Standing Orders. Licensing Officer role to take certain decisions from ELP – implementation due end of 2015.	To be put in place – Sam Hartley Licensing Officer role – December 2015 (postponed from June 2015) Delegations in SOs – April 2016				
		Failing to demonstrate competence as a regulator	Update of compliance and enforcement policy.	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - 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
	TRIM training and guidance/induction in records management in place. Head level 6 month contract to be recruited to manage the office move and review records management.	In place – SMT Head post recruitment in progress September 2015 - SMT
	The IfQ website management project has reviewed the retention schedule.	Completed – August 2015 – Juliet Tizzard
	Guidance/induction in handling FOI requests, available to all staff.	In place – Sam Hartley
	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

Update of compliance and enforcement policy.	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - 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		
Tolerance threshold:			8 Medium				
Causes/ sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Inability to extract reliable data from the Register.		Detailed planning and programme management in place to ensure this will be possible after migration. Migration strategy developed, and significant work being done to identify all of the data that will require correction before migration can be done. Decisions are being made about the degree of reliability required in each data field. For those fields where 100% reliability is needed, inaccurate or missing data will be addressed as part of project delivery.	All aspects – detailed project planning in place – Nick Jones		Above tolerance.  Managing these risks has formed an intrinsic and essential part of the detailed project planning and tendering, throughout.  Following a lengthy delay, we received formal approval for both the data and digital elements of IfQ in late April 2015.  The digital side of the programme 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		
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. This was elaborated further during sprint 1, in Aug/Sept 2015.	In place and ongoing – Dec 2014 onwards – Nick Jones				
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 were taken into account as an important factor in consideration of contract tenders and negotiations.	In place and now completed – Dec 2014 to June 2015 – Nick Jones				

Redeveloped website does not meet the needs and expectations of our various user types.	<p>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.</p> <p>User research done, to properly understand needs and reasons.</p> <p>Tendering and selection process included clear articulation of needs and expectations.</p>	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.	<p>Initial external business cases agreed and user research completed.</p> <p>Final business case for whole IfQ programme was submitted and eventually accepted.</p>	<p>In place (Nov 2014) – Juliet Tizzard</p> <p>In place (Dec 2014) – Nick Jones (decision received April 2015)</p>	
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.	<p>Programme management resources and quality assurance mechanisms in place for IfQ to manage (among other things) contractor delivery.</p> <p>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.</p> <p>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.</p> <p>Ability to consider deprioritising other work, through CMG, if necessary.</p>	In place – Juliet Tizzard	
New CMS (content management software) is ineffective or unreliable.	CMS options being scrutinised as part of project.	In progress – December 2015 – 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)	

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 2016, in that this will coincide with the delivery period for some IfQ milestones.	Early awareness of the potential for disruption means that this can be managed through careful planning.	For further thought once there is certainty about the timetable for the move (September 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 later).	In place – Nick Jones/Dave Moysen				
Increased reporting needs mean we later discover a barrier to achieving this, or that an unanticipated level of accuracy is required, with data or fields which we do not currently focus on or deem critical for accuracy.		IfQ planning work incorporates consideration of fields and reporting needs are agreed. Decisions about the required data quality for each field were ‘future proofed’ as much as possible through engagement with stakeholders to anticipate future needs and build these into the design.	In place – Nick Jones				
Reliability of existing infrastructure systems – (eg, Register, EDI, network, backups).		Maintenance of desktop, network, backups, etc. core part of IT business as usual delivery.	In place – Dave Moysen				
System interdependencies change / are not recognised		Strong interdependency mapping being done between IfQ and business as usual.	Done (April 2015) – Nick Jones				
Benefits not maximised and internalised into ways of working.		During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedding into new ways of working.	In place (June 2015) – Nick Jones				

Potential risks associated with the HFEA's likely office move in April 2016, in that this will coincide with the delivery period for some IfQ milestones.

Early awareness of the potential for disruption means that this can be managed through careful planning.

For further thought once there is certainty about the timetable for the move (September 2015) – Nick Jones/Sue Gallone

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
IfQ  IfQ 3: Delivery of promised efficiencies	There is a risk that the HFEA's promises of efficiency improvements in Register data collection and submission are not ultimately delivered.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			↔ ↔ ↔ ↔	Nick Jones
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	3	9 Medium		
Tolerance threshold:			9 Medium				
Causes/ sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Poor user acceptance of changes, or expectations not managed.		Stakeholder involvement strategy in place and user testing being incorporated into implementation phase of projects.	In place – Nick Jones/Juliet Tizzard		At tolerance.		
Clinics not consulted/involved enough.		Working with stakeholders has been central to the development of IfQ, and will continue to be. Advisory Group and expert groups have ended, but a stakeholder group for the implementation phase is in place.	In place – Nick Jones/Juliet Tizzard				
Scoping and specification are insufficient for realistic resourcing and on-time delivery of changes.		Scoping and specification were elaborated with stakeholder input, so as to inform the tender. Resourcing and timely delivery were a critical part of the decision in awarding the contract.	In place and contracts awarded – Nick Jones – July 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 only awarded to bidders who made an affordable proposal.	In place (July 2015) – Nick Jones				

Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedding into new ways of working.	In place (June 2015) – Nick Jones	
Potential risks associated with the HFEA's likely office move in April 2016, in that this will coincide with the delivery period for some IfQ milestones.	Early awareness of the potential for disruption means that this can be managed through careful planning.	For further thought once there is certainty about the timetable for the move (October 2015) – Nick Jones/Sue Gallone	

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
<b>Legal challenge</b>  LC 1: Resource diversion	There is a risk that the HFEA is legally challenged in such a way that resources are diverted from strategic delivery.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Peter Thompson
			Likelihood	Impact	Inherent risk		
			4	5	20 Very high		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
3	5	15 High					
Tolerance threshold:			12 High				
Causes/sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Complex and controversial area.		Panel of legal advisors from various firms at our disposal for advice, as well as in-house Head of Legal.	In place – Peter Thompson		Above tolerance.  One case decided in the HFEA's favour at summary judgement, but is now to be appealed.  Appeal completed in September (the decision was to award the licence).		
		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		A recent judgement on consents for parenthood may have administrative consequences for the HFEA. Further court cases are also likely, although the HFEA is unlikely to participate in legal proceedings directly.		
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				

Subjectivity of judgments means the HFEA often cannot know in advance which way a ruling will go, and the extent to which costs and other resource demands may result from a case.	Scenario planning is undertaken at the initiation of any likely action.	In place – Peter Thompson
HFEA could face unexpected high legal costs or damages which it could not fund.	Discussion with the Department of Health would need to take place regarding possible cover for any extraordinary costs, since it is not possible for the HFEA to insure itself against such an eventuality, and not reasonable for the HFEA's small budget to include a large legal contingency.	In place – Peter Thompson
Legal proceedings can be lengthy and resource draining.	Panel in place, as above, enabling us to outsource some elements of the work.	In place – Peter Thompson
	Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise work should this become necessary.	In place – Peter Thompson
Adverse judgments requiring us to alter or intensify our processes, sometimes more than once.	Licensing SOPs, committee decision trees in place.	In place – 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.	In place – Dave Moysen				
		Robust information security arrangements, in line with the Information Governance Toolkit, including a security policy for staff, secure and confidential storage of and limited access to Register information, and stringent data encryption standards.	In place – Dave Moysen				
Cyber-attack and similar external risks.		Secure system in place as above, with regular penetration testing.	In place – Dave Moysen				
Infrastructure turns out to be insecure, or we lose connection and cannot access our data.		IT strategy agreed, including a thorough investigation of the Cloud option, security, and reliability.	In place – Dave Moysen				
		Deliberate internal damage to infrastructure, or data, is controlled for through off-site back-ups and the fact that any malicious tampering would be a criminal act.	In place (March 2015) – Nick Jones				

Business continuity issue.	BCP in place and staff communication procedure 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



Answers in Hansard may not always reflect advice from HFEA.	The PQ team attempts to catch any changes to drafted wording that may unwittingly have changed the meaning. HFEA's suggested answer and DH's final submission both to be captured in new PQ log.	In place – Sam Hartley / Peter Thompson
Insufficient understanding of underlying system abilities and limitations, and/or of the topic or question, leading to data being misinterpreted or wrong data being elicited.	As above – expert staff with the appropriate knowledge and understanding in place.	In place – Juliet Tizzard / Nick Jones
Servicing data requests for researchers - poor quality of consents obtained by clinics for disclosure of data to researchers.	There is a recognised risk of centres reporting research consents inaccurately. Work to address consent reporting issues is being planned.	Actions to be confirmed end of September – Nick Jones

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
<b>Donor conception</b>  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-September 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		
<b>Donor conception</b>  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		
<b>3</b>	<b>3</b>	<b>9 Medium</b>					
Tolerance threshold:			9 Medium				
<b>Causes/ sources</b>		<b>Mitigations</b>	<b>Timescale and ownership of mitigations</b>		<b>Effectiveness – commentary</b>		
Lack of counselling availability for applicants.		Counselling service pilot 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.	In place – Nick Jones		The pilot counselling service has been in place since 1 June, and we will make further assessments based on early uptake and the delivery experience. Reporting to the Authority will occur annually during the pilot period.		
Risk of inadequate handling of a request.		Trained staff, SOPs and quality assurance in place.	In place – Nick Jones				
		SOPs reviewed by Register staff, CMG and PAC-UK, as part of the pilot set-up. Contract in place with PAC-UK for pilot delivery.	Done (May 2015) – In June the ongoing management of the Pilot transferred to Rosetta Wotton.				

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
<b>Financial viability</b>  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 took place on 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 March 2015. Capital allocation agreed as requested, in June 2015.	In place – Sue Gallone				
Budget setting process is poor due to lack of information from directorates		Quarterly meetings with directorates flags any short-fall or further funding requirements.	Quarterly meetings (on-going) – Morounke Akingbola				
Unforeseen increase in costs eg, legal, IfQ or extra in-year work required		Use of reserves, up to contingency level available. DH kept abreast of current situation and are a final source of additional funding if required.	Monthly – Sue Gallone				
		IfQ Programme Board regularly reviews the budget and costs.	Monthly – IfQ Programme Board				

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		
<b>Capability</b>  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.  When the period of highest turnover appeared to be ending (May 2015), CMG reduced (slightly) the likelihood of this risk, but still decided to retain it, given that high turnover could recur.  In May 2015, CMG also reviewed the tolerance level for this risk, and agreed it should		
A programme of development work is planned to ensure staff have the skills needed, so as to ensure they and the organisation are equipped under any future model, maximising our resilience and flexibility as much as possible. Staff can access civil service learning (CSL); organisational standard is five working days per year of learning and development for each member of staff.		In place – Rachel Hopkins					
Organisational knowledge captured via records management (TRIM), case manager software, project records, handovers and induction notes, and manager engagement.		In place – Rachel Hopkins					

The new UK government may implement further cuts across all ALBs, resulting in further staffing reductions. This would lead to the HFEA having to reduce its workload in some way.	The HFEA has 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.	In place – Peter Thompson	remain at 6. Since the HFEA has become a much smaller organisation over the past few years, leaving less intrinsic resilience, it seems prudent to have a low tolerance for this risk.
Poor morale leading to decreased effectiveness and performance failures.	Engagement with the issue by managers. Ensuring managers have team meetings and one-to-one meetings to obtain feedback and identify actions to be taken.	In place – Peter Thompson	
	Staff survey and implementation of outcomes, following up on Oct 2014 all staff conference.	Survey done (Jan 2015) – Rachel Hopkins Follow-up communications in place (Staff Bulletin etc.) – Peter Thompson	
Differential impacts of IfQ-related change and other pressures for particular teams could lead to specific areas of knowledge loss and low performance.	Staff kept informed of likely developments and next steps, and when applicable of personal role impacts and choices.	In place – Nick Jones	
	Policies and processes to treat staff fairly and consistently, particularly if people are ‘at risk’.	In place – Peter Thompson	
Additional avenues of work open up, or reactive diversions arise, and need to be accommodated alongside the major IfQ programme.	Careful planning and prioritisation of both business plan work and business flow through our Committees. Regular oversight by CMG.	In place – Paula Robinson	
	Early emphasis given to team-level service delivery planning for 2015, with active involvement of team members. Delivery (and resources) in Q1 to date were also considered at monthly CMG in May, and delivery is currently on track. CMG will continue to review this.	In place (Jan 2015) – Paula Robinson	

	Moratorium on new project work under consideration in planning for remainder of 2015/16 and for 2016/17, so as to prioritise IfQ delivery and therefore strategy delivery) within our limited resources.	Ongoing dialogue about this in place as part of business planning (August 2015 onwards) – Paula Robinson
	IfQ has some of its own dedicated resources.	In place – Nick Jones
	There is a degree of flexibility within our resources, and increasing resilience is a key consideration whenever a post becomes vacant. Staff are encouraged to identify personal development opportunities with their manager, through the PDP process, making good use of Civil Service Learning.	In place – Peter Thompson
Regarding the 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).	Future needs (capability and capacity) relating to mitochondrial replacement techniques and licensing applications are starting to be considered now, but will not be known for sure until later. No controls can yet be put in place, but the potential issue is on our radar.	New issue for consideration – Juliet Tizzard