

Strategic risks

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

Details:

Meeting Audit and Governance Committee

Agenda item 11

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Output:

For information or decision? Information and comment.

Recommendation AGC is asked to note the latest edition of the risk register, set out in the annex.

Resource implications In budget.

Implementation date Strategic risk register and operational risk monitoring: ongoing.

CMG reviews risk quarterly in advance of each AGC meeting.
AGC reviews the strategic risk register at every meeting.
The Authority reviews the strategic risk register periodically.

Organisational risk Low Medium High

Annexes Annex 1: Strategic risk register

1. Strategic risk register

Latest reviews

- 1.1. The Authority will receive the risk register at its meeting on 15 March. Any comments will be reported verbally at the meeting.
- 1.2. CMG reviewed the risk register at its meeting on 8 February. CMG reviewed all risks, controls and scores, and agreed to add a new risk relating to the forthcoming organisational changes that are being planned.
- 1.3. CMG also reviewed the two risks relating to donor conception and agreed to merge these into one single risk centred on running a good Opening the Register service.
- 1.4. CMG's comments are summarised on the second page of the risk register, which is attached at Annex A. The annex also includes the graphical overview of residual risks plotted against risk tolerances.
- 1.5. Four of the twelve risks are currently above tolerance.
- 1.6. This will be the last outing for the 2016/17 version of the strategic risk register. CMG will review the risk register afresh at its next meeting, to ensure alignment with the new strategy for 2017-2020, which will take effect in April.

2. Recommendation

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

HFEA strategic risk register 2016/17

Risk summary: high to low residual risks

Risk area	Risk title	Strategic linkage ¹	Residual risk	Current status	Trend*
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	D2: Incorrect data released	Efficiency, economy and value	12 – High	Above tolerance	↔↔↔↑↔
Capability	C1: Knowledge and capability	Efficiency, economy and value	12 – High	Above tolerance	↔↔↔↑↔
Legal challenge	LC1: Resource diversion	Efficiency, economy and value	12 – High	At tolerance	↔↔↔↔↔
Data	D1: Data loss or breach	Efficiency, economy and value	10 – Medium	At tolerance	↔↔↔↔↔
Organisational change	OC1: Change-related instability	Efficiency, economy and value	9 – Medium	At tolerance	• new
Financial viability	FV1: Financial resources	Efficiency, economy and value	9 – 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	↔↔↔↔↔
Regulatory model	RM1: Quality and safety of care	Setting standards: quality and safety	4 – Low	Below tolerance	↔↔↔↔↓
Opening the Register	OTR1: OTR service quality	Setting standards: donor conception	4 – Low	At tolerance	• new

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

Recent review points are: CMG 7 September/AGC 21 September ⇒ Authority 16 November ⇒ CMG 23 November/AGC 7 December ⇒ CMG 8 February

¹ Strategic objectives 2014-2017 (these will be updated in April when the new strategy has been launched):

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)

AGC – December 2016 meeting

The committee focused mainly on the three risks above tolerance at the time, which included Information for Quality (IfQ3) – delivery of promised efficiencies, Data (D2) – incorrect data release and Capability (C1) – knowledge and capability.

The committee questioned whether the Business Continuity Plan had been tested and was informed that there was an incident involving loss of power at the new HFEA premises in the summer of 2016 and the plan had been put into action. There were some lessons learned but generally things worked well.

The committee was concerned about the fluctuation of Parliamentary Questions that need to be answered within a tight timeframe and questioned how the organisation manages this area of work. The committee was informed that some questions could be tricky to answer. There is a small team of people in the organisation handling the questions, however the work is often extended to other staff with specialist knowledge to contribute to the answers. Answering parliamentary questions always takes priority in the organisation.

CMG – February 2017 meeting

CMG discussed in particular how best to reflect the risks associated with organisational change in the risk register. It was agreed that this should be presented as a separate, new, risk, in addition to the existing ‘business as usual’ risk relating to knowledge and capability.

We agreed that the financial viability risk should be updated, since year end and a new strategic period are approaching.

We also considered the two donor conception risks, and agreed that these should now be merged into one single risk centred on running a good Opening the Register service.

CMG updated all the remaining risks and controls and adjusted some of the residual risk scores to reflect the current situation.

We also noted that the risk register would need a comprehensive review as soon as the new strategy for 2017-2020 had been finalised, to ensure that it reflected the risks to delivering the strategy. It was agreed that the Chief Executive and the Head of Business Planning would work together to produce a draft, for comment at the next CMG risk meeting, in early May.

The Department of Health ALB risk network would be running a workshop on 28 February on risk interdependencies within the health system, between ALBs or with the Department itself. The HFEA would participate in this workshop, and the new version of the risk register would need to incorporate a section under each risk, identifying any interdependencies with other ALBs or the Department, within each risk. It had also been agreed that each ALB should prepare a report for its Audit Committee on risk interdependencies – this will be prepared for the next available AGC meeting after the notes of the workshop have been released (probably the June meeting, which would fit well with the Committee’s first review of the new version of the risk register to reflect the new strategy). Further reporting on health system risk interdependencies to DH or to auditors may be requested in the future, so it would be beneficial to have interdependencies identified separately and clearly in our risk register, along with any resulting controls or actions.

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

The risk summary above is arranged in rank order according to the severity of the current residual risk score.

Risk trend

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

Risk scoring system

See last page.

Assessing inherent risk

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

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

System-wide risk interdependencies

From April 2017 onwards, we will also explicitly consider whether any HFEA strategic risks or controls have a potential impact for, or interdependency with, the Department or any other ALBs. A distinct section to record any such interdependencies beneath each risk will be added to the risk register when it is reviewed to reflect the new strategy for 2017-2020, so as to be sure we identify and manage risk interdependencies in collaboration with relevant other bodies, and so that we can report easily and transparently on such interdependencies to DH or auditors as required.

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Regulatory model RM 1: Quality and safety of care	There is a risk of adverse effects on the quality and safety of care if the HFEA were to fail to deliver its duties under the HFE Act (1990) as amended.	Setting standards: improving the quality and safety of care through our regulatory activities.	Inherent risk level:			⇔ ⇔ ⇔ ↓	Peter Thompson
			Likelihood	Impact	Inherent risk		
			3	5	15 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
1	4	4 Low					
Tolerance threshold:			8 Medium				
Causes / sources		Mitigations	Timescale and ownership of mitigations		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		Below tolerance. Some elements of this risk, associated with staff turnover and legal parenthood issues, have now reduced in likelihood, and so the residual risk level has reduced.		
		Audit of Epicentre conducted to reveal data errors in 2014/15. Error correction completed in 2016.	In place – Siobhain Kelly				
		Inspector training, competency-based recruitment, induction process, SOPs, QMS, and quality assurance all robust.	In place – Sharon Fensome-Rimmer				
Regulatory monitoring processes may be disrupted as a result of the temporary inability of Electronic Patient Record System (EPRS) providers to submit data to the new register structure until their software has been updated. This could impact performance information used in inspection notebooks and RBAT alerts.		Earlier agreements to extend IfQ delivery help to address this risk by extending the release date for the EDI replacement (IfQ release 2). Mitigation plans for this risk have been agreed as part of planning.	Mitigation in place - Nick Jones		On legal parenthood, a strong set of actions is in place and continues to be implemented. The inspection team continue to work with colleagues in licensed centres, with a focus on ensuring all affected patients are informed and appropriately supported.		
Monitoring failure.		Outstanding recommendations from inspection reports are tracked and followed up by the team.	In place – Sharon Fensome-Rimmer				
Unresponsiveness to or mishandling of non-compliances or grade A incidents.		Up to date compliance and enforcement policy.	In place – Nick Jones				
		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				
Insufficient inspectors, administrative or licensing staff		Inspection team running at full complement.	In place – Nick Jones				
		Business support is operating below complement, and this will be addressed over the next few months, as part of organisational change implementation and the completion of IfQ.	To be addressed after IfQ, in the course of organisational restructuring – Sharon Fensome-Rimmer				

	Licensing team up to complement following earlier recruitment.	In place – Siobhain Kelly
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
	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; introduction of mitochondrial treatment decision-making).	Staffing model amended in May 2015, to release an extra inspector post out of the previous establishment. This increased general resilience, enabling more flex when there is an especially high inspection/report writing/application processing workload.	In place – Sharon Fensome-Rimmer
	Greater sector insight into our PGD application handling processes and decision-making steps achieved in the past few years; coupled with our increased processing rate since efficiency improvements were made in 2013 (acknowledged by the sector).	In place – Sharon Fensome-Rimmer
Some unanticipated event occurs that has a big diversionary impact on key resources, eg, legal parenthood consent issues, or several major Grade A incidents occur at once.	Resilient staffing model in place.	In place – Sharon Fensome-Rimmer
	Up to date compliance and enforcement policy and related procedures.	In place – Nick Jones / Sharon Fensome-Rimmer
	A detailed action plan in response to the legal parenthood judgment is in place.	In progress – Nick Jones/Sharon Fensome-Rimmer

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		Commentary		
Failures or weaknesses in decision making processes.		Keeping up to date the standard operating procedures (SOPs) for licensing, representations and appeals.	In place – Siobhain Kelly		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 – Siobhain Kelly				
		Appeals Committee membership maintained. Ongoing process in place for regular appointments whenever vacancies occur or terms of office end.	In place – Siobhain Kelly				
		Staffing structure for sufficient committee support.	In place – Siobhain Kelly				
		Decision trees; legal advisers familiar.	In place – Siobhain Kelly				
		Proactive management of quoracy for meetings.	In place – Siobhain Kelly				
		New (ie, first application) T&S licences delegated to ELP. Licensing Officer role in place to take certain administrative decisions from ELP.	In place – Siobhain Kelly				
Failing to demonstrate competence as a regulator		Up to date compliance and enforcement policy and related procedures.	In place – Nick Jones / Sharon Fensome-Rimmer				
		Inspector training, competency-based recruitment, induction process, SOPs, quality management system (QMS) and quality assurance all robust.	In place – Sharon Fensome-Rimmer				
Effect of publicised grade A incidents.		Staffing model provide resilience in inspection team for such events – dealing with high-impact cases, additional incident inspections, etc.	In place – Sharon Fensome-Rimmer				
		SOPs and protocols with Communications team.	In place – Sharon Fensome-Rimmer				
		Fairness and transparency in licensing committee information.	In place – Sharon Fensome-Rimmer				

	Dedicated section on website, so that the public can openly see our activities in the broader context.	In place – Sharon Fensome-Rimmer
Administrative or information security failure, eg, document management, risk and incident management, data security.	Staff have annual information security training (and on induction).	In place – Dave Moysen
	A comprehensive review of our records management practices and document management system (TRIM) will be conducted in 2017, following planned organisational changes and the conclusion of IfQ.	To follow – Peter Thompson
	Guidance/induction in handling FOI requests, available to all staff.	In place – Siobhain Kelly
	The IfQ website management project has reviewed the retention schedule.	Completed – August 2015 – Juliet Tizzard
Until the IfQ website project has been completed, there is a continued risk of HFEA website outages, as well as difficulties in uploading updates to web pages.	Alternative mechanisms are in place for clinics to get information about materials such as the Code of Practice (eg, direct communications with inspectors, Clinic Focus).	In place – Sharon Fensome-Rimmer
	The IfQ work on the new website will completely mitigate this risk (the new content management system will remove the current instability we are experiencing from using RedDot). This risk has informed our decisions about which content to move first to the beta version of the new site.	In progress – go live expected in March 2017 – 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 – Siobhain Kelly
	Up to date compliance and enforcement policy and related procedures.	In place – 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		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 requires correction before migration. 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. It has been necessary to remain in beta for the website for far longer than originally planned, owing partly to a judicial review whose outcome is still awaited, and partly to protracted contractor resource negotiations and end-stage planning (now concluded, with final work in progress). Our final 'go live' GDS assessment for the website took place on 8 March.		
Reduced ability to provide for patient choice based on CaFC information as a result of EPRS inability to submit/correct data in the new register structure if they do not update their systems in time to comply. This could impact the publication of CaFC data.		Proposals on an updated IfQ delivery plan were agreed at August IfQ Programme Board, these should help address this risk. A mitigation and communication plan for this risk is in place, including ongoing dialogue with EPRS centres and providers.	In place - Nick Jones		In the same time period, we are completing a detailed data verification process to update Choose a Fertility Clinic in readiness for Register migration and the new system, and this is proving challenging for the sector. Controls are in place, and it remains important for us		
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				

<p>Preparatory work to verify data in advance of the Register migration is effortful for clinics, with some struggling, and a risk that they could become disenchanted with IfQ or fail to see the future benefits.</p>	<p>Frequent sector communications about the current CaFC verification process, the reasons for it, and the ultimate pay-offs. Regular internal performance reports to track progress and problems. Focused support for the clinics who are struggling the most.</p>	<p>In place throughout the verification exercise – Nick Jones</p>	<p>to reiterate that the ultimate benefits of IfQ for the sector will make the extra effort invested now worthwhile.</p>
<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 (although these have improved markedly).</p>	<p>Costs were taken into account as an important factor in consideration of contract tenders and negotiations. Following earlier long timelines and unsuccessful attempts to discuss with GDS, our experience at the Beta gateway has been much improved and feedback was almost immediate. Watching brief being kept.</p>	<p>In place – Nick Jones In place – Nick Jones</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. User research done, to properly understand needs and reasons. Tendering and selection process included clear articulation of needs and expectations. GDS Beta assessment was passed on all 18 points.</p>	<p>In place – user research delivered end Oct 2016 – Juliet Tizzard</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. Final business case for whole IfQ programme was submitted and eventually accepted. All GDS approvals sought so far have been granted, albeit with some delays to the earlier ones. Additional sprints of work were incorporated in beta, in an attempt to allow sufficient time (and resources) for the remaining GDS gateway review processes and subsequent formal approval mechanisms. The beta timeline was extended by 3 months to compensate for previous and anticipated future delays.</p>	<p>In place – Juliet Tizzard In place – Nick Jones (decision received April 2015) In place – Nick Jones</p>	

Resource conflicts between delivery of website and business as usual (BAU).	Backfilling where possible/affordable to free up the necessary staff time, eg, Websites and Publishing Project Manager post backfilled to free up core staff for IfQ work.	In place – Juliet Tizzard
Delivery quality is very supplier dependent. Contractor management has at times been very resource-intensive for staff. Work delivered by one or more suppliers could be poor quality and/or overrun, causing knock-on problems.	<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 delivery.</p> <p>Previous lessons learned and knowledge exist in the organisation from managing previous projects.</p> <p>Ability to consider deprioritising other work, through CMG, if necessary.</p> <p>Regular contract meetings in place.</p>	In place – Juliet Tizzard
New CMS (content management software) is ineffective or unreliable.	CMS options were scrutinised carefully as part of project. Appropriate new CMS chosen, and all involved teams happy with the selection.	In progress – implemented in beta phase, July 2016 – Juliet Tizzard
Benefits not maximised and internalised into ways of working.	<p>During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedded into new ways of working.</p> <p>Knowledge handover with the contractors will take place.</p>	In place – Nick Jones

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
IfQ IfQ 2: Register data	HFEA Register data becomes lost, corrupted, or is otherwise adversely affected during IfQ programme delivery.	Increasing and informing choice: using the data in the Register of Treatments to improve outcomes and research.	Inherent risk level:	↔ ↔ ↔ ↔	Nick Jones		
			Likelihood			Impact	Inherent risk
			2			5	10 Medium
			Residual risk level:				
			Likelihood			Impact	Residual risk
2	4	8 Medium					
Tolerance threshold:			8 Medium				
Causes / sources		Mitigations	Timescale and ownership of mitigations	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.			
The firm (Avoca) which was scheduled to provide assurance on data migration has gone out of business.		The HFEA has considered other sources of assurance and sourced a supplier. Work is in progress.	In place – Nick Jones	This risk is being intensively managed – a major focus of IfQ planning work, particularly around data migration.			
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				

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		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		In November 2016, in light of delays to release two of the portal (which includes the new electronic data interchange system for data submission by clinics), we increased the risk level. The delays stem from the intensive work in progress to complete release one of the website, which requires the attention of the same staff who are needed for release two of the portal.		
Scoping and specification are insufficient for realistic resourcing and on-time delivery of changes.		Scoping and specification were elaborated with stakeholder input, so as to inform the tender. Resourcing and timely delivery were a critical part of the decision in awarding the contract.	In place and contracts awarded (July 2015) – Nick Jones				
Efficiencies cannot, in the end, be delivered.		Detailed scoping phase included stakeholder input to identify clinic users' needs accurately. Specific focus in IfQ projects on efficiencies in data collected, submission and verification, etc.	In place – Nick Jones				
Cost of improvements becomes too prohibitive, or resources are insufficient to complete the Programme.		Contracts only awarded to bidders who made an affordable proposal. Detailed planning for release two (which includes the second iteration of the portal and the introduction of the new EDI interface) is in progress and the HFEA will continue to work within agreed costs.	In place (July 2015) – Nick Jones In progress (September 2016 to present) – Nick Jones				

	<p>A contingency amount was built into the budget, although this has now been used.</p> <p>The support function has been re-shaped and streamlined to deal with the departure in November 2016 of the release two project manager.</p>	In place (from November 2016) – Nick Jones
Delivery is delayed, causing reputational damage to the HFEA.	Ongoing communication with clinics via Clinic Focus and direct correspondence, to keep them up to date and make them aware of delays.	In place – Nick Jones
Required GDS gateway approvals are delayed or approval is not given.	<p>All GDS approvals sought so far have been granted, albeit with some delays to earlier gateways.</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>	In place – Nick Jones
Benefits not maximised and internalised into ways of working.	<p>During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedded into new ways of working.</p> <p>Knowledge handover with the contractors will take place.</p>	In place (from June 2015) – Nick Jones
Planned organisational changes to ensure the HFEA can make full use of the new functionality delivered through IfQ could create risks to the completion of IfQ (release 2).	<p>Staff consultation in progress.</p> <p>Additional resources within IfQ to ensure that delivery continues.</p> <p>In the event of turnover or other disruption to IfQ arising from organisational change, we will continue as now to seek temporary cover for vacancies.</p>	In place – Nick Jones

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Legal challenge LC 1: Resource diversion	There is a risk that the HFEA is legally challenged in such a way that resources are significantly 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		
			5	4	30 Very high		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
4	3	12 High					
			Tolerance threshold:		12 High		
Causes / sources		Mitigations	Timescale and ownership of mitigations		Commentary		
Complex and controversial area.		Panel of legal advisors from various firms at our disposal for advice, as well as in-house Head of Legal.	In place – Peter Thompson		At tolerance. Current cases: The judgment in 2015 and subsequent cases on consents for parenthood have administrative and policy consequences for the HFEA. Further cases are going through court.		
		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		The HFEA is unlikely to participate in most of these legal proceedings directly, though the court has required us to provide information and clarification in relation to six legal parenthood cases. The hearing for these six cases is listed for May 2017. A judicial review hearing of one discrete element of the IfQ CaFC project was held in December 2016 and January 2017.		
Decisions and actions of the HFEA and its committees may be contested.		Panel in place, as above.	In place – Peter Thompson				
New guide to licensing and inspection rating (effective from go-live of new website) on CaFC may mean that more clinics make representations against licensing decisions.		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 – Siobhain Kelly				
		Well-evidenced recommendations in inspection reports.	In place – Sharon Fensome-Rimmer				
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		The outcome may impact on the presentation of our data in the new version of choose a fertility clinic.		

<p>HFEA could face unexpected high legal costs or damages which it could not fund.</p>	<p>If this risk was to become an issue then discussion with the Department of Health would need to take place regarding possible cover for any extraordinary costs, since it is not possible for the HFEA to insure itself against such an eventuality, and not reasonable for the HFEA's small budget to include a large legal contingency. This is therefore an accepted, rather than mitigated risk. It is also interdependent risk because DH would be involved in resolving it.</p>	<p>In place – Peter Thompson</p>
<p>Legal proceedings can be lengthy and resource draining.</p>	<p>Panel in place, as above, enabling us to outsource some elements of the work.</p>	<p>In place – Peter Thompson</p>
	<p>Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise work should this become necessary.</p>	<p>In place – Peter Thompson</p>
<p>Adverse judgments requiring us to alter or intensify our processes, sometimes more than once.</p>	<p>Licensing SOPs, committee decision trees in place.</p>	<p>In place – Siobhain Kelly</p>

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		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 new BCP is being produced by the Head of IT to reflect the changes to this following changes to infrastructure and the office move.	In place – Richard Sydee Update done Dave Moysen – September 2016				
Register data becomes corrupted or lost somehow.		Back-ups and warehouse in place to ensure data cannot be lost.	In place – Nick Jones/Dave Moysen				

Other HFEA data (system or paper) is lost or corrupted.	As above. Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality.	In place – Dave Moysen	
Poor records management	A comprehensive review of our records management practices and document management system (TRIM) will be conducted in 2017, following planned organisational changes and the conclusion of IfQ.	To follow – Peter Thompson	

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Data D 2: Incorrect data released	There is a risk that incorrect data is released in response to a Parliamentary question (PQ), or a Freedom of Information (FOI) or data protection request.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			↔ ↔ ↑ ↔	Juliet Tizzard
			Likelihood	Impact	Inherent risk		
			5	4	20 Very high		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
3	4	12 High					
Tolerance threshold:			8 Medium				
Causes / sources		Mitigations	Timescale and ownership of mitigations		Commentary		
Poor record keeping		A comprehensive review of our records management practices and document management system (TRIM) will be conducted in 2017, following planned organisational changes and the conclusion of IfQ.	To follow – Peter Thompson		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.		
		Audit of Epicentre completed in 2014/15, errors corrected in 2016.	In place – Siobhain Kelly				
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 - Siobhain Kelly				

Staff turnover resulting in the loss of corporate knowledge regarding the history and handling of PQs, in particular, resulting in slower handling and therefore potential reputational effect with the Department of Health.	Staff have access to past records to inform new responses. Recruitment completed in January 2017. Additional legal advice will be sought when beneficial. Good lines of communication with the Department so that any difficulties can be highlighted at the earliest possible point.	In place – Siobhain Kelly
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 – Siobhain Kelly / 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

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Opening the Register OTR 1: OTR service quality	There is a risk that OTR service quality is adversely affected by data accuracy, inadequate support, or human error.	Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.	Inherent risk level:			<ul style="list-style-type: none"> New (combined from two previous risks) 	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			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 low for this risk). The pilot counselling service has been in place since 1 June 2015, with annual assessment reports to Authority.	
		Audit programme to check information provision and accuracy.	In place – Nick Jones				
		IfQ work has identified data accuracy requirements for different fields as part of migration planning, and will put in place 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				
		Data verification work (February 2017) in preparation for Register migration will improve overall data accuracy, and the exercise includes tailored support for individual clinics that are struggling.	In place – Nick Jones				
Lack of counselling availability for applicants.		Counselling service established with external contractor in place.	In place (June 2015 onwards) – Nick Jones				

Insufficient Register team resource to deal properly with OTR enquiries and associated conversations.	Additional member of staff dedicated to handling such enquiries. IfQ delivery means there is still pressure on team capacity, and there has been a long term vacancy in the team, but this post has now been filled (start date 20 February 2017).	In place, with team capacity issue close to resolution (February 2017) – Nick Jones
Risk of inadequate handling of a request.	Trained staff, SOPs and quality assurance in place.	In place – Nick Jones
	SOPs reviewed by Register staff, CMG and PAC-UK, as part of the pilot set-up. Contract in place with PAC-UK for pilot delivery.	Done (May 2015) – ongoing management of the pilot by Rosetta Wotton.
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		
Financial viability FV 1: Income and expenditure	There is a risk that the HFEA has insufficient financial resources to fund its regulatory activity and strategic aims.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇄ ⇄ ⇄ ⇄	Richard Sydee
			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		Commentary		
The complexity of accurately forecasting income, which is linked directly to treatment activity in licensed establishments, exposes HFEA to significant variability in annual income.	Activity levels are tracked and change is discussed at CMG, who would consider what work to deprioritise and reduce expenditure.	Monthly (on-going) – Richard Sydee	At tolerance. At M10 (January) we have a surplus of £642k before IfQ. The increase in fees approved by Treasury in 2015/16 continues to impact on the surplus being reported and we expect this to continue into the new business year. We will continue to monitor activity levels monthly. The creation of the Intelligence team post IfQ implementation allows for more detailed analysis and potentially forecasting of activity levels.				
	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 ongoing – Richard Sydee					
	Worked planned in 2017/18 to better understand the likely future trends in treatment cycle activity.	Being planned – Richard Sydee					
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.	Accountability Quarterly meetings (on-going) – Richard Sydee	We will continue to monitor activity levels monthly. The creation of the Intelligence team post IfQ implementation allows for more detailed analysis and potentially forecasting of activity levels.				
	Annual budget agreed with DH Finance team alongside draft business plan submission. GIA funding has been provisionally agreed through to 2020.	December annually – Richard Sydee					
	Detailed budgets for 2017/18 have been agreed with Directors. DH has previously agreed our resource envelope.	In place – Morounke Akingbola					
Annual budget setting process lacks information from directorates on variable/additional activity that will impact on planned spend.	Annual budgets are agreed in detail between Finance and Directorates with all planning assumptions noted. Quarterly meetings with directorates flags any shortfall or further funding requirements.	Quarterly meetings (on-going) – Morounke Akingbola					
Legal costs materially exceed annual budget as a result of unforeseen litigation.	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 – Morounke Akingbola					

Upwards scope creep during projects, or emerging during early development of projects.	Senior Finance staff present at Programme Board. Periodic review of actual and budgeted spend by IfQ project board and monthly budget meetings with finance.	Ongoing – Richard Sydee or Morounke Akingbola
	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		
4	3	12 High					
Tolerance threshold:			6 Medium				
Causes / sources		Mitigations	Timescale and ownership of mitigations		Commentary		
Organisational change		See separate risk, below.					
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 business as usual capability, rather than capacity. There are obviously some linkages between capability and capacity, since managing turnover and churn also means managing fluctuations in capability and ensuring knowledge and skills are successfully nurtured and/or handed over. Organisational change is also a factor that can affect this general risk – this has been identified as a separate strategic risk (see below). Since the HFEA is a small organisation, with little intrinsic resilience, it seems prudent to retain a low tolerance level for this risk. Several staff (including end of contract IfQ staff) have left the organisation in the past six months. This means we are currently in a period of turnover		
		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				
		Vacancies are addressed speedily, and any needed changes to ways of working or backfill arrangements receive immediate attention.	In place – Peter Thompson				
		Staff are encouraged to identify personal development opportunities with their manager, through the PDP process, making good use of CSL.	In place – Peter Thompson				
The 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, and our recent Triennial 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	and internal churn, with some knowledge gaps, and IfQ work ongoing for both release one (although this is now close to completion) and release two.
	Staff survey and implementation of outcomes, followed up after December 2016 all staff conference. Task and Finish Groups working on recommendations for improvements.	Survey and staff conference done – Rachel Hopkins Follow-up plan and communications in place – Peter Thompson	
Particular changes or other pressures for individual teams could lead to specific areas of knowledge loss and low performance.	CMG and managers prioritise work appropriately when workload peaks arise.	In place – Peter Thompson	
	Policies and processes to treat staff fairly and consistently, particularly in scenarios where people are or could be 'at risk'.	In place – Peter Thompson	
Additional avenues of work open up, or reactive diversions arise, and need to be accommodated alongside business as usual and (at present) 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 in preparation for the next business year, with active involvement of team members. CMG will continue to review planning and delivery.	In place – Paula Robinson	
	Planning prioritises IfQ delivery, and therefore strategy delivery, within our limited resources.	In place as part of business planning until IfQ ends (2015 to 2017) – 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.	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, since it could impact on staff and committee capacity. For now it seems clear that only one clinic will be making applications and that there will not be large numbers of these. New licensing processes are in place, ready for first use (decision trees etc.).	Issue for further consideration when applications begin to be considered – Juliet Tizzard	

<p>Our IT communications systems are an inherent part of our general capability, and since our office move in 2016, we have experienced some technical infrastructure issues with Skype. This leads to poor service (missed calls, poor quality Skype meetings), reputational impacts, additional costs (meetings having to be held externally using non-Skype videoconferencing equipment), and potentially to complaints. Staff are incurring additional work and additional travel, to find and test their own work-arounds so as to avoid using Skype for decision-making meetings until the problems are fixed. This is compounded by a shortage of non-Skype-based videoconferencing solutions in conference venues.</p>	<p>IT team working to identify and resolve the issues, with staff encouraged to continue to send support tickets. External expert commissioned to assist. Staff running meetings continue to source external venues with appropriate facilities so as to avoid reliance on our own equipment until the problems have been solved. Use of mailboxes to provide an alternative channel when Skype calls are not received (however there are also some problems with these too).</p>	<p>In progress – Dave Moysen and Nick Jones</p>	
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Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Organisational change OC1: Change-related instability	There is a risk that the implementation of organisational changes is poor, resulting in instability, loss of capability and capacity, and delays in the 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:			● New	Peter Thompson
			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		Commentary		
<p>Until the new model is formally decided, there will be a level of uncertainty among staff about their own or their colleagues' future roles.</p> <p>This initial phase and then the change period itself may lead to dips in morale, commitment, discretionary effort and goodwill.</p> <p>Anxieties about change during the whole process may sometimes lead to stress behaviours which decrease performance and damage delivery. It is possible that we could reach a tipping point where staff are less productive, or even counter-productive, or become unwell.</p> <p>There are likely to be differential impacts as different changes affect different groups of staff at different times.</p> <p>Risks are to the delivery of current work, including IfQ, and possibly technical or business continuity risks, arising from impacts on motivation, performance and effective capacity.</p>		Clear published process, with documentation	In place – Peter Thompson		At tolerance.		
		Consultation, discussion and communication, with opportunity to comment, and being responsive and empathetic about staff concerns.	Completed – Peter Thompson				
		Relatively short timeline for decision making, so that uncertainty does not linger.	In place – Peter Thompson				
		Staff kept informed of likely developments and next steps, and when applicable of personal role impacts and choices.	In place – Nick Jones				
		HR policies and processes are in place to enable us to manage any individual situations that arise.	In place – Rachel Hopkins				
		Employee assistance programme (EAP) support accessible by all. Effective line management training done for bands 4 and 3, with some band 2s also having this training now.	In place – Peter Thompson				

Organisational change combined with other pressures for particular teams could lead to specific areas of knowledge loss lasting some months (pending recruitment to fill any gaps). Such instances could affect our general capability and capacity for a period of time, and our ability to mitigate effectively against risks and issues.	Policies and processes (and the law) are in place to ensure we treat staff fairly and consistently, particularly if people are 'at risk'. We will seek to slot staff who are at risk into other roles (suitable alternative employment).	In place – Peter Thompson
	Well established recruitment processes, which can be followed quickly in the event of unplanned establishment leavers.	In place – Rachel Hopkins
	Good decision-making and risk management mechanisms in place. Knowledge retention via good records management practice, SOPs and documentation.	In place – Peter Thompson
The above risk factors could potentially challenge our ability to complete delivery of IfQ on time.	Ability to use more contract staff if need be.	In place – Peter Thompson
Once the new structure has been agreed, there will be significant additional work involved across several teams (eg recruitment, changed ways of working, communications) to set it in place and embed it so that the benefits are realised.	Business plan discussions acknowledging that the first part of the year will include completion of IfQ and change management, so should not be loaded up too much with new work (except in teams that are relatively uninvolved in delivering IfQ or organisational change).	In place – Paula Robinson
	CMG able to change priorities or timescales in the event that this becomes necessary, in order to ensure that change is managed well.	In place – Paula Robinson
	Organisational development activity will continue, including summer awayday, to support new ways of working development	In place for coming year – Rachel Hopkins
At the start of a new business year, there are particular pressures for some teams, and for all managers (service delivery planning, Annual Report and end of year accounts, PDPs, for example). This reality plus ongoing pressures from IfQ means that implementing change at this time could be particularly difficult.	Changes will be phased in at different times, depending on factors including IfQ work and formal HR processes. Changes will not all take effect in April.	In place – Peter Thompson
	CMG remains in place and will continue to consider resources, prioritisation questions, planning, risk and performance. We have also scheduled regular informal meetings to allow managers to discuss issues arising from change, so that these can be addressed and mutual support provided.	

Additional pressure on SMT, HR and Heads, arising from the need to manage different impacts, reactions and responses in a sensitive way, while also implementing formal processes and continuing to ensure that work is delivered throughout the change period.	Recognition that change management requires extra attention and work, which can have knock-on effects on other planned work and on capacity overall. Ability to reprioritise other work if necessary.	In place – Peter Thompson
	Time being set aside by managers to discuss the changes with staff as needed, with messaging about change repeated via different channels to ensure that communications are received and understood.	In place – Peter Thompson
	SMT/CMG additional informal meetings arranged to enable mutual support of managers, to help people retain personal resilience and be better able to support their teams.	In place – Paula Robinson
Levels of service to Authority members may suffer while the changes are implemented, negatively impacting on the relationship between staff and members.	Recognition that we need to communicate the changes clearly to Authority members so that they understand when staff are implementing changes, or are particularly under pressure, and that they will have reduced capacity for a period. Members will also need to be informed when staff are new in post, and to understand that those staff need the opportunity to learn and to get up to speed.	To be implemented – Peter Thompson
Once the changes have been implemented, a number of staff will simultaneously be new in post (either new to the organisation, or in a different role). This carries a higher than normal risk of internal incidents and timeline slippages while people learn and teams adapt.	There will need to be a settling period where staff are inducted and can learn, and teams can develop new ways of working. Formal training and skills development will be provided where required. Knowledge management via records management and documentation	To be implemented – Peter Thompson
Bedding down the new structure will necessarily involve some team building time, the development of new processes, staff away days to discuss new ways of working, etc. This is essential to make the changes work well, but will be challenging to achieve given small organisational capacity and ongoing delivery of business as usual.	Change management will be prioritised so that bedding down occurs and is effective, and does not take an unduly long time.	To be implemented – Peter Thompson
	Continuing programme of leadership development for Heads and SMT.	Being planned – Rachel Hopkins

<p>Over time, particularly once IfQ has finished, some staff may decide the changes are not for them, and that they will move on. Other staff may have different residual responses – some may fail to adapt quickly or warm to the improvements, leading to slower delivery of work and possible negative behaviours.</p>	<p>Processes and policies in place to manage performance and behavioural issues, recruitment, turnover, and induction of new staff, in this scenario as in any other.</p>	<p>In place – Peter Thompson</p>
<p>The new model may not achieve the desired benefits, or transition to the new model could take too long. In either case, staff could lose faith in the model and it may require adjustment later.</p>	<p>The people strategy for 2017-2020 will focus on supporting and developing our staff to equip them for delivering the HFEA strategy under the new organisational model.</p> <p>Management are aware of this risk, and are balancing full consideration of our needs, plus consideration of points raised by staff in the consultation exercise, with well planned phased implementation and ongoing communication throughout. The changes will be made without delay, but not all at once.</p> <p>Communication will be clear as to when each phase of the changes will be implemented. We will continue to explain that change will not be ‘big bang’ or linear.</p> <p>The model will be kept under review following implementation to ensure it yields the intended benefits.</p>	<p>To be implemented – Rachel Hopkins</p> <p>To be implemented – Peter Thompson</p>

Scoring system

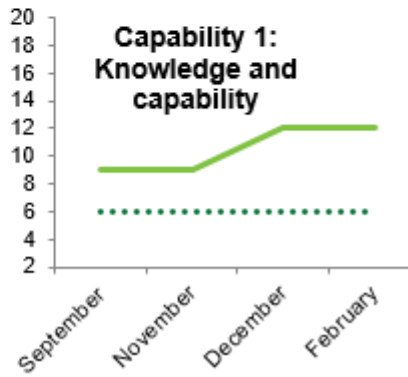
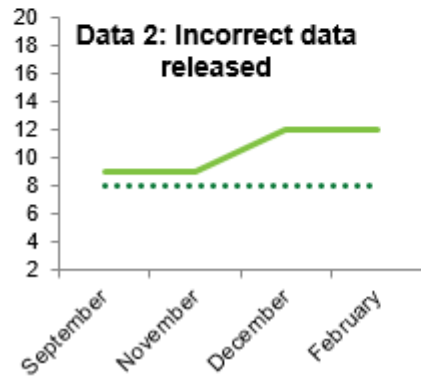
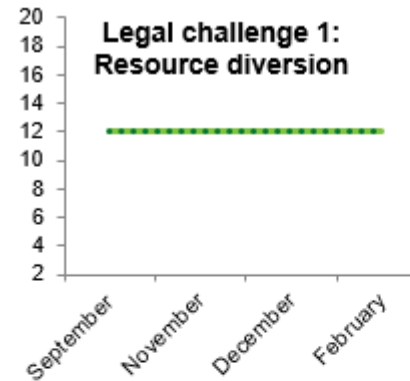
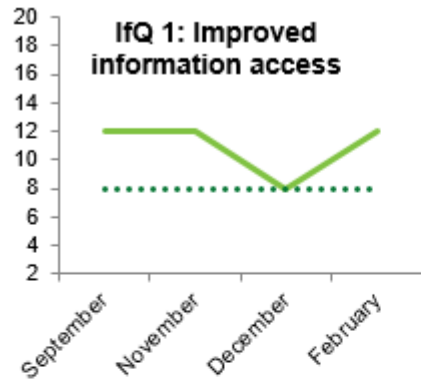
The HFEA uses the five-point rating system when assigning a rating to both the likelihood and impact of individual risks:

Likelihood:	1=Very unlikely	2=Unlikely	3=Possible	4=Likely	5=Almost certain
Impact:	1=Insignificant	2=Minor	3=Moderate	4=Major	5=Catastrophic

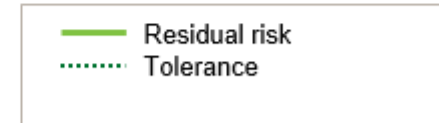
		Risk scoring matrix				
Impact	5. Very high	5 Medium	10 Medium	15 High	20 Very High	25 Very High
	4. High	4 Low	8 Medium	12 High	16 High	20 Very High
	3. Medium	3 Low	6 Medium	9 Medium	12 High	15 High
	2. Low	2 Very Low	4 Low	6 Medium	8 Medium	10 Medium
	1. Very Low	1 Very Low	2 Very Low	3 Low	4 Low	5 Medium
Risk Score = Impact x Likelihood		1. Rare (≤10%)	2. Unlikely (11%-33%)	3. Possible (34%-67%)	4. Likely (68%-89%)	5. Almost Certain (≥90%)
Likelihood						

Tolerance vs Residual Risk:

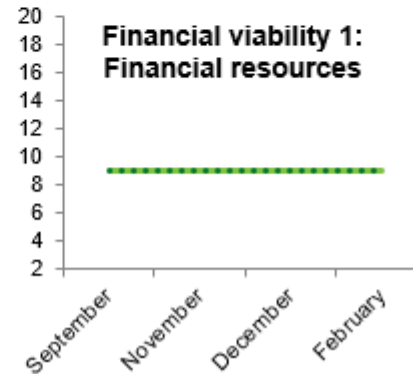
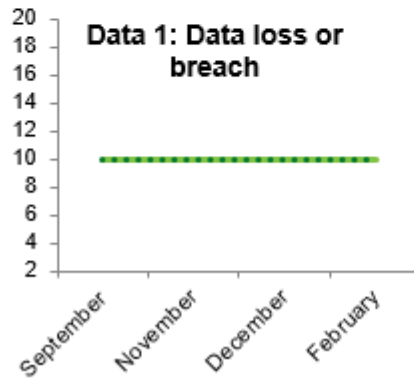
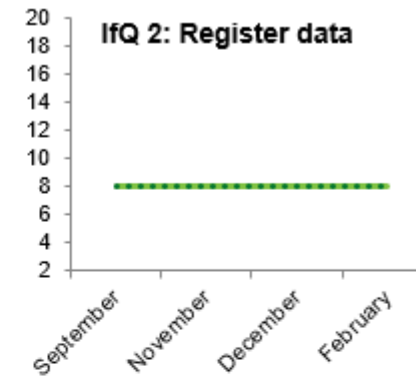
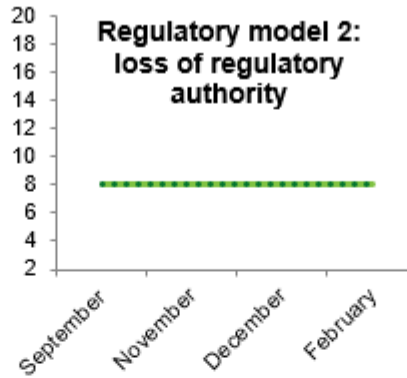
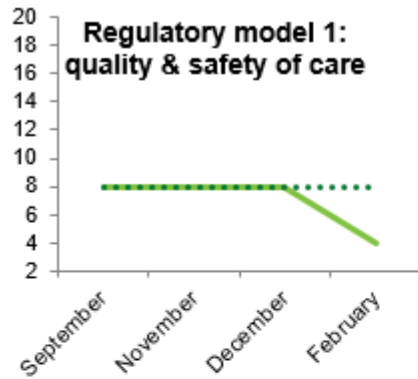
High and above tolerance risks



Key:



Lower level / in tolerance risks



Additional new risks:

OTR1 – Opening the Register service quality – formed from two earlier risks which can now be merged. Residual risk and tolerance both 4 (low).

OC1 – Organisational change-related instability – introduced this month, as we approach finalisation of a new organisational structure to be implemented in the new business year. Residual risk and tolerance both 9 (medium).