

Strategic risk register

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

Details:

Meeting Authority

Agenda item 7

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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 last reviewed the risk register at its meeting on 15 June.

Organisational risk Low Medium High

Annexes Annex 1: Strategic risk register

1. Latest reviews

- 1.1. CMG reviewed the risk register at its meeting on 18 May. Four of the twelve risks are above tolerance. CMG reviewed all risks, controls and scores, although IfQ and legal risks were reviewed in more depth and updated at additional meetings, since these had changed since the previous review. CMG's specific comments are contained in the risk register at Annex A.
- 1.2. The risk register was last discussed at AGC on 15 June. AGC did not amend any of the risk scores. Comments from this meeting are also included in the register at Annex A.

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 2016/17

Risk summary: high to low residual risks

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

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

Recent review points are: CMG 4 February ⇒ AGC 16 March ⇒ CMG 18 May ⇒ AGC 15 June.

¹ Strategic objectives 2014-2017:

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

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

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

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

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

CMG overview – summary from May risk meeting

CMG reviewed the risk register and risk scores at its meeting on 18 May. Detailed review and update of IfQ (IfQ1, IfQ2 and IfQ3) and Legal (LC1) risks was completed offline with the risk owners.

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

When reviewing RM2 (the risk of a loss of regulatory authority), CMG discussed the records management mitigation which had originally been assigned to the Head of Corporate Projects, who had now left the organisation, meaning this mitigation was no longer in place. We agreed that, in the event, this part of the role had not been made a priority. CMG agreed the organisation's records management practices had not worsened, so the risk rating should remain the same. Work is now being planned on records management, probably to be managed as a project.

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

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

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

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

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

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

Criteria for inclusion of risks:

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

Rank

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

Risk trend

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

Risk scoring system

See last page.

Assessing inherent risk

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

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

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Regulatory model RM 1: Quality and safety of care	There is a risk of adverse effects on the quality and safety of care if the HFEA were to fail to deliver its duties under the HFE Act (1990) as amended.	Setting standards: improving the quality and safety of care through our regulatory activities.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Peter Thompson
			Likelihood	Impact	Inherent risk		
			3	5	15 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			2	4	8 Medium		
Tolerance threshold:			8 Medium				
Causes / sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Inspection/reporting failure.		Inspections are scheduled for the whole year, using licence information held on Epicentre, and items are also scheduled to committees well in advance.	In place – Sharon Fensome-Rimmer		At tolerance. The Head of Corporate Governance and Chief Inspector have now started in their posts. While they are bedding into the organisation it is likely that some degree of ownership of controls will sit with both the respective Directors as well as the Heads themselves until they are fully trained.		
		Audit of Epicentre conducted to reveal data errors. Queries now routed through Licensing, who hold a definitive list of all licensing details.	Completed October 2015 – Ian Brown				
		Inspector training, competency-based recruitment, induction process, SOPs, QMS, and quality assurance all robust.	In place – Sharon Fensome-Rimmer				
Monitoring failure.		Outstanding recommendations from inspection reports are tracked and followed up by the team.	In place – Sharon Fensome-Rimmer		The need to manage this training period, together with the action plan being implemented in connection with legal parenthood consent issues, has raised the residual risk likelihood from 1 (very unlikely) to 2 (unlikely) – from November through to at least June 2016.		
		Update of compliance and enforcement policy.	Completed following Authority approval of new policy March 2016 - Nick Jones				
Unresponsiveness to or mishandling of non-compliances or grade A incidents.		Staffing model provides resilience in the inspection team for such events – dealing with high-impact cases, additional incident inspections, etc.	In place – Sharon Fensome-Rimmer				
		Inspection team up to complement. The new Chief Inspector joined the HFEA in early May 2016.	In place – Nick Jones				
Insufficient inspectors or licensing staff		Licensing team up to complement following earlier recruitment. The new Head of Corporate Governance joined the HFEA in March 2016.	In place – Ian Brown				

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

provided assurances about current practice.
Through a detailed review of every clinic's responses, a summary list of all concerns is being produced.
Management review meetings took place for all clinics at which there are handling concerns or anomalies.
Plan of action in place to address all of the concerns identified, with direct follow up with centres who did not respond at all.
Where there are engagement concerns, we will do short-notice inspections, focused on parenthood consent.
Range of lessons learned identified.

20 licensed centres where there are anomalies. The focus is on ensuring all affected patients are informed and appropriately supported.

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

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

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

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

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
IfQ IfQ 1: Improved information access	If the information for Quality (IfQ) programme does not enable us to provide better information and data, and improved engagement channels, patients will not be able to access the improved information they need to assist them in making important choices.	Increasing and informing choice: ensuring that patients have access to high quality meaningful information.	Inherent risk level:			↔ ↔ ↔ ↔	Juliet Tizzard
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	4	12 High		
Tolerance threshold:			8 Medium				
Causes / sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Inability to extract reliable data from the Register.		Detailed planning and programme management in place to ensure this will be possible after migration. Migration strategy developed, and significant work being done to identify and cleanse all of the data that will require correction before migration can be done. Decisions have been made about the degree of reliability required in each data field. For those fields where 100% reliability is needed, inaccurate or missing data is being addressed as part of project delivery.	All aspects – detailed project planning in place – Nick Jones		Above tolerance. 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.		
Stakeholders dislike or fail to accept the new model for CaFC. Stakeholders not on board with the changes.		In-depth stakeholder engagement and extensive user research completed to inform the programme's intended outcomes, products and benefits. This included, consultation, expert groups and Advisory Board and this continues to be an intrinsic part of programme approach.	In place and ongoing – Juliet Tizzard /Nick Jones		The digital side of the programme received only partial approval; full delivery still required an additional gateway approval (ie, prior to commencing beta). The Department of Health gateway review took place in November 2015 and awarded a		

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

<p>Delivery quality is very supplier dependent. Contractor management could become very resource-intensive for staff, or the work delivered by one or more suppliers could be poor quality and/or overrun, causing knock-on problems.</p>	<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. 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> <p>Regular contract meetings in place.</p> <p>This remains a challenge.</p>	<p>In place – Juliet Tizzard</p>
<p>New CMS (content management software) is ineffective or unreliable.</p>	<p>CMS options were scrutinised carefully as part of project. Appropriate new CMS chosen, and all involved teams happy with the selection.</p>	<p>In progress – implemented in beta phase, July 2016 – Juliet Tizzard</p>
<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 embedded into new ways of working.</p> <p>Knowledge handover with the contractors will take place.</p>	<p>In place – Nick Jones</p>
<p>Colocation in the HFEA's smaller office at Spring Gardens is harder to achieve with the risk that Product Owners have less oversight of contractor delivery.</p>	<p>Disruption during the move was minimised through careful planning.</p> <p>Since the move, some colocation has been possible at Reading Room and other options are being explored, including a resumption of colocation at Spring Gardens to the extent possible.</p>	<p>Considered and further action in progress – Nick Jones</p>

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
IfQ IfQ 2: Register data	HFEA Register data becomes lost, corrupted, or is otherwise adversely affected during IfQ programme delivery.	Increasing and informing choice: using the data in the Register of Treatments to improve outcomes and research.	Inherent risk level:			↔ ↔ ↔ ↔	Nick Jones
			Likelihood	Impact	Inherent risk		
			2	5	10 Medium		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			2	4	8 Medium		
Tolerance threshold:			8 Medium				
Causes / sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Risks associated with data migration to new structure, together with records accuracy and data integrity issues.		IfQ programme groundwork focused on current state of Register. Extensive planning in place, including detailed research and migration strategy.	In place – Nick Jones/Dave Moysen		At tolerance. This risk is being intensively managed – a major focus of IfQ detailed planning work, particularly around data migration.		
The firm (Avoca) which was scheduled to provide assurance on data migration has gone out of business.		The HFEA is considering other sources of assurance, and will agree a new plan shortly.	To be resolved. Update to be provided to June AGC – Nick Jones				
Historic data cleansing is needed prior to migration.		A detailed migration strategy is in place, and data cleansing is in progress.	In place – Nick Jones/Dave Moysen				
Increased reporting needs mean we later discover a barrier to achieving this, or that an unanticipated level of accuracy is required, with data or fields which we do not currently focus on or deem critical for accuracy.		IfQ planning work incorporated consideration of fields and reporting needs were agreed. Decisions about the required data quality for each field were ‘future proofed’ as much as possible through engagement with stakeholders to anticipate future needs and build these into the design.	In place – Nick Jones				
Reliability of existing infrastructure systems – (eg, Register, EDI, network, backups).		Maintenance of desktop, network, backups, etc. core part of IT business as usual delivery.	In place – Dave Moysen				
System interdependencies change / are not recognised		Strong interdependency mapping done between IfQ and business as usual.	Done – Nick Jones				

Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedding into new ways of working. Knowledge handover with the contractors will take place.	In place – Nick Jones
Colocation in the HFEA's smaller office at Spring Gardens is harder to achieve with the risk that Product Owners have less oversight of contractor delivery.	Disruption during the move was minimised through careful planning. Since the move, some colocation has been possible at Reading Room and other options are being explored, including a resumption of colocation at Spring Gardens to the extent possible.	Considered and further action in progress – Nick Jones

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
IfQ IfQ 3: Delivery of promised efficiencies	There is a risk that the HFEA's promises of efficiency improvements in Register data collection and submission are not ultimately delivered.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			↑ ↔ ↔ ↔	Nick Jones
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
3	4	12 High					
Tolerance threshold:			9 Medium				
Causes / sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Poor user acceptance of changes, or expectations not managed.		Stakeholder involvement strategy in place and user testing being incorporated into implementation phases of projects.	In place – Nick Jones/Juliet Tizzard		Above tolerance.		
Clinics not consulted/involved enough.		Working with stakeholders has been central to the development of IfQ, and will continue to be. Advisory Group and expert groups have ended, but a stakeholder group for the implementation phase is in place. Workshops were delivered with the sector regarding how information will be collected through the clinic portal. From beta live onwards we will receive feedback and iteratively develop the products.	In place – Nick Jones/Juliet Tizzard		This risk is also affected by GDS approvals and associated requirements (see IfQ1).		
Scoping and specification are insufficient for realistic resourcing and on-time delivery of changes.		Scoping and specification were elaborated with stakeholder input, so as to inform the tender. Resourcing and timely delivery were a critical part of the decision in awarding the contract.	In place and contracts awarded (July 2015) – Nick Jones				
Efficiencies cannot, in the end, be delivered.		Detailed scoping phase included stakeholder input to identify clinic users' needs accurately. Specific focus in IfQ projects on efficiencies in data collected, submission and verification, etc.	In place – Nick Jones				

<p>Cost of improvements becomes too prohibitive.</p>	<p>Contracts only awarded to bidders who made an affordable proposal.</p> <p>Detailed planning for release two (which includes the second iteration of the portal and the introduction of the new EDI interface) is in progress and the HFEA will continue to work within agreed costs.</p>	<p>In place (July 2015) – Nick Jones</p> <p>In progress (May 2016) – Nick Jones</p>
<p>Required GDS gateway approvals are delayed or approval is not given.</p>	<p>All GDS approvals sought so far have been granted, albeit with some delays to earlier gateways.</p> <p>Our detailed planning includes addressing the requirements laid down by GDS as conditions of alpha and beta phase approval.</p> <p>Additional sprints of work were incorporated into beta, in an attempt to allow sufficient time (and resources) for the remaining GDS gateway review processes and subsequent formal approval mechanisms.</p> <p>The beta timeline was extended by 3 months to compensate for previous and anticipated future delays.</p>	<p>In place – Nick Jones</p>
<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 embedded into new ways of working.</p> <p>Knowledge handover with the contractors will take place.</p>	<p>In place (June 2015) – Nick Jones</p>
<p>Colocation in the HFEA's smaller office at Spring Gardens is harder to achieve with the risk that Product Owners have less oversight of contractor delivery.</p>	<p>Disruption during the move was minimised through careful planning.</p> <p>Since the move, some colocation has been possible at Reading Room and other options are being explored, including a resumption of colocation at Spring Gardens to the extent possible.</p>	<p>Considered and further action in progress – Nick Jones</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	4	12 High					
Tolerance threshold:			12 High				
Causes / sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Complex and controversial area.		Panel of legal advisors from various firms at our disposal for advice, as well as in-house Head of Legal.	In place – Peter Thompson		At tolerance. Current cases: The judgment in 2015 on consents for parenthood has had administrative and policy consequences for the HFEA. Further court cases are coming to light now, and more are also likely, although the frequency of these cases is reducing. The HFEA is unlikely to participate in legal proceedings directly. There has been a pre-action protocol letter challenging one discrete element of the IfQ CaFC project. If the case were lost then this would impact on the presentation of data. There is also an outstanding pre-action protocol letter regarding a decision of the ELP.		
		Evidence-based policy decision-making and horizon scanning for new techniques.	In place – Joanne Anton				
		Robust and transparent processes in place for seeking expert opinion – eg, external expert advisers, transparent process for gathering evidence, meetings minuted, papers available online.	In place – Joanne Anton/Juliet Tizzard				
HFE Act and regulations lead to the possibility of there being differing legal opinions from different legal advisers, that then have to be decided by a court.		Panel in place, as above, to get the best possible advice. Case by case decisions regarding what to argue in court cases, so as to clarify the position.	In place – Peter Thompson				
Decisions and actions of the HFEA and its committees may be contested. New guide to licensing and inspection rating on CaFC may mean that more clinics make representations against licensing decisions.		Panel in place, as above. Maintaining, keeping up to date and publishing licensing SOPs, committee decision trees etc. consistent decision making at licence committees supported by effective tools for committees Standard licensing pack completely refreshed and distributed to members/advisers (April 2015).	In place – Peter Thompson In place – Ian Brown				

	Well-evidenced recommendations in inspection reports.	In place – Sharon Fensome-Rimmer	<p>The matter has now been considered by the Licence Committee and this may mean that the pre-action is dropped.</p> <p>A patient has brought an application for a declaration seeking clarification about the continued storage of her embryos. We are hopeful that the matter can be resolved by way of agreement.</p>
Subjectivity of judgments means the HFEA often cannot know in advance which way a ruling will go, and the extent to which costs and other resource demands may result from a case.	Scenario planning is undertaken at the initiation of any likely action.	In place – Peter Thompson	
HFEA could face unexpected high legal costs or damages which it could not fund.	Discussion with the Department of Health would need to take place regarding possible cover for any extraordinary costs, since it is not possible for the HFEA to insure itself against such an eventuality, and not reasonable for the HFEA's small budget to include a large legal contingency.	In place – Peter Thompson	
Legal proceedings can be lengthy and resource draining.	Panel in place, as above, enabling us to outsource some elements of the work.	In place – Peter Thompson	
	Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise work should this become necessary.	In place – Peter Thompson	
Adverse judgments requiring us to alter or intensify our processes, sometimes more than once.	Licensing SOPs, committee decision trees in place.	In place – Ian Brown	

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Data D 1: Data loss or breach	There is a risk that HFEA data is lost, becomes inaccessible, is inadvertently released or is inappropriately accessed.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			↔ ↔ ↔ ↔	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 through off-site back-ups and the fact that any malicious tampering would be a criminal act.	In place (March 2015) – Nick Jones				

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

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Data D 2: Incorrect data released	There is a risk that incorrect data is released in response to a Parliamentary question (PQ), or a Freedom of Information (FOI) or data protection request.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			↑ ↔ ↓ ↔	Juliet Tizzard
			Likelihood	Impact	Inherent risk		
			5	4	20 Very high		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	3	9 Medium		
Tolerance threshold:			8 Medium				
Causes / sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Poor record keeping		Refresher training and reminders about good records management practice.	In place – SMT		Above tolerance. Although we have some good controls in place for dealing with PQs and other externally generated requests, it should be noted that we cannot control incoming volumes, complexity or deadlines. After a period of reduced volumes at the end of 2015, January and February 2016 saw an increase. This seems to be levelling off again as of May 2016, so in the light of this the residual risk level has been reduced somewhat.		
		TRIM review and retention policy implementation work – subsumed by IT strategy.	To sync in with IT strategy – Dave Moysen/Ian Brown				
		Audit of Epicentre to reveal any data errors. All queries being routed through Licensing, who have a definitive list of all licensing details.	Completed October 2015 – Ian Brown Implementation of actions following Epicentre audit planned and to be completed in Q2 2016/17 – Ian Brown				
Excessive demand on systems and over-reliance on a few key expert individuals – request overload – leading to errors		PQs, FOIs and OTRs have dedicated expert staff/teams to deal with them. If more time is needed for a complex PQ, it is occasionally necessary to take the issue out of the very tightly timed PQ process and replace this with a more detailed and considered letter back to the enquirer so as to provide the necessary level of detail and accuracy in the answer. We also refer back to previous answers so as to give a check, and to ensure consistent presentation of similar data. FOI requests are refused when there are grounds for this.	In place – Juliet Tizzard / Nick Jones				

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

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

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

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Financial viability FV 1: Income and expenditure	There is a risk that the HFEA could significantly overspend (where significantly = 5% of budget, £250k)	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			↓ ↔ ↔ ↔	Sue Gallone
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	3	9 Medium		
Tolerance threshold:			9 Medium				
Causes / sources		Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary			
Fee regime makes us dependent on sector activity levels.		Activity levels are tracked and change is discussed at CMG, who would consider what work to deprioritise and reduce expenditure.	Monthly (on-going) – Sue Gallone	At tolerance. For 2015/16 we achieved a small under-spend but the risk of additional legal costs remains. The increase of per-cycle fees by £5 (to £80) and the end of the small 'eSET discount' for elective single embryo transfer has now been implemented following Treasury approval in February 2016. This should help secure sufficient funds going forward.			
		Fees Group created enabling dialogue with sector about fee levels. Fee increase was agreed and approved by Treasury. This was implemented and the eSET discount ended (April 2016).	In place. Fees Group meeting in October, ongoing – Sue Gallone				
GIA funding could be reduced due to changes in Government/policy		A good relationship with DH Sponsors, who are well informed about our work and our funding model.	Quarterly meetings (on-going) – Sue Gallone	It is too early for us to tell whether this reduces this risk further. The situation will be clearer following IfQ implementation.			
		Annual budget agreed with DH Finance team alongside draft business plan submission.	December annually – Sue Gallone				
		Detailed budgets for 2016/17 have been agreed with Directors. DH has previously agreed our resource envelope.	In place – Sue Gallone				
Budget setting process is poor due to lack of information from directorates		Quarterly meetings with directorates flags any shortfall or further funding requirements.	Quarterly meetings (on-going) – Morounke Akingbola				
Unforeseen increase in costs eg, legal, IfQ or extra in-year work required		Use of reserves, up to contingency level available. DH kept abreast of current situation and are a final source of additional funding if required.	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.	Periodic review of actual and budgeted spend by IfQ project board and monthly budget meetings with finance.	Ongoing – Wilhelmina Crown
	Cash flow forecast updated.	Monthly (on-going) – Morounke Akingbola

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

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