

# Strategic risk register

Strategic delivery:	☑ Setting standards	☑ Increasing and informing choice	☑ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	10		
Paper number	HFEA (09/03/2016) 790	0	
Meeting date	9 March 2016		
Author	Paula Robinson, Head	of Business Planning	
Output:			
For information or decision?	For information		
Recommendation	The Authority is asked strategic risk register.	to note and comment on	the latest edition of the
Resource implications	In budget		
Implementation date	Ongoing		
Communication(s)	(CMG), and presented meeting. AGC last review	at every Audit and Gove	rporate Management Group rnance Committee (AGC) its meeting on 9 December, its March.
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 14 February. Six of the thirteen risks are above tolerance. CMG reviewed all risks, controls and scores. CMG's specific comments are contained in the risk register at Annex A.
- 1.2. The risk register was last discussed at AGC on 9 December, and the Committee will receive the risk register again at its meeting on 16 March. Any comments from the Authority will be fed back to the Committee then. No changes were proposed in December.

## 2. Risk assurance mapping

- **2.1.** The new activity of risk assurance mapping has recently started up in the HFEA, as part of the internal audit programme. The Department of Health internal audit team ran a half day workshop with managers on 10 February, focusing on our highest risk operational area, people management and resourcing (capacity, capability, resource prioritisation, etc.).
- 2.2. The workshop approach was well received by staff, and we now have a report for consideration internally, making a number of suggestions for possible additional risk mitigations in this area.

## 3. Recommendation

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

# Annex A - HFEA strategic risk register 2015/16

Risk summary: high to low residual risks

Risk area	Risk title	Strategic linkage <sup>1</sup>	Residual risk	Current status	Trend*
Office move	OM1: Office move	Efficiency, economy and value	16 – High	Above tolerance	⊙⇔⇔
Legal challenge	LC1: Resource diversion	Efficiency, economy and value	15 – High	Above tolerance	$\Leftrightarrow \Leftrightarrow \Leftrightarrow \Leftrightarrow$
Information for Quality	IfQ1: Improved information access	Increasing and informing choice: information	12 – High	Above tolerance	$\Leftrightarrow \Leftrightarrow \Leftrightarrow \Leftrightarrow$
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	⇔↓⇔⇧
Data	D1: Data loss or breach	Efficiency, economy and value	10 – Medium	At tolerance	$\Leftrightarrow \Leftrightarrow \Leftrightarrow \Leftrightarrow$
Financial viability	FV1: Income and expenditure	Efficiency, economy and value	9 – Medium	At tolerance	$\Leftrightarrow \Leftrightarrow \Leftrightarrow \emptyset$
Donor conception	DC2: Support for OTR applicants	Setting standards: donor conception	9 – Medium	At tolerance	$\Leftrightarrow \Leftrightarrow \Leftrightarrow \Leftrightarrow$
Capability	C1: Knowledge and capability	Efficiency, economy and value	9 – Medium	Above tolerance	$\Leftrightarrow \Leftrightarrow \Leftrightarrow \Leftrightarrow$
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	$\Leftrightarrow \Leftrightarrow \Leftrightarrow \Leftrightarrow$
Information for Quality	IfQ2: Register data	Increasing and informing choice: Register data	8 – Medium	At tolerance	$\Leftrightarrow \Leftrightarrow \Leftrightarrow \Leftrightarrow$
Donor conception	DC1: OTR inaccuracy	Setting standards: donor conception	4 – Low	At tolerance	$\Leftrightarrow \Leftrightarrow \Leftrightarrow \Leftrightarrow$

<sup>\*</sup> This column tracks the four most recent reviews by AGC, CMG, or the Authority (e.g. ① 🗢 🗸 ⇔).

Recent review points are: AGC 7 October ⇒ CMG 18 November ⇒ AGC 9 December ⇒ CMG 4 February.

<sup>&</sup>lt;sup>1</sup> Strategic objectives 2014-2017:

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

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

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

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

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

#### CMG overview – summary from February risk meeting

CMG reviewed the risk register and discussed each risk in detail at its meeting on 4 February.

CMG confirmed that the departure of three Heads (two for new jobs, one on maternity leave) was being managed by Directors covering the roles in the interim while recruitment was completed. Recruitment to the Head of Policy post had successfully taken place internally, so there was no gap between post holders. Recruitment for the other two posts, Head of Corporate Governance and Chief Inspector, was also successful, but there has been an unavoidable gap of several months before the successful candidates could take up their posts, leading to some additional pressures across affected teams.

CMG reviewed the three strategic risks relating to IfQ, in particular to see if their relative scores seemed correct. The discussion identified that IfQ3 (the risk of not achieving planned efficiency savings) was partly subject to the same GDS gateway review requirements as IfQ1 (engagement channels), and that the risk levels of the two risks should therefore be the same. Therefore, CMG raised the risk level of IfQ3 to 12.

CMG updated the legal challenge risk (LC1) to reflect the latest position on active legal cases, but made no change to the score for this risk.

CMG raised the risk level for D2 (release of incorrect data) to 12, to reflect a resurgence in the volume of PQs received after a quieter period. This was potentially compounded by the recent loss of some corporate knowledge, owing to turnover.

CMG also discussed risks relating to the office move, and agreed that further assurance was needed to ensure that all managers had a good grasp of the tasks and timelines. Cultural risks were also recognised, given that the HFEA would be moving into the same space as another organisation. It was agreed that further corporate discussion was needed after the meeting, to ensure that surrounding themes, some of which may be outside the scope of the move project, were picked up effectively (ie, the right channel could be the ways of working group, SMT or CMG, rather than the move project).

CMG also considered operational risks (under a separate report), and noted the need to add floor security to our operational risks. The building was now largely empty, and on a number of recent occasions, workmen had been found in the HFEA's offices before and after normal working hours. It was not always the case that there was a good explanation for this, although the majority of the occurrences had proved to be legitimate. The landlord had already been reminded of their obligation to inform us every time workmen needed to visit the floor. HFEA staff had challenged the individuals each time this had happened, which may itself reduce the incidence. The possibility is also being explored of isolating the floor from external visitors via the door security system.

## **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  $\Leftrightarrow$ , Rising  $\hat{U}$  or Reducing  $\mathbb{Q}$ .

#### 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 score	S		Recent trend	Risk owner
Regulatory	There is a risk of adverse	Setting standards: improving the quality and safety	Inherent ris	sk level:		⇔⇧⇔⇔	Peter
model	effects on the quality and	of care through our regulatory activities.	Likelihood	Impact	Inherent risk		Thompson
DN 4	safety of care if the HFEA were to fail to deliver its		3	5	15 High		
RM 1: Quality and	duties under the HFE Act		Residual ı	risk level:			
safety of	(1990) as amended.		Likelihood	Impact	Residual risk		
care			2	4	8 Medium		
			Tolerance	threshold:	8 Medium		
Causes / so	urces	Mitigations	Timescale mitigations	and owners	ship of	Effectiveness -	- commentary
Inspection/re	porting 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 – N	lick Jones		At tolerance.  The Head of Go	vernance and
		Audit of Epicentre conducted to reveal data errors.  Queries now routed through Licensing, who hold a definitive list of all licensing details.	Completed Tizzard	October 2018	5 – Juliet	Licensing and the Chief Inspector have both left the HFEA (in late November and	
		Inspector training, competency-based recruitment, induction process, SOPs, QMS, and quality assurance all robust.	In place – N	lick Jones		mid January, res Recruitment has but neither of the	taken place, e new members
Monitoring fa	ilure.	Outstanding recommendations from inspection reports are tracked and followed up by the team.	In place – N	lick Jones		of staff have star Meanwhile owne controls has mo	ership of
•	eness to or mishandling of nees or grade A incidents.	Update of compliance and enforcement policy.	discussed a			the relevant Dire	ector.
		Staffing model provides resilience in the inspection team for such events – dealing with high-impact cases, additional incident inspections, etc	- Nick Jone In place – N			together with the being implement connection with parenthood cons	ted in legal
Insufficient in	spectors or licensing staff	Inspection team up to complement. The new Chief Inspector is expected to join the HFEA in early May 2016.	In progress	– Nick Jones	5	raised the residulikelihood from 1 to 2 (unlikely) — through to June	(very unlikely) from November

	Licensing team up to complement following earlier recruitment. The new Head of Corporate Governance is expected to join the HFEA in March 2016.	In progress – Juliet Tizzard
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 – Nick Jones
	Additional temporary resources available during periods of vacancy and transition.	In place – Rachel Hopkins
	Group induction sessions put in place where possible.	In place – Nick Jones
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	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 – Nick Jones
particular issue).	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 from efficiency improvements made in 2013 (acknowledged by the sector).	In place – Nick Jones
Some unanticipated event occurs that	Resilient staffing model in place.	In place – Nick Jones
has a big diversionary impact on key resources, eg, legal parenthood consent issues, or several major Grade A incidents occur at once.	Update of compliance and enforcement policy (and application of existing policy, meanwhile).	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 – Nick Jones

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

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

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

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

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

Management review meetings are taking 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.

In progress – Nick Jones

On legal parenthood, a strong set of actions is in place and continues to be implemented. As at 20 January 2016, 28 of our 92 clinics had one or more anomaly. < 5 clinics are now subject to ongoing inquiry. Seven cases have been determined in court to date. Nine cases are currently under consideration. There is no certainty about future cases.

Risk area	Description and impact	Strategic objective linkage	Risk score	s		Recent trend	Risk owner
Regulatory	There is a risk that the	Setting standards: improving the quality and safety	Inherent ris	sk level:		$\Leftrightarrow \Leftrightarrow \Leftrightarrow \Leftrightarrow$	Peter
model	HFEA could lose authority	of care through our regulatory activities.	Likelihood	Impact	Inherent risk		Thompson
	as a regulator, jeopardising		3	5	15 High		
RM 2:	its regulatory effectiveness, owing to a loss of public /		Residual ı	risk level:			
Loss of	sector confidence.		Likelihood	Impact	Residual risk		
regulatory authority			2	4	8 Medium		
dutionty			Tolerance	threshold:	8 Medium		
Causes / so	urces	Mitigations	Timescale mitigations	and owners	ship of	Effectiveness -	- commentary
Failures or we making proce	eaknesses in decision esses.	Keeping up to date the standard operating procedures (SOPs) for licensing, representations and appeals.	In place – J	uliet Tizzard		At tolerance.  Although two ad	ditional risk
		Learning from past representations and Appeal Committee hearings incorporated into processes.	In place – J	uliet Tizzard		sources exist at (website outages	•
		Appeals Committee membership maintained. Ongoing process in place for regular appointments whenever vacancies occur or terms of office end.	In place – J	uliet Tizzard		beta website is li of work to addre parenthood cons	ss legal sent issues),
		Staffing structure for sufficient committee support.	In place – J	uliet Tizzard		these are being	_
		Decision trees; legal advisers familiar.	In place – J	uliet Tizzard		and/or tolerated, risk score has no	
		Proactive management of quoracy for meetings.	In place – J	uliet Tizzard		TISK SCOTE TIAS TR	or moreasea.
		New (ie, first application) T&S licences delegated to ELP. Delegations to be revisited during 2016 review of Standing Orders. Licensing Officer role to take certain decisions from ELP – implementation due end of 2015.	Licensing C pending red Corporate C	n place – Julie Officer role – p cruitment of H Governance s in SOs – Ap	oostponed ead of		

Failing to demonstrate competence as a regulator	Update of compliance and enforcement policy (and application of existing policy, meanwhile).	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - Nick Jones
	Inspector training, competency-based recruitment, induction process, SOPs, quality management system (QMS) and quality assurance all robust.	In place – Nick Jones
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 – Nick Jones
	SOPs and protocols with Communications team.	In place – Nick Jones
	Fairness and transparency in licensing committee information.	In place – Nick Jones
	Dedicated section on website, so that the public can openly see our activities in the broader context.	In place – Nick Jones
Administrative or information security failure, eg, document management, risk	Staff have annual information security training (and on induction).	In place – Dave Moysen
and incident management, data security.	TRIM training and guidance/induction in records management in place. Head level 6 month contract recruited to manage the office move and review records management.	In place – SMT
	The IfQ website management project has reviewed the retention schedule.	Completed – August 2015 – Juliet Tizzard
	Guidance/induction in handling FOI requests, available to all staff.	In place – Juliet Tizzard
	Further work planned on records management in parallel with IT strategy.	Linked to IT strategy work – in progress – Jamie Munro/David Moysen
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 – Nick Jones

	T	
	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 Red-Dot). 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	Licensing SOPs, committee decision trees in place. Mitochondria donation application tools completed.	In place – Juliet Tizzard
weaken cases that are otherwise sound, or which generate additional regulatory sanctions activity (eg, legal parenthood consent).	Update of compliance and enforcement policy (and application of existing policy meanwhile).	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - Nick Jones
	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 – Nick Jones

Risk area	Description and impact	Strategic objective linkage	Risk score	es		Recent trend	Risk owner
IfQ	If the information for	Increasing and informing choice: ensuring that	Inherent ri	sk level:		$\Leftrightarrow \Leftrightarrow \Leftrightarrow \Leftrightarrow$	Juliet Tizzard
	Quality (IfQ) programme	patients have access to high quality meaningful	Likelihood	Impact	Inherent risk		
IfQ 1:	does not enable us to	information.	4	4	16 High		
Improved	provide better information and data, and improved		Residual	risk level:			
information access	engagement channels,		Likelihood	Impact	Residual risk		
access	patients will not be able to		3	4	12 High		
	access the improved information they need to assist them in making important choices.		Tolerance	threshold:	8 Medium		
Causes / so	ources	Mitigations	Timescale mitigations	and owners	ship of	Effectiveness -	- commentary
Inability to ex Register.	ktract reliable data from the	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 are being made about the degree of reliability required in each data field. For those fields where 100% reliability is needed, inaccurate or missing data will be addressed as part of project delivery.	All aspects in place – N	•	oject planning	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	
CaFC, and/o	ork out how best to improve or failure to find out what tion patients really need.	Stakeholder engagement and extensive user research completed as intrinsic part of programme approach. This is being elaborated further during subsequent sprints.	In place and ongoing – Juliet Tizzard		The digital side of the programme received only parti approval; full delivery still		
Stakeholders changes.	s not on board with the	In-depth stakeholder engagement done, to inform the programme's intended outcomes, products and benefits – including user research consultation, expert groups and Advisory Board.	In place an Nick Jones		Juliet Tizzard/	requires addition approvals at this to beta).	•

Cost of delivering better information becomes too prohibitive, either because the work needed is larger than anticipated, or as a result of the protracted approval periods associated with required DH/GDS gateway reviews.	Costs were taken into account as an important factor in consideration of contract tenders and negotiations.  Attempts have been made to discuss the GDS review process and long timelines with those responsible at DH, although so far our approaches have unfortunately not met with success.	In place – Nick Jones  Being pursued – Nick Jones	The Department of Health gateway review took place in November and awarded a high score to the HFEA, but we still did not receive a formal decision on this by the Government Digital Service board until mid-January (a
Redeveloped website does not meet the needs and expectations of our various user types.	Programme approach and some dedicated resources in place to manage the complexities of specifying web needs, clarifying design requirements and costs, managing changeable Government delegation and permissions structures, etc.  User research done, to properly understand needs and reasons.  Tendering and selection process included clear articulation of needs and expectations.	In progress – delivery by end June 2016 – Juliet Tizzard	month later than expected).  This meant that the beta (build) stage initially had to proceed at risk (now resolved).  However, obtaining this approval also meant committing to a number of requirements and conditions which need to be added to the delivery; and a
Government and DH permissions structures are complex, lengthy, multistranded, and sometimes change midprocess.	Initial external business cases agreed and user research completed. Final business case for whole IfQ programme was submitted and eventually accepted. Both GDS approvals sought so far have been granted, albeit with some delays. Additional sprints of work have been 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 has been extended by 3 months to compensate for previous and anticipated future delays.	In place – Juliet Tizzard  In place – Nick Jones (decision received April 2015)  In place – Nick Jones	further two approval gateways are still to come. If there are further blockages at those stages (public beta and go-live), this will have more of an impact, since this will mean pausing the work (ie, it will not be possible to proceed at risk at those stages).  Therefore, there remains an ongoing risk of negative impact from the lengthy GDS gateway review processes.  Owing to the previous delays, it has been necessary to extend

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	In place – Juliet Tizzard	the timeline for the beta phase from March to June 2016.
	Project Manager post backfilled to free up core staff for IfQ work.		
Delivery quality is very supplier dependent. Contractor management could become very resource-intensive for staff, or the work delivered by one or more suppliers could be poor quality and/or overrun, causing knock-on problems.	Programme management resources and quality assurance mechanisms in place for IfQ to manage (among other things) contractor delivery.  Agile project approach includes a 'one team' ethos and required close joint working and communication among all involved contractors during the Sprint Zero start-up phase and beyond. Sound project management practices in place to monitor.  Previous lessons learned and knowledge exist in the organisation from managing some previous projects where poor supplier delivery was an issue requiring significant hands-on management.  Ability to consider deprioritising other work, through CMG, if necessary.	In place – Juliet Tizzard	
New CMS (content management software) is ineffective or unreliable.	CMS options were scrutinised carefully as part of project. Appropriate new CMS now chosen, and all involved teams happy with the selection.	In progress – implemented in beta phase, June 2016 – Juliet Tizzard	
Communications infrastructure incapable of supporting the planned changes.	Needs to be updated as part of IfQ in order to support the changes.	In place – set out in business case – Juliet Tizzard (Dec 2014)	
Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedded into new ways of working.	In place – Nick Jones	

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

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

A 'null sprint' has been scheduled across the time of the move, both to allow for some disruption while staff move and unpack, but also to allow for any unanticipated business continuity issue that could arise.

Considered and in place – Nick Jones/Sue Gallone/Jamie Munro

HFEA Register data becomes lost, corrupted, or	Increasing and informing choice: using the data in					
becomes lost, corrupted, or	moreasing and informing sholds, doing the data in	Inherent ris	sk level:		$\Leftrightarrow \Leftrightarrow \Leftrightarrow \Leftrightarrow$	Nick Jones
· ·	the Register of Treatments to improve outcomes	Likelihood	Impact	Inherent risk		
is otherwise adversely	and research.	2	5	10 Medium		
affected during IfQ		Residual r	isk level:			
programme delivery.		Likelihood	Impact	Residual risk		
		2	4	8 Medium		
		Tolerance	threshold:	8 Medium		
urces	Mitigations			ship of	Effectiveness -	- commentary
ated with data migration to e, together with records I data integrity issues.	IfQ programme groundwork focusing on current state of Register. Extensive planning in progress, including detailed research and migration strategy.	In place – N	place – Nick Jones/Dave Moysen		At tolerance. This risk is being intensively managed – a major focus of	
oca) which was scheduled to rance on data migration has usiness.	The HFEA is considering other sources of assurance, and will agree a new plan shortly.	To be resolved by end March – Nick detailed pla		particularly arou	_	
cleansing is needed prior to	A detailed migration strategy is in place, and data cleansing is in progress.	In place – N	lick Jones/Da	ve Moysen		
porting needs mean we later arrier to achieving this, or that ated level of accuracy is a data or fields which we do focus on or deem critical for	IfQ planning work incorporates consideration of fields and reporting needs are agreed.  Decisions about the required data quality for each field were 'future proofed' as much as possible through engagement with stakeholders to anticipate future needs and build these into the design.	In place – N	lick Jones			
existing infrastructure g, Register, EDI, network,	Maintenance of desktop, network, backups, etc. core part of IT business as usual delivery.	In place – D	ave Moysen			
dependencies change / are ed	Strong interdependency mapping being done between IfQ and business as usual.	Done – Nick	( Jones			
	programme delivery.  urces  ated with data migration to e, together with records data integrity issues.  aca) which was scheduled to rance on data migration has usiness.  cleansing is needed prior to corting needs mean we later rrier to achieving this, or that ted level of accuracy is a data or fields which we do focus on or deem critical for existing infrastructure g, Register, EDI, network,	programme delivery.  Mitigations  IfQ programme groundwork focusing on current state of Register. Extensive planning in progress, including detailed research and migration strategy.  The HFEA is considering other sources of assurance, and will agree a new plan shortly.  A detailed migration strategy is in place, and data cleansing is needed prior to  Cleansing is needed prior to  Dorting needs mean we later ririer to achieving this, or that ted level of accuracy is adata or fields which we do focus on or deem critical for  Existing infrastructure gr, Register, EDI, network,  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.  Maintenance of desktop, network, backups, etc. core part of IT business as usual delivery.  Strong interdependency mapping being done	programme delivery.    Discreption   Comparison   Compari	programme delivery.    Likelihood   Impact 2 4   Tolerance threshold:   Timescale and owners mitigations   IfQ programme groundwork focusing on current state of Register. Extensive planning in progress, including detailed research and migration strategy.   In place – Nick Jones/Data place and owners mitigations   IfQ programme groundwork focusing on current state of Register. Extensive planning in progress, including detailed research and migration strategy.   In place – Nick Jones/Data place and will agree a new plan shortly.   To be resolved by end M Jones   Jones	programme delivery.    Likelihood   Impact   Residual risk   2   4   8 Medium   Tolerance threshold: 8 Medium   Tolerance thre	programme delivery.    Likelihood   Impact   Residual risk   Revieus

Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedding into new ways of working.	In place – Nick Jones	
Potential risks associated with the HFEA's likely office move in April 2016, in that this will coincide with the delivery period for some IfQ milestones.	Early awareness of the potential for disruption means that this can be managed through careful planning.  A 'null sprint' has been scheduled across the time of the move, both to allow for some disruption while staff move and unpack, but also to allow for any unanticipated business continuity issue that could arise.	Considered and in place – Nick Jones/Sue Gallone/Jamie Munro	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner	
IfQ	There is a risk that the	Efficiency, economy and value: ensuring the HFEA	Inherent risk level:			⇔⇔☆	Nick Jones	
	HFEA's promises of	remains demonstrably good value for the public, the Likelihood Impact Inherent risk						
IfQ 3:	efficiency improvements in	sector and Government.	4	4	16 High			
Delivery of	Register data collection and submission are not		Residual risk level:					
promised efficiencies	ultimately delivered.		Likelihood	Impact	Residual risk			
Omoronoro	·		3	4	12 High			
			Tolerance	threshold:	9 Medium			
Causes / so	ources	Mitigations	Timescale mitigations	and owners	ship of	Effectiveness -	- commentary	
	ceptance of changes, or not managed.	Stakeholder involvement strategy in place and user testing being incorporated into implementation	In place – Nick Jones/Juliet Tizzard		Above tolerance.			
		phase of projects.				This risk is also affected by		
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 are planned with the sector regarding how information will be collected through the clinic portal.	In place – Nick Jones/Juliet Tizzard			GDS approvals and the associated delays (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  In place – Nick Jones  In place (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.						
Cost of improvements becomes too prohibitive.		Contracts only awarded to bidders who made an affordable proposal.						

Required GDS gateway approvals are delayed or approval is not given.	Both GDS approvals sought so far have been granted, albeit with some delays. Our detailed planning includes addressing the requirements laid down by GDS as conditions of alpha phase approval. Additional sprints of work have been 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 has been extended by 3 months to compensate for previous and anticipated future delays.	In place – 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 embedded into new ways of working.	In place (June 2015) – Nick Jones
Potential risks associated with the HFEA's likely office move in April 2016, in that this will coincide with the delivery period for some IfQ milestones.	Early awareness of the potential for disruption means that this can be managed through careful planning.  A 'null sprint' has been scheduled across the time of the move, both to allow for some disruption while staff move and unpack, but also to allow for any unanticipated business continuity issue that could arise.	Considered and in place – Nick Jones/Sue Gallone/Jamie Munro

Risk area	Description and impact	Strategic objective linkage	Risk score	S		Recent trend	Risk owner	
Legal	There is a risk that the	Efficiency, economy and value: ensuring the HFEA	Inherent ris	sk level:		$\Leftrightarrow \Leftrightarrow \Leftrightarrow \Leftrightarrow$	Peter	
challenge	HFEA is legally challenged	remains demonstrably good value for the public, the	Likelihood	Impact	Inherent risk		Thompson	
104	in such a way that resources are diverted	sector and Government.	4	5	20 Very high			
LC 1: Resource	from strategic delivery.		Residual ri	sk level:				
diversion	,		Likelihood	Impact	Residual risk			
			3	5	15 High			
			Tolerance		12 High			
Causes / so	purces	Mitigations	Timescale mitigations	and owners	ship of	Effectiveness -	- commentary	
Complex and	l controversial area.	Panel of legal advisors from various firms at our disposal for advice, as well as in-house Head of Legal.	In place – Peter Thompson			Above tolerance.  Current cases: One case decided in the		
		Evidence-based policy decision-making and horizon scanning for new techniques.	In place – ⊢	lannah Verdi	n	HFEA's favour at summary judgment, but has now been		
		Robust and transparent processes in place for seeking expert opinion – eg, external expert	In place – Hannah Verdin/Juliet Tizzard			appealed (8 February 2016 – outcome not yet known).  The 'M' case regarding the export of gametes for treatment abroad has been granted permission to proceed to trial (in April 2016).  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		
		advisers, transparent process for gathering evidence, meetings minuted, papers available online.						
leading to the	y in HFE Act and regulations, e possibility of there being	advice.	In place – Peter Thompson					
differing legal opinions from different legal advisers, that then have to be decided by a court. (eg, one current case challenging the long-held policy position on storage regulations may need to be decided by a court).		Case by case decisions regarding what to argue in court cases, so as to clarify the position.						
	d actions of the HFEA and	Panel in place, as above.	In place – P	eter Thomps	son	likely, although t		
its committees may be contested.		Maintaining, keeping up to date and publishing licensing SOPs, committee decision trees etc. Standard licensing pack completely refreshed and distributed to members/advisers (April 2015).	In place – Juliet Tizzard			unlikely to participate in legal proceedings directly.		

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 – Juliet Tizzard.

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Data	There is a risk that HFEA	Efficiency, economy and value: ensuring the HFEA	Inherent risk level:			$\Leftrightarrow \Leftrightarrow \Leftrightarrow \Leftrightarrow$	Nick Jones
	data is lost, becomes	remains demonstrably good value for the public, the sector and Government.	Likelihood	Impact	Inherent risk		
D 1:	inaccessible, is	sector and Government.	4	5	20 Very high		
Data loss or	inadvertently released or is inappropriately accessed.		Residual r	isk level:	_		
breach	mappropriately accessed.		Likelihood	Impact	Residual risk		
			2	5	10 Medium		
			Tolerance	threshold:	10 Medium		
Causes / so	urces	Mitigations	Timescale mitigations	and owners	ship of	Effectiveness	<ul><li>commentary</li></ul>
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 Regis	ster or other data.	As above.	In place - Dave Moysen				
		Robust information security arrangements, in line with the Information Governance Toolkit, including a security policy for staff, secure and confidential storage of and limited access to Register information, and stringent data encryption standards.	In place – Dave Moysen				
Cyber-attack	and similar external risks.	Secure system in place as above, with regular penetration testing.	In place – Dave Moysen				
Infrastructure turns out to be insecure, or we lose connection and cannot access our data.		IT strategy agreed, including a thorough investigation of the Cloud option, security, and reliability.	In place – Dave Moysen				
		Deliberate internal damage to infrastructure, or data, is controlled for through off-site back-ups and the fact that any malicious tampering would be a criminal act.	In place (M	arch 2015) –	Nick Jones		

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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 will be 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	

Strategic risk register

Risk area	Description and impact	Strategic objective linkage	Risk score	es .		Recent trend	Risk owner	
Data	There is a risk that	Efficiency, economy and value: ensuring the HFEA	Inherent ri	sk level:		⇔⇩⇔⇧	Juliet Tizzard	
	incorrect data is released	remains demonstrably good value for the public, the sector and Government.	Likelihood	Impact	Inherent risk			
D 2:	in response to a	sector and Government.	5	4	20 Very high			
Incorrect	Parliamentary question (PQ), or a Freedom of		Residual risk level:					
data released	Information (FOI) or data		Likelihood	Impact	Residual risk			
releaseu	protection request.		4	3	12 High			
			Tolerance	threshold:	8 Medium			
Causes / so	ources	Mitigations	Timescale mitigations	and owners	ship of	Effectiveness -	- commentary	
Poor record	keeping	Refresher training and reminders about good	In place – S			Above tolerance.		
		records management practice. Head level 6 month	Head post in place - SMT		Although we have some good controls in place for dealing with PQs and other externally generated requests, it should be noted that we cannot control incoming volumes, which in January 2015 (for example)			
		contract recruited to manage the office move and review records management.	To sync in with IT strategy – Dave Moysen/Juliet Tizzard					
		TRIM review and retention policy implementation						
		work – subsumed by IT strategy.						
		,	Completed October 2015 – Juliet					
		queries being routed through Licensing, who have a definitive list of all licensing details.	Tizzard					
	emand on systems and over- a few key expert individuals –	PQs, FOIs and OTRs have dedicated expert staff/teams to deal with them.	In place – J	uliet Tizzard	/ Nick Jones	were among the highest we have ever experienced.		
	rload – leading to errors	If more time is needed for a complex PQ, attempts				Volumes decrea		
	<b>3</b> · · · · ·	are made to take the issue out of the very tightly				second half of 2	•	
		timed PQ process and replace this with a more				now increased a	igain.	
		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.						

	PQ SOP revised and log created, to be maintained by new Committee and Information Officer/Scientific Policy Manager.	In place - Juliet Tizzard
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 – Juliet Tizzard / Peter Thompson
Insufficient understanding of underlying system abilities and limitations, and/or of the topic or question, leading to data being misinterpreted or wrong data being elicited.	As above – expert staff with the appropriate knowledge and understanding in place.	In place – Juliet Tizzard / Nick Jones
Servicing data requests for researchers - poor quality of consents obtained by clinics for disclosure of data to researchers.	There is a recognised risk of centres reporting research consents inaccurately. Work to address consent reporting issues is being planned.	Actions to be confirmed – under discussion in February 2016 – Nick Jones

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner		
Donor	There is a risk that an OTR	Setting standards: improving the lifelong experience	Inherent risk level:			Inherent risk level:		$\Leftrightarrow \Leftrightarrow \Leftrightarrow \Leftrightarrow$	Nick Jones
conception	applicant is given incorrect	for donors, donor-conceived people, patients using	Likelihood	Impact	Inherent risk				
	data.	donor conception, and their wider families.	3	5	15 High				
DC 1:			Residual ri	sk level:					
OTR			Likelihood	Impact	Residual risk				
inaccuracy			1	4	4 Low				
			Tolerance	threshold:	4 Low				
Causes / so	urces	Mitigations	Timescale mitigations	and owners	ship of	Effectiveness -	- commentary		
Data accurac	y 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 lifelong support for donors, donor-conceived people and parents.	In place – N	lick Jones	At tolerance (which is very low for this risk).				
		Audit programme to check information provision and accuracy.	In place – N	lick 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 – N	lick 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 wro	ong 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			7			

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner	
Donor	There is a risk that	Setting standards: improving the lifelong experience	Inherent risk level:			⇔⇔⇔ Nick Jones	Nick Jones	
conception	inadequate support is	for donors, donor-conceived people, patients using	Likelihood	Impact	Inherent risk			
	provided for donor-	donor conception, and their wider families.	4	4	16 High			
DC 2:	conceived people or		Residual ri	sk level:				
Support for	donors at the point of making an OTR request.		Likelihood	Impact	Residual risk			
OTR	making an OTK request.		3	3	9 Medium			
applicants			Tolerance	threshold:	9 Medium			
Causes / so	urces	Mitigations	Timescale and ownership of mitigations			Effectiveness – commentary		
Lack of couns	selling availability for	Counselling service pilot established with external	In place (June 2015) – Nick Jones			At tolerance. The pilot counselling service		
applicants.		contractor in place.						
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).			has been in place since 1 June 2015, and we will make further assessments based on early uptake and the delivery experience. Reporting to the Authority will occur annually			
Risk of inade	quate handling of a request.	Trained staff, SOPs and quality assurance in place.	In place – N	lick Jones		during the pilot p	eriod.	
raide of madequate namaling of a request.		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					

Risk area	Description and impact	Strategic objective linkage	Risk score	S		Recent trend	Risk owner	
Financial	There is a risk that the	Efficiency, economy and value: ensuring the HFEA	Inherent risk level:			$\Leftrightarrow \Leftrightarrow \Leftrightarrow 1$	Sue Gallone	
viability	HFEA could significantly		Likelihood	Impact	Inherent risk			
	overspend (where	sector and Government.	4	4	16 High			
FV 1:	significantly = 5% of budget, £250k)		Residual ri	sk level:				
Income and	budget, £250k)		Likelihood	Impact	Residual risk			
expenditure			3	3	9 Medium			
			Tolerance	threshold:	9 Medium			
Causes / so	urces	Mitigations	Timescale mitigations	and owners	hip of	Effectiveness -	commentary	
Fee regime n	nakes us dependent on	Activity levels are tracked and change is discussed	Monthly (on	-going) – Sue	e Gallone	At tolerance.		
sector activity	y levels.	at CMG, who would consider what work to deprioritise and reduce expenditure.					Previous 2014/15 overspend was able to be met from	
		Fees Group created enabling dialogue with sector about fee levels. Fee increase agreed (November 2015), Treasury approval received (February 2016), and eSET discount to end.		es Group me r, ongoing – 9	etings in April Sue Gallone	reserves. 2015/16 on course for small under-spend but risk of legal costs remains.		
_	could be reduced due to covernment/policy	A good relationship with DH Sponsors, who are well informed about our work and our funding model.	Quarterly meetings (on-going) – Sue Gallone			In November 2015, the Authority approved a proposal to increase per-cycle fees by £5 (to £80) and to end the small 'eSET discount' for elective		
		Annual budget agreed with DH Finance team alongside draft business plan submission.	December annually – Sue Gallone					
Budget setting process is poor due to lack of information from directorates  Unforeseen increase in costs eg, legal, IfQ or extra in-year work required		Detailed budgets for 2016/17 are being prepared for Directorate Review				single embryo transfer, which has been in place for a few years to assist with the introduction of the Authority's multiple births policy (now firmly established and in place). This		
		DH has previously agreed our resource envelope.  Quarterly meetings with directorates flags any short-fall or further funding requirements.						
		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		should help secure sufficient funds going forward. Treasury approval for the fee change has been received (February 2016).			
		IfQ Programme Board regularly reviews the budget and costs.	Monthly – IfQ Programme Board					

Strategic risk register	Huma	an Fertilisation and Embryology Author	ity <b>29</b>
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	There is a risk that the HFEA experiences	Efficiency, economy and value: ensuring the HFEA	Inherent risk level:			$\Leftrightarrow \Leftrightarrow \Leftrightarrow \Leftrightarrow$	Peter	
		remains demonstrably good value for the public, the	Likelihood	Impact	Inherent risk		Thompson	
C 1:	unforeseen knowledge and	sector and Government.	4	4	16 High			
Knowledge	capability gaps, threatening delivery of the		Residual risk level:				l	
and capability	strategy.	To the state of th	Likelihood	Impact	Residual risk			
capability			3	3	9 Medium			
			Tolerance	threshold:	6 Medium			
Causes / so	urces	Mitigations	Timescale	and owners	ship of	Effectiveness -	commentary	
			mitigations					
•	r, sick leave etc. leading to	People strategy will partially mitigate.	Done – May	/ 2015 – Rac	hel Hopkins	Above tolerance.		
	owledge loss and capability	Mixed approach of retention, staff development, and				This risk and the set of controls remains focused on capability,		
gaps.		effective management of vacancies and recruitment						
		processes.	rather than capa		•			
		Staff have access to civil service learning (CSL); organisational standard is five working days per	In place – Rachel Hopkins			obviously some linkages, since managing turnover and churn also means managing		
		year of learning and development for each member						
		of staff.				fluctuations in capability and ensuring knowledge and skills are successfully nurtured and/o handed over.		
		Organisational knowledge captured via records	In place – Rachel Hopkins					
		management (TRIM), case manager software,						
		project records, handovers and induction notes, and						
		manager engagement.				Since the HFEA		
	government may implement	The HFEA was proactive in reducing its headcount	In place – Peter Thompson		organisation, with little intrinsic resilience, it seems prudent to have a low tolerance level for			
	cross all ALBs, resulting in	and other costs to minimal levels over a number of years.						
further staffing reductions. This would lead to the HFEA having to reduce its workload in some way.		We have also been reviewed extensively (including				this risk.  At present we are carrying two Head vacancies pending new		
		the McCracken review).						
		Turnover is variable, and so this risk will be retained						
		on the risk register, and will continue to receive				starters.		
		ongoing management attention.						

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	Staff kept informed of likely developments and next steps, and when applicable of personal role impacts and choices.	In place – Nick Jones	
loss and low performance.	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

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner	
Office move	There is a risk that the office move could	remains demonstrably good value for the public, the	Inherent risk level:			New ⊙⇔⇔	Sue Gallone	
			Likelihood	Impact	Inherent risk			
OM 1:	compromise our capability	sector and Government.	5	4	20 Very high			
Office move	and capacity to deliver our strategy.	<u> </u>	Residual risk level:					
	Stratogy.		Likelihood	Impact	Residual risk			
			4	4	16 High			
			Tolerance	threshold:	6 Medium			
Causes / sou	urces	Mitigations	Timescale and ownership of mitigations			Effectiveness – commentary		
Contractual ri	sks.	Contract signed.	In place (December 2015) - Sue Gallone			Above tolerance.		
Preparation and space planning risks, including establishing clarity about the facilities available in the building (eg, lockers).		Project manager in place. Staff engagement group established. Detailed information available about the new office space. Visits started, building relationship with NICE facilities team.	From now until the move – Jamie Munro					
Storage availability will be limited. The HFEA has some unavoidable paper records in Register team, Legal, Finance.		Planning work being done to identify unavoidable paper records, and to determine whether any of these can be scanned to reduce storage needs.  Contractor to be hired to take on all the scanning.	Plan agreed in February 2016 – to be implemented in February/March – Jamie Munro					
Potential for culture clash with other organisations that share the same space but have a different culture and their own staff rules.		Project team giving consideration to NICE's staff rules and whether the HFEA wishes to adopt them.  Communication with staff about any non-negotiable considerations that may impact on culture.	move – Jan	on of actions				
		There may need to be some senior level negotiation with NICE about messaging and the HFEA retaining its own culture and rules.						
		We will allow some time after the move for people to adapt to the changed environment, and will then consider whether any changes or further negotiations with NICE (or the British Council) are needed.						

The office will be shared with another organisation, and there will be generally less space, and limited meeting room availability.	The meeting room risk partly applies to smaller meetings such as one to ones. Larger meeting room availability in the building is limited and will be a challenge. Some meeting rooms are being secured in advance from April/May onwards (on a like-for-like basis). Further thought will need to be given to how to secure the rest of the needed meeting space.  Staff engagement group to consider cultural and ways of working impact of having less 'free space' in which to have impromptu or small meetings.  Trips to the new office will be planned so that staff can see the space.  Our IT kit will be replaced with laptops/tablets before the move, so that smaller desks will not be an issue.  There will be preparation planned in before the move, to deal with the reality of reduced storage	From now until the move and slightly beyond – Jamie Munro
The actual move – practical risks.	(eg, 'Tidy Fridays' etc but staff capacity for this will be very limited owing to IfQ and other high workloads).  We will be moving minimal kit and no desks,	From now until the move – Jamie
	reducing both risk and cost.  Detailed planning and communications will take place with all involved, including contractors, NICE and HFEA staff.  Following procurement framework to select contractors, and selecting carefully.	Munro
Cabling risks – ensuring communications lines are available to HFEA in new office.	Establish needs and place orders as necessary.	From now until the move – David Moysen

IT risks (information security, business continuity, introduction of new equipment	Office 365 upgrade project in place to include issuing of new laptops.	From now until the move and slightly beyond – David Moysen
and Office 365 upgrade in advance of move).	Register safeguards will be put in place; security of new Comms Room will be considered with NICE.	
	Business continuity plan already in place, and arrangements will continue for now – to be reviewed after move.	
	Planned timing of surrounding tasks (eg, lfQ milestone delivery) will need to allow for some down-time.	
	Back-ups will continue and will be stored off site as now.	
People risks: resources to participate in planning, packing etc., turnover and/or extra management work resulting from change of location, engagement on ways	Staff engagement, communications and HR contractual considerations built into project plan. Staff engagement group being established and first meeting being planned.	In place and ongoing – Jo Triggs
of working, willingness to adapt etc.	Staff being issued with new, smarter IT kit, including tablets/laptops replacing PCs, a better access method for secure HFEA login, and Office 365 available.	
Diversion from business. Coincides with the delivery period for some IfQ milestones, which are key to delivering our strategy to publicly announced timescales. Some other work will also coincide because of year-end considerations.	Early awareness of the potential for disruption means that this can be managed through careful planning and prioritisation.	Detailed planning and awareness raising from November 2015 onwards – Paula Robinson (and all managers)

Cost increase compared to current rent (potentially including additional costs for both internal and external meeting rooms).	Unavoidable, but in keeping with DH requirements which will reduce costs overall for the health ALBs as a whole group. Costs factored into to funding required from 2016/17.  Business case includes ensuring the HFEA is in line with Government Estates Strategy.	In place – Sue Gallone	
Project failure - The move could fail to take place if unforeseen issues arise, or the timetable could be jeopardised by factors outside the HFEA's control.	Contract secured and planning is in place. Should the new building become unavailable for some reason, at any point, (eg, fire, flood), business continuity arrangements would apply while a new plan was put in place. (There is no option to stay on in Finsbury Tower beyond April.)	Detailed risk-based planning in place  – Jamie Munro	

# **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 1=Insignificant 2=Minor 3=Moderate 4=Major 5=Catastrophic

	Risk scoring matrix							
	5.Very high	5 Medium	10 Medium	15 High	20 Very High	25 Very High		
	5.	Wediam		111911	very riigii	vory riigir		
	2. Low 3. Medium 4. High	4	8	12	16	20		
		Low	Medium	High	High	Very High		
Impact		3	6	9	12	15		
<u>=</u>		Low	Medium	Medium	High	High		
		2	4	6	8	10		
	7	Very Low	Low	Medium	Medium	Medium		
	1. Very Low	1	2	3	4	5		
	,	Very Low	Very Low	Low	Low	Medium		
	Score	1. Rare (≤10%)	2. Unlikely (11%-33%)	3. Possible (34%-67%)	4. Likely (68%-89%)	5. Almost Certain (≥90%)		
	elihood			Likelihood				