Strategic risks

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Audit and Governance Committee		
Agenda item	7		
Paper number	[AGC (07/12/2016) 515 PR]		
Meeting date	7 December 2016		
Author	Paula Robinson, Head of Business Planning		
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 noted the risk register at its meeting on 16 November. CMG reviewed the risk register on 23 November 2016. CMG discussed all risks, their controls, and scores. Three of the twelve risks are currently above tolerance.

1.2. The current strategic risk register is attached at Annex A, and includes an overview of CMG's recent discussions about the risk register. The annex includes the graphical overview of residual risks plotted against risk tolerances.

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 Annex A

Risk summary: high to low residual risks

Risk area	Risk title	Strategic linkage[1]	Residual risk	Current status	Trend*
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	⇔⇔⇔⇔
Financial viability	FV1: Income and expenditure	Efficiency, economy and value	9 – Medium	At tolerance	⇔⇔⇔⇔
Donor conception	DC2: Support for OTR applicants	Setting standards: donor conception	9 – Medium	At tolerance	⇔⇔⇔⇔
Regulatory model	RM1: Quality and safety of care	Setting standards: quality and safety	8 – Medium	At tolerance	⇔⇔⇔⇔
Regulatory model	RM2: Loss of regulatory authority	Setting standards: quality and safety	8 – Medium	At tolerance	⇔⇔⇔⇔
Information for Quality	IfQ1: Improved information access	Increasing and informing choice: information	8 – Medium	At tolerance	⇔⇔⇔⇩
Information for Quality	IfQ2: Register data	Increasing and informing choice: Register data	8 – Medium	At tolerance	⇔⇔⇔⇔
Donor conception	DC1: OTR inaccuracy	Setting standards: donor conception	4 – Low	At tolerance	⇔⇔⇔⇔

* This column tracks the four most recent reviews by AGC, CMG, or the Authority (eg,⇧⇔⇩⇔).

Recent review points are: Authority 6 July ⇨ CMG 7 September/AGC 21 September ⇨ Authority 16 November (noted) ⇨ CMG 23 November

[1] Strategic objectives 2014-2017:

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

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

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

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

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

CMG overview – summary from November risk meeting

CMG reviewed the risk register and risk scores at its meeting on 23 November.

CMG updated various risks and scores, and especially discussed IfQ risks – both in the context of strategic risks and related operational risks within teams. The ongoing IfQ work alongside business as usual is undoubtedly causing pressures on resources across the organisation. This was reflected in teams' operational risk logs as well as the strategic risk register. CMG lowered the residual risk for IfQ1, improved information access, since much of the improvement in our engagement channels and information has been completed, and is available in beta. CMG raised the risk level for IfQ3, delivery of promised efficiencies. This risk relates to release two of the clinic portal, incorporating the new electronic data interchange, which is being delayed by competing resource demands from the tail end of release one (website, choose a fertility clinic, and the portal).

Coupled with IfQ delivery, we are going through a period of turnover and internal churn, as a combined result of IfQ contracted resources coming to an end (meaning that staff need to take over their roles), and other incidental turnover. Some internal interim recruitment to bridge gaps has resulted in other recruitment activity to replace or backfill the staff who are moving into different roles. Some of the turnover involves staff with good knowledge of dealing with Parliamentary Questions. Therefore, CMG raised the risk level for Data 2, incorrect data released, and Capability 1, knowledge and capability.

AGC feedback from September meeting

The committee asked the executive to give more consideration to 'plan B' for the website, in the event of an adverse JR judgment, or in the event of Red Dot (the current, outgoing content management system, which was old and unsupported) failing completely.

CMG discussed this issue at its monthly meeting in September, and confirmed that the new website was capable of being used in place of the current website, and that if we needed to deploy it before the JR was resolved, the information under dispute could be removed as a short term measure. The new website made use of a different content management system, Umbraco, which was up to date and supported, as well as more stable and reliable than RedDot. This option meant that our communications channels would remain open, and this seemed sufficient mitigation. In addition, the HFEA had a range of other channels for communicating important information to clinics and other stakeholders, including the clinic portal, social media, Clinic Focus, and email. This was felt to provide a sufficient range of options for important communications should the worst happen and access to the current website be lost.

Authority – November meeting

In the event, the Authority did not actively consider the item, but agreed to note it and submit any comments after the meeting. To date, no comments have been received.

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 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

We also consider whether any HFEA strategic risks or controls have a potential impact for the Department or any other ALBs.

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Regulatory model RM 1: Quality and safety of care	There is a risk of adverse effects on the quality and safety of care if the HFEA were to fail to deliver its duties under the HFE Act (1990) as amended.	Setting standards: improving the quality and safety of care through our regulatory activities.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Peter Thompson
			Likelihood	Impact	Inherent risk		
			3	5	15 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			2	**4**	**8 Medium**		
			Tolerance threshold:		8 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Inspection/reporting failure.	Inspections are scheduled for the whole year, using licence information held on Epicentre, and items are also scheduled to committees well in advance.	In place – Sharon Fensome-Rimmer	At tolerance. The Head of Corporate Governance and Chief Inspector started in their posts (in March and May 2016 respectively). The Head of Corporate Governance subsequently left the HFEA in September 2016, leaving a head vacancy again (now filled internally on an interim basis). The need to manage recent Heads vacancies, the continuing training period and also the action plan being implemented in connection with legal parenthood consent issues, has raised the residual risk likelihood from 1 (very unlikely) to 2 (unlikely) – through to at least December 2016.
	Audit of Epicentre conducted to reveal data errors. Queries now routed through Licensing, who hold a definitive list of all licensing details. The correction of errors found is in progress and should be complete shortly.	Audit completed October 2015 – Siobhain Kelly Corrective work in progress for completion in November 2016 – 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	Proposals on an updated IfQ delivery plan were made to August IfQ Programme Board, these should help address this risk by extending the release date for the EDI replacement by 3 months (IfQ release 2). Mitigation plans for this risk are in the process of being prepared and agreed with SMT as at September.	Mitigation planning in progress in September - Nick Jones	
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.	Update of compliance and enforcement policy.	Completed following Authority approval of new policy March 2016 - 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	On legal parenthood, a strong set of actions is in place and continues to be implemented. The issue will also be picked up during the next review of the Code of Practice. The inspection team continue to work with colleagues in licensed centres where there are anomalies. The focus is on ensuring all affected patients are informed and appropriately supported.
Insufficient inspectors, administrative or licensing staff	Inspection team up to complement. The new Chief Inspector joined the HFEA in early May 2016.	In place – Nick Jones	
	Business support is operating below complement, and this will be addressed shortly, as part of addressing gaps resulting from internal recruitment and churn.	To be addressed shortly – 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).	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	
	Update of compliance and enforcement policy and implementation of new policy and related procedures.	In place – revised policy agreed Spring 2016 – Nick Jones / Sharon Fensome-Rimmer	
	A detailed action plan in response to the legal parenthood judgment is in place. There has been correspondence with clinics, who have completed full audits. PRs are responsible for the robustness of the audit. The HFEA has required that clinics support affected patients – using Barts as a good example. In working with clinics, the HFEA has experienced good cooperation. All clinics engaged and have provided assurances about current practice. Through a detailed review of every clinic's responses, a summary list of all concerns is being produced. Management review meetings took place for all clinics at which there are handling concerns or anomalies. Plan of action in place to address all of the concerns identified, with direct follow up with centres who did not respond at all. Where there are engagement concerns, we will do short-notice inspections, focused on parenthood consent.	In progress – Nick Jones/Sharon Fensome-Rimmer	
	The policy team will develop a range of tools to support licensed clinics in ensuring patients provide effective consent. Range of lessons learned identified.	Policy team tools – development in 2017/18 business year – Joanne Anton	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Regulatory model RM 2: Loss of regulatory authority	There is a risk that the HFEA could lose authority as a regulator, jeopardising its regulatory effectiveness, owing to a loss of public / sector confidence.	Setting standards: improving the quality and safety of care through our regulatory activities.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Peter Thompson
			Likelihood	Impact	Inherent risk		
			3	5	15 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			2	**4**	**8 Medium**		
			Tolerance threshold:		8 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Failures or weaknesses in decision making processes.	Keeping up to date the standard operating procedures (SOPs) for licensing, representations and appeals.	In place – 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. Delegations were revisited during 2016 review of Standing Orders. Licensing Officer role to take certain decisions from ELP –the documentation for recording Licensing Officer decisions is complete as at September 2016 and this process is ready for implementation.	In place – Siobhain Kelly Licensing Officer role – ready for implementation September 2016 – Siobhain Kelly Delegations in SOs were put in place - Spring 2016	
Failing to demonstrate competence as a regulator	Update of compliance and enforcement policy and implementation of new policy and related procedures.	In place – revised policy agreed Spring 2016 – Nick Jones / Sharon Fensome-Rimmer	

	Inspector training, competency-based recruitment, induction process, SOPs, quality management 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
	TRIM training and guidance/induction in records management in place pending new work on records management to be commenced in autumn 2016 (see below).	New work in development as at September 2016
	Further work planned on records management in parallel with IT strategy. This piece of work is currently being scoped.	Linked to IT strategy work – in progress – Siobhain Kelly / David Moysen
	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 – beta phase February 2016 – Juliet Tizzard

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

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
IfQ IfQ 1: Improved information access	If the information for Quality (IfQ) programme does not enable us to provide better information and data, and improved engagement channels, patients will not be able to access the improved information they need to assist them in making important choices.	Increasing and informing choice: ensuring that patients have access to high quality meaningful information.	Inherent risk level:			⇔ ⇔ ⇔ ⇩	Juliet Tizzard
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			2	**4**	**8 Medium**		
			Tolerance threshold:		8 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Inability to extract reliable data from the Register.	Detailed planning and programme management in place to ensure this will be possible after migration. Migration strategy developed, and significant work being done to identify and cleanse all of the data that 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	At tolerance. The approval process has had to be tightly managed; a summary is set out below. The first Department of Health gateway review took place in November 2015 and awarded a high score to the HFEA, but the formal decision on this was still not made by the Government Digital Service board until mid-January (a month later than expected). This meant that the beta (build) stage initially had to proceed at risk (subsequently resolved).
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	

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	Approval also carried a number of requirements and conditions which need to be added to the delivery. Owing to these delays, it was necessary to extend the timeline for the private beta phase from March to June 2016. The live beta gateway approval in May was much more efficient, with approvals received within days of the assessment taking place. However, there were a number of requirements to address before implementing live beta. The move to public beta was delayed by an injunction brought by a licensed clinic. We successfully managed to have the injunction lifted, but it meant that we could not issue the new website to public beta testing until August 2016. Due partly to this, the timeline was extended further, with additional work impacting on the planned start-up of release two work, and on the timelines for go live GDS assessments for both the portal and the website. The GDS go live assessment for the portal subsequently took place in November. No date has
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.	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.	In place – Nick Jones In place – Nick Jones	
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. GDS Beta assessment was passed on all 18 points.	In place – user research delivered end Oct 2016 – Juliet Tizzard	
Government and DH permissions structures are complex, lengthy, multi-stranded, and sometimes change mid-process.	Initial external business cases agreed and user research completed. Final business case for whole IfQ programme 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	In place – Juliet Tizzard In place – Nick Jones (decision received April 2015) In place – Nick Jones	

	compensate for previous and anticipated future delays.		yet been set for the go live gateway assessment for the website.
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 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 requires close joint working and communication among all involved contractors. Sound project management practices in place to monitor delivery. 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. Regular contract meetings in place. This remains a challenge.	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.	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. 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 2: Register data	HFEA Register data becomes lost, corrupted, or is otherwise adversely affected during IfQ programme delivery.	Increasing and informing choice: using the data in the Register of Treatments to improve outcomes and research.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Nick Jones
			Likelihood	Impact	Inherent risk		
			2	5	10 Medium		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			2	**4**	**8 Medium**		
			Tolerance threshold:		8 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Risks associated with data migration to new structure, together with records accuracy and data integrity issues.	IfQ programme groundwork focused on current state of Register. Extensive planning in place, including detailed research and migration strategy.	In place – Nick Jones/Dave Moysen	At tolerance. This risk is being intensively managed – a major focus of IfQ detailed planning work, particularly around data migration.
The firm (Avoca) which was scheduled to provide assurance on data migration has gone out of business.	The HFEA has considered other sources of assurance and have now sourced a supplier and is currently going through procurement processes to appoint them.	Pending a successful appointment process, we would expect the new company to begin providing assurance in September/October– Nick Jones	
Historic data cleansing is needed prior to migration.	A detailed migration strategy is in place, and data cleansing is in progress.	In place – Nick Jones/Dave Moysen	
Increased reporting needs mean we later discover a barrier to achieving this, or that an unanticipated level of accuracy is required, with data or fields which we do not currently focus on or deem critical for accuracy.	IfQ planning work incorporated consideration of fields and reporting needs were agreed. Decisions about the required data quality for each field were 'future proofed' as much as possible through engagement with stakeholders to anticipate future needs and build these into the design.	In place – Nick Jones	
Reliability of existing infrastructure systems – (eg, Register, EDI, network, backups).	Maintenance of desktop, network, backups, etc. core part of IT business as usual delivery.	In place – Dave Moysen	
System interdependencies change / are not recognised	Strong interdependency mapping done between IfQ and business as usual.	Done – Nick Jones	
Benefits not maximised and internalised	During IfQ delivery, product owners are in place, as	In place – Nick Jones	

into ways of working.	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.		

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
IfQ IfQ 3: Delivery of promised efficiencies	There is a risk that the HFEA's promises of efficiency improvements in Register data collection and submission are not ultimately delivered.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇔ ⇩ ⇔ ⇧	Nick Jones
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	**4**	**12 High**		
			Tolerance threshold:		9 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Poor user acceptance of changes, or expectations not managed.	Stakeholder involvement strategy in place and user testing being incorporated into implementation phases of projects.	In place – Nick Jones/Juliet Tizzard	Above tolerance. In September 2016, since we believed that the mitigations that are in place are working effectively and mean that we are on track to achieve the promised efficiencies, we reduced the level of likelihood for this risk. This in turn brought the risk to below the tolerance threshold of 9. This risk is also affected by GDS approvals and associated requirements (see IfQ1). 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 this risk again. The delays stem from the
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	
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	In place (July 2015) – Nick Jones In progress (September 2016) – Nick Jones	

	introduction of the new EDI interface) is in progress and the HFEA will continue to work within agreed costs. A contingency amount was built into the budget, although this has now been used. The support function is being re-shaped and streamlined to deal with the departure in November of the release two project manager.	In progress (November 2016) – Nick Jones	ongoing work still needed on release one, which requires the attention of the same staff who are needed for release two. In addition, some key IfQ contracted staff are coming to the end of their contracts with work still ongoing.
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.	All GDS approvals sought so far have been granted, albeit with some delays to earlier gateways. Our detailed planning includes addressing the requirements laid down by GDS as conditions of alpha and beta phase approval. 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. The beta timeline was 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. Knowledge handover with the contractors will take place.	In place (June 2015) – 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	20 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	Effectiveness – commentary
Complex and controversial area.	Panel of legal advisors from various firms at our disposal for advice, as well as in-house Head of Legal.	In place – Peter Thompson	At tolerance. **Current cases:** The judgment in 2015 and subsequent cases on consents for parenthood have administrative and policy consequences for the HFEA. Further cases are going through court, although there have been no cases arising from new incidents post the 2015 judgment. 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. A judicial review hearing of one discrete element of the IfQ CaFC project has been set for December. Authority decisions in November may impact on the scope of the JR. We are advised that our case is strong;
	Evidence-based policy decision-making and horizon scanning for new techniques.	In place – Joanne Anton	
	Robust and transparent processes in place for seeking expert opinion – eg, external expert advisers, transparent process for gathering evidence, meetings minuted, papers available online.	In place – Joanne Anton/Juliet Tizzard	
HFE Act and regulations lead to the possibility of there being differing legal opinions from different legal advisers, that then have to be decided by a court.	Panel in place, as above, to get the best possible advice. Case by case decisions regarding what to argue in court cases, so as to clarify the position.	In place – Peter Thompson	
Decisions and actions of the HFEA and its committees may be contested. New guide to licensing and inspection rating (effective from go-live of new website) on CaFC may mean that more clinics make representations against licensing decisions.	Panel in place, as above.	In place – Peter Thompson	
	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	Scenario planning is undertaken at the initiation of	In place – Peter Thompson	

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.	any likely action.		however, if it were lost then it may impact on aspects of the presentation of data.
HFEA could face unexpected high legal costs or damages which it could not fund.	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.	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 – Siobhain Kelly	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend
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:			⇔ ⇔ ⇔ ⇔
			Likelihood	Impact	Inherent risk	
			4	5	20 Very high	
			Residual risk level:			
			Likelihood	Impact	Residual risk	
			2	**5**	**10 Medium**	
			Tolerance threshold:		10 Medium	

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Confidentiality breach of Register data.	Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality. Secure working arrangements for Register team, including when working at home.	In place – Dave Moysen	At tolerance.
Loss of Register or other data.	As above.	In place – Dave Moysen	
	Robust information security arrangements, in line with the Information Governance Toolkit, including a security policy for staff, secure and confidential storage of and limited access to Register information, and stringent data encryption standards.	In place – Dave Moysen	
Cyber-attack and similar external risks.	Secure system in place as above, with regular penetration testing.	In place – Dave Moysen	
Infrastructure turns out to be insecure, or we lose connection and cannot access our data.	IT strategy agreed, including a thorough investigation of the Cloud option, security, and reliability.	In place – Dave Moysen	
	Deliberate internal damage to infrastructure, or data, is controlled through off-site back-ups and the fact that any malicious tampering would be a criminal act.	In place (March 2015) – Nick Jones	
Business continuity issue.	BCP in place and staff communication procedure	In place – Richard Sydee	

	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.	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	TRIM training and guidance/induction in records management in place pending new work on records management to be commenced in autumn 2016 (see below). New work in development as at September 2016	New work in development as at September 2016	
	Further work planned on records management in parallel with IT strategy. This piece of work is currently being scoped. Linked to IT strategy work – in progress – Siobhain Kelly / David Moysen	Linked to IT strategy work – in progress – Siobhain Kelly / David Moysen	

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner
Data D 2: Incorrect data released	There is a risk that incorrect data is released in response to a Parliamentary question (PQ), or a Freedom of Information (FOI) or data protection request.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level: Likelihood: 5 / Impact: 4 / Inherent risk: 20 Very high Residual risk level: Likelihood: **3** / Impact: **4** / Residual risk: **12 High** Tolerance threshold: 8 Medium	⇔ ⇔ ⇔ ⇧	Juliet Tizzard

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Poor record keeping	Refresher training and reminders about good records management practice.	In place – SMT	Above tolerance. Although we have some good controls in place for dealing with PQs and other externally generated requests, it should be noted that we cannot control incoming volumes, complexity or deadlines. In September 2016 we have not yet registered an unusual spike in volumes following on from recess (during which time there were no PQs). However, with the current work on the mitochondria scientific review, due to be published in December, this situation is likely to change in future months. We continue to closely monitor volumes.
	TRIM review and retention policy implementation work – part of records management project	To sync in with IT strategy. RM project to start autumn 2016 – Dave Moysen/ Siobhain Kelly	
	Audit of Epicentre to reveal any data errors. All queries being routed through Licensing, who have a definitive list of all licensing details.	Completed October 2015 – Siobhain Kelly Implementation of actions following Epicentre audit planned and to be completed by November 2016– 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 in progress. 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 Recruitment in progress – 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
Servicing data requests for researchers - poor quality of consents obtained by clinics for disclosure of data to researchers.	There is a recognised risk of centres reporting research consents inaccurately. Work is ongoing to address consent reporting issues	Inspections now routinely sample check a clinic's performance comparing original consent form with the detail held on the Register, to ensure it has been transcribed effectively. Where the error rate is above tolerance the clinic must undertake a full audit and carry out corrections to the Register as necessary – Nick Jones

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Donor conception DC 1: OTR inaccuracy	There is a risk that an OTR applicant is given incorrect data.	Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Nick Jones
			Likelihood	Impact	Inherent risk		
			3	5	15 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			1	**4**	**4 Low**		
			Tolerance threshold:		4 Low		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Data accuracy in Register submissions.	Continuous work with clinics on data quality, including current verification processes, steps in the OTR process, regular audit alongside inspections, and continued emphasis on the importance of life-long support for donors, donor-conceived people and parents.	In place – Nick Jones	At tolerance (which is very low for this risk).
	Audit programme to check information provision and accuracy.	In place – Nick Jones	
	IfQ work will identify data accuracy requirements for different fields as part of the migration process, and will establish more efficient processes.	In place – Nick Jones	
	If subsequent work or data submissions reveal an unpreventable earlier inaccuracy (or an error), we explain this transparently to the recipient of the information, so it is clear to them what the position is and why this differs from the earlier provided data.	In place – Nick Jones	
Issuing of wrong person's data.	OTR process has an SOP that includes specific steps to check the information given and that it relates to the right person.	In place – Nick Jones	
Process error or human error.	As above.	In place – Nick Jones	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Donor conception DC 2: Support for OTR applicants	There is a risk that inadequate support is provided for donor-conceived people or donors at the point of making an OTR request.	Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Nick Jones
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	**3**	**9 Medium**		
			Tolerance threshold:		9 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Lack of counselling availability for applicants.	Counselling service established with external contractor in place.	In place (June 2015) – Nick Jones	At tolerance. The pilot counselling service has been in place since 1 June 2015, and we will make further assessments based on uptake and the delivery experience. Reporting to the Authority will occur annually during the pilot period, and the first such report was provided to the July Authority meeting.
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 returning to work from long term sick leave, and this together with work pressures from IfQ delivery means there is still some pressure on team capacity (being discussed by managers).	In place, with ongoing team capacity issue under discussion – 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.	

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner
Financial viability FV 1: Income and expenditure	There is a risk that the HFEA could significantly overspend (where significantly = 5% of budget, £250k)	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level: Likelihood: 4 / Impact: 4 / Inherent risk: 16 High Residual risk level: Likelihood: **3** / Impact: **3** / Residual risk: **9 Medium** Tolerance threshold: 9 Medium	⇔ ⇔ ⇔ ⇔	Richard Sydee

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Fee regime makes us dependent on sector activity levels.	Activity levels are tracked and change is discussed at CMG, who would consider what work to deprioritise and reduce expenditure.	Monthly (on-going) – Morounke Akingbola	At tolerance. 2015/16 achieved a small under-spend but risk of additional legal costs remains. The increase of per-cycle fees by £5 (to £80) and the end of the small 'eSET discount' for elective single embryo transfer has now been implemented following Treasury approval in February 2016. This should help secure sufficient funds going forward. It is too early for us to tell whether this reduces this risk further. The situation will be clearer following IfQ implementation. The potential impact of the IfQ risk here, related to EPRS suppliers and the impact on treatment fees, is not yet fully
	Fees Group created enabling dialogue with sector about fee levels. Fee increase was agreed and approved by Treasury. This was implemented and the eSET discount ended (April 2016).	In place. Fees Group meeting in October, ongoing – Morounke Akingbola	
EPRS suppliers may not make required changes to their systems in line with IfQ data submission mechanism (EDI, Register) changes. Clinics using these suppliers would be unable to provide treatment data leading to deferral of fee payment since we could not bill centres for treatments.	Proposals were made to August IfQ Programme Board for adjustments to the IfQ schedule which would impact when this risk is likely to be felt. Further discussions are needed with Finance to understand the scale of the potential impact of this risk and to plan for an effective mitigation to secure cash flow. These discussions will be ongoing while IfQ release 2 develops further.	Ongoing -Nick Jones	
GIA funding could be reduced due to changes in Government/policy	A good relationship with DH Sponsors, who are well informed about our work and our funding model.	Quarterly meetings (on-going) – Morounke Akingbola	
	Annual budget agreed with DH Finance team alongside draft business plan submission.	December annually – Morounke Akingbola	
	Detailed budgets for 2016/17 have been agreed with Directors. DH has previously agreed our resource envelope.	In place – Morounke Akingbola	

Budget setting process is poor due to lack of information from directorates	Quarterly meetings with directorates flags any shortfall or further funding requirements.	Quarterly meetings (on-going) – Morounke Akingbola	understood. It is also clear that this would not potentially impact the organisation until 2017, so the risk level is not affected at this time. Meanwhile, the IfQ team will work together closely with the finance team and the mitigation for this risk will be updated once more information is gathered and a plan agreed. We will keep this under review.
Unforeseen increase in costs eg, legal, IfQ or extra in-year work required	Use of reserves, up to contingency level available. DH kept abreast of current situation and are a final source of additional funding if required. IfQ Programme Board regularly reviews the budget and costs.	Monthly – Morounke Akingbola Monthly – IfQ Programme Board	
Upwards scope creep during projects, or emerging during early development of projects eg, IfQ.	Periodic review of actual and budgeted spend by IfQ project board and monthly budget meetings with finance.	Ongoing – Wilhelmina Crown	
	Cash flow forecast updated.	Monthly (on-going) – Morounke Akingbola	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Capability C 1: Knowledge and capability	There is a risk that the HFEA experiences unforeseen knowledge and capability gaps, threatening delivery of the strategy.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇔ ⇔ ⇔ ⇧	Peter Thompson
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			4	**3**	**12 High**		
			Tolerance threshold:		6 Medium		

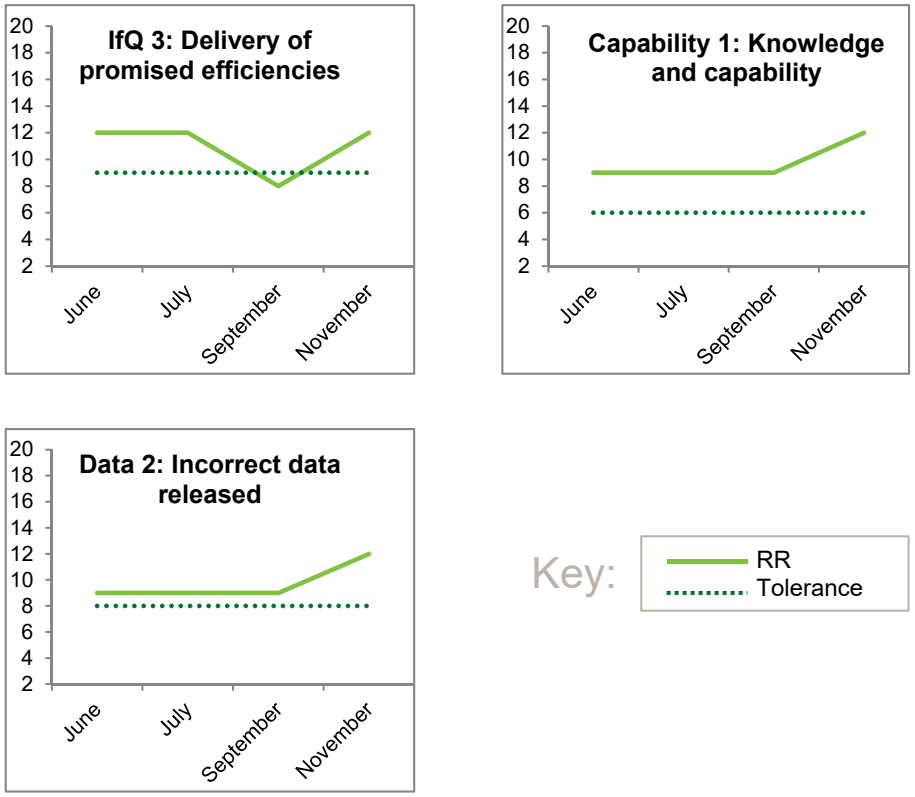
Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
High turnover, sick leave etc. leading to temporary knowledge loss and capability gaps.	People strategy will partially mitigate. Mixed approach of retention, staff development, and effective management of vacancies and recruitment processes.	Done – May 2015 – Rachel Hopkins	Above tolerance. This risk and the set of controls remains focused on capability, rather than capacity. There are obviously some linkages, since managing turnover and churn also means managing fluctuations in capability and ensuring knowledge and skills are successfully nurtured and/or handed over. Since the HFEA is a small organisation, with little intrinsic resilience, it seems prudent to retain a low tolerance level for this risk. Our Head vacancies earlier in 2016, in Licensing and Compliance, were initially filled (in March and May 2016 respectively). However the Head of Corporate Governance subsequently left in September 2016, and has been replaced
	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	
The new UK government may implement further cuts across all ALBs, resulting in further staffing reductions. This would lead to the HFEA having to reduce its workload in some way.	The HFEA was proactive in reducing its headcount and other costs to minimal levels over a number of years. We have also been reviewed extensively (including the McCracken review). Turnover is variable, and so this risk will be retained on the risk register, and will continue to receive ongoing management attention.	In place – Peter Thompson	
Poor morale leading to decreased	Engagement with the issue by managers. Ensuring	In place – Peter Thompson	

effectiveness and performance failures.	managers have team meetings and one-to-one meetings to obtain feedback and identify actions to be taken.		internally on an interim basis, with associated recruitment activity needed in the team.
	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	Several staff (including end of contract IfQ staff) have left the organisation recently, with two more establishment staff leaving before the end of the year. This means we are currently in a period of turnover and internal churn, with some knowledge gaps, and IfQ work ongoing for both release one and release two.
Differential impacts of IfQ-related change and other pressures for particular teams could lead to specific areas of knowledge loss and low performance.	Staff kept informed of likely developments and next steps, and when applicable of personal role impacts and choices.	In place – Nick Jones	
	Policies and processes to treat staff fairly and consistently, particularly if people are 'at risk'.	In place – Peter Thompson	
Additional avenues of work open up, or reactive diversions arise, and need to be accommodated alongside the major IfQ programme.	Careful planning and prioritisation of both business plan work and business flow through our Committees. Regular oversight by CMG – standing item on planning and resources.	In place – Paula Robinson	
	Early emphasis given to team-level service delivery planning, with active involvement of team members. CMG will continue to review planning and delivery.	In place – Paula Robinson	
	Planning for 2016/17 prioritises IfQ delivery, and therefore strategy delivery, within our limited resources.	In place as part of business planning (2015 onwards) – Paula Robinson	
	IfQ has some of its own dedicated resources.	In place – Nick Jones	
	There is a degree of flexibility within our resources, and increasing resilience is a key consideration whenever a post becomes vacant. Staff are encouraged to identify personal development opportunities with their manager, through the PDP process, making good use of CSL.	In place – Peter Thompson	
Regarding the recent work on licensing mitochondrial replacement techniques, there is a possible future risk that we will	Future needs (capability and capacity) relating to mitochondrial replacement techniques and licensing applications are starting to be considered now, but	Issue for consideration when applications commence – Juliet Tizzard	

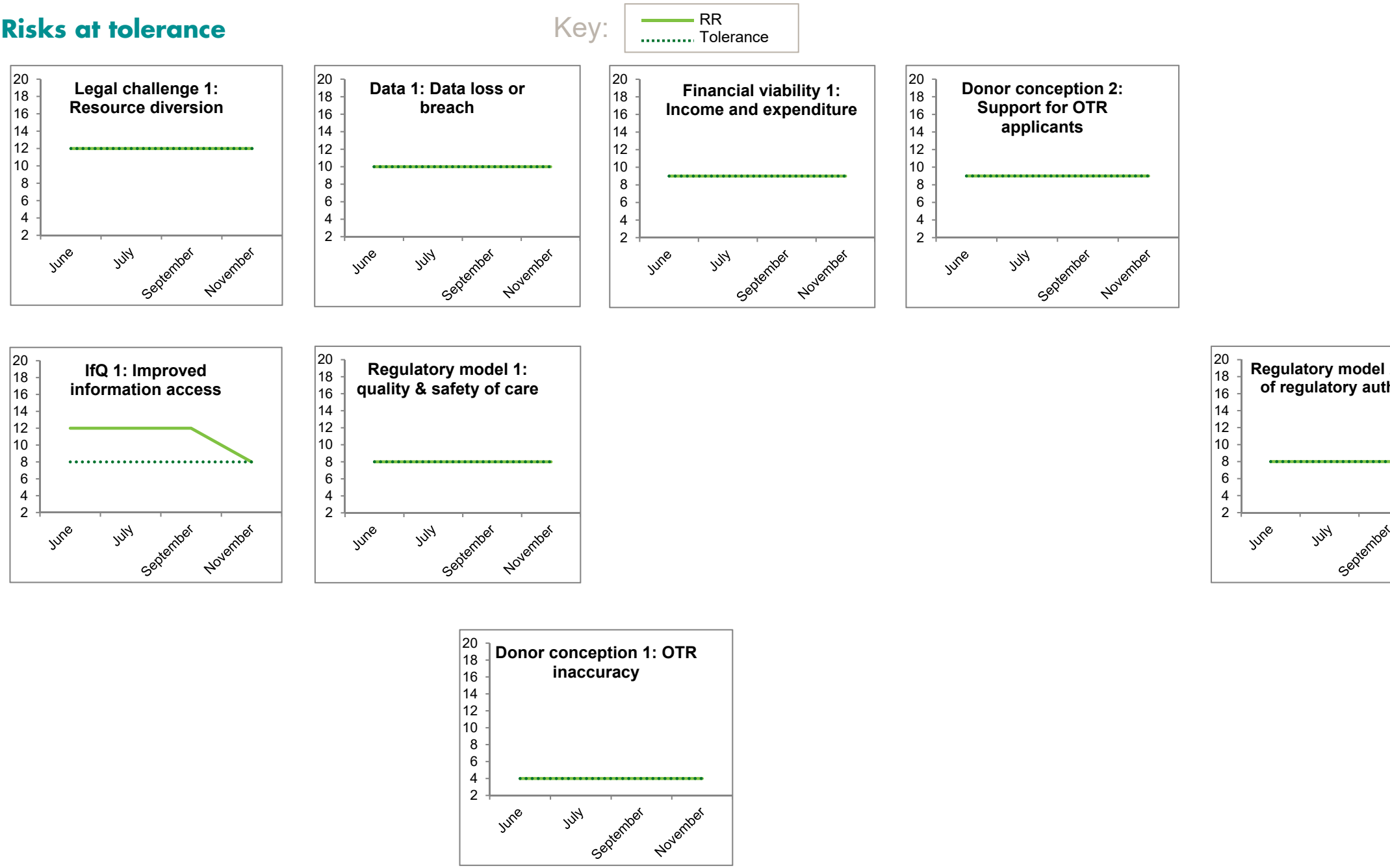
need to increase both capability and capacity in this area, depending on uptake (this is not yet certain).	will not be known for sure until later. No controls can yet be put in place, but the potential issue is on our radar.		

Tolerance vs Residual Risk:

Risks above tolerance



Risks at tolerance



Risk below tolerance

None.

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	1. Rare (≤10%)	2. Unlikely (11%-33%)	3. Possible (34%-67%)	4. Likely (68%-89%)	5. Almost Certain (≥90%)
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

Likelihood

Health Group Internal Audit

Health Group Internal Audit provides an objective and independent assurance, analysis and consulting service to the Department of Health and its arm's length bodies, bringing a disciplined approach to evaluating and improving the effectiveness of risk management, control and governance processes.

The focuses on business priorities and key risks, delivering its service through three core approaches across all corporate and programme activity:

- **Review and evaluation** of internal controls and processes;
- **Advice to support management** in making improvements in risk management, control and governance; and
- **Analysis of policies, procedures and operations** against good practice.

Our findings and recommendations:

- Form the basis of an independent opinion to the Accounting Officers and Audit Committees of the Department of Health and its arm's length bodies on the degree to which risk management, control and governance support the achievement of objectives; and
- Add value to management by providing a basis and catalyst for improving operations.

INTERNAL AUDIT PROGRESS REPORT DECEMBER 2016

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CONTENTS **PAGE**

HFEA Internal Audit Progress Report December 2016

1) Introduction

This paper sets out the progress in completing the 2016/17 Internal Audit Plan since the last meeting of the Audit and Governance Committee in September 2016.

2) Progress against 2016/17 Internal Audit Plan

2.1 Status of agreed plan:

The table below summarises the progress against each of the review areas in the 2016/17 Audit Plan:

Reviews per 201/17 IA plan	Audit scope	Status	Findings			Overall report rating	Audit days per plan	Actual audit days
			High	Medium	Low			
Income generation process	These reviews were merged into one as they both focused on the revenue process. We mapped the income generation and invoicing process from receipt of the electronic treatment forms from clinics to the raising of an invoice. In addition, we evaluated the design and operating effectiveness of controls over the data being used within the income process, considering the mechanisms to ensure that the original source data is of appropriate quality to support invoicing and the checks in place to ensure that integrity of data is maintained during the income and invoicing process. Management also requested that we review the risk management process in place in	Final report issued September 2016	0	1	4	**Moderate**	5	9
Quality and efficiency of revenue data							4	

Reviews per 201/17 IA plan	Audit scope	Status	Findings			Overall report rating	Audit days per plan	Actual audit days
			High	Medium	Low			
	relation to the transition of income processing to the Integrated Clinic Portal.							
Information standards	Initially this review was to be aimed at providing assurance over the application of a new policy on the publication of patient oriented information on the HFEA's website. However, NHS England are assessing the information governance arrangements of the patient oriented information to ensure published information is up to date and accurate. Following a scoping meeting with the Audit Sponsor and to avoid duplication, it has therefore been agreed that our work should focus on the application of the policy to corporate information and information provided to clinics.	Scoping meeting held and date for review in January agreed.					5	0.25
Board effectiveness	This review has been a high level review to assess the Board effectiveness via a self-assessment survey and follow-up interviews.	Draft report issued	0	0	2	Not rated	6	6
Management of Cyber Penetration threat	Following scoping discussions with the Head of IT, it has been agreed that this work will be focussed on identifying security risks relating to a cloud environment and identifying any gaps in HFEA's security control framework.	Draft terms of reference issued. Fieldwork to be undertaken in December 2016.					5	0.75
Assurance	We will deliver an assurance mapping	Scope to be				Not	3	0

Reviews per 201/17 IA plan	Audit scope	Status	Findings			Overall report rating	Audit days per plan	Actual audit days
			High	Medium	Low			
mapping	workshop, having prepared a controls assessment framework for the area under review and agreed that with management. The area to be mapped will be agreed in consultation with management and the Audit and Governance Committee. There is the potential for this to be directed towards further considerations on Cyber Security, depending on the outcome of the initial work in that area as outlined above.	determined.				applicable – no rating will be provided as it is workshop		
Audit Management	All aspects of audit management to include: • Attendance at liaison meetings and HFEA Audit and Governance committees; • Drafting committee papers/progress reports; • Follow-up work; • Resourcing and risk management; and • Contingency.	Ongoing	Not applicable			Not applicable	7	5
Contingency							5	-
		Total Findings:	**0**	**1**	**4**			
						Total days	**40**	**21**

2.2 Summary of reports issued since the last Audit and Governance Committee:

Since the last Audit and Governance Committee in September 2016 we have issued the report on Board Effectiveness.

2.3 Follow-up work:

The HFEA performs its own follow-up work, reviewing the status of agreed audit actions and reporting progress to the Audit and Governance Committee.

As such, Internal Audit has been asked to provide independent assurance of the completion of agreed actions only over those actions which relate to high priority recommendations. This approach was agreed with the former Director of Finance and Resources.

No high priority actions have resulted from us undertaking the 2016/17 audit reviews to date and none were outstanding at the start of the year from previous audit work. Accordingly, there have been no outstanding high priority recommendations requiring internal audit follow-up work in the year to date.

2.4 Impact on Annual Governance Statement:

All reports issued with an overall Limited or Unsatisfactory rating, or with report findings that are individually rated high priority, should be considered for their possible impact on the Authority's Annual Governance Statement (AGS). To date, no Limited reports and no high priority issues have been raised as a result of us completing the work forming part of the 2016/17 audit plan and all actions relating to previous high priority issues have been completed. Accordingly, there are no matters arising from our work to date that we believe may require reference in the AGS.

Appendix 1 – Report Rating Definitions

Risk Ratings of individual findings:

Priority	Description
High	Fundamental weaknesses in control which expose the Accounting Officer / Director to high risk or significant loss or exposure in terms of failure to achieve key objectives, impropriety or fraud. Senior managers are expected to oversee the prompt implementation of agreed actions, or to confirm in writing that they accept the risks of not implementing a high priority internal audit recommendation.
Medium	Significant weaknesses in control, which, although not fundamental, expose the Accounting Officer / Director to a risk of loss, exposure or poor value for money. Managers are expected to oversee the prompt implementation of agreed actions, or to confirm in writing that they accept the risks of not implementing a medium priority internal audit recommendation. Failure to implement recommendations to mitigate these risks could result in the risk moving to the High category.
Low	Minor weakness in control which expose the Accounting Officer / Director to relatively low risk of loss or exposure. However, there is the opportunity to improve the control environment by complying with best practice. Suggestions made if adopted would mitigate the low level risks identified.

Ratings of audit reports

Substantial	In Internal Audit's opinion, the framework of governance, risk management and control is adequate and effective.
Moderate	In Internal Audit's opinion, some improvements are required to enhance the adequacy and effectiveness of the framework of governance, risk management and control.
Limited	In Internal Audit's opinion, there are significant weaknesses in the framework of governance, risk management and control such that it could be or could become inadequate and ineffective.
Unsatisfactory	In Internal Audit's opinion, there are fundamental weaknesses in the framework of governance, risk management and control such that it is inadequate and ineffective or is likely to fail.

Appendix 2 - Limitations and responsibilities

Internal control

Internal control systems, no matter how well designed and operated, are affected by inherent limitations. These include the possibility of poor judgment in decision-making, human error, control processes being deliberately circumvented by employees and others, management overriding controls and the occurrence of unforeseeable circumstances.

Future periods

Historic evaluation of effectiveness is not relevant to future periods due to the risk that:

- the design of controls may become inadequate because of changes in operating environment, law, regulation or other; or
- the degree of compliance with policies and procedures may deteriorate.

Responsibilities of management and internal auditors

It is management's responsibility to develop and maintain sound systems of risk management, internal control and governance and for the prevention and detection of irregularities and fraud. Internal audit work should not be seen as a substitute for management's responsibilities for the design and operation of these systems. We endeavour to plan our work so that we have a reasonable expectation of detecting significant control weaknesses and, if detected, we shall carry out additional work directed towards identification of consequent fraud or other irregularities. However, internal audit procedures alone, even when carried out with due professional care, do not guarantee that fraud will be detected. Accordingly, our examinations as internal auditors should not be relied upon solely to disclose fraud, defalcations or other irregularities which may exist.

Human Fertilisation and Embryology Authority

Audit planning report on the 2016-17 financial statement audit

REPORT TO THOSE CHARGED WITH GOVERNANCE
December 2016

http://www.nao.org.uk/

Contents

We have pleasure in setting out details of our proposed financial statement audit approach for the Human Fertilisation and Embryology Authority (HFEA) for the year ending 31 March 2017.

We have prepared this report for HFEA's sole use although you may also share it with the Department of Health. You must not disclose it to any other third party, quote or refer to it, without our written consent and we assume no responsibility to any other person.

Financial statement audit plan

What work will we complete?

Our audit, which will be conducted in accordance with International Standards on Auditing (UK and Ireland) (ISAs (UK and Ireland)), will enable the C&AG to give an opinion on the financial statements.

Further details of the scope of the audit, as well as our respective responsibilities in relation to this engagement, have been set out in our Letter of Understanding issued on 23 October 2013 which has previously been separately provided to the audit committee.

Member of the Audit Committee are invited to consider and discuss:

- Whether our assessment of the risks of material misstatement to the financial statements is complete;
- Our proposed audit plan to address these risks; and
- Whether the financial statement could be materially misstated due to fraud, and communicate any areas of concern to management and the audit team.

How are we going to conduct the audit?

Risk based approach

We plan our audit of the financial statements to respond to the risks of material[1]:

- misstatement to transactions and balances; and
- irregular transactions.

The auditing standards ISA 240 state that there is a significant risk in all entities for:

- Management override of controls to perpetrate fraud; and
- Presumed risk of fraud arising from revenue recognition.

Further details of these risks and our response are set out on pages 8-9.

In addition to these significant risks we have also identified one 'risk factor' i.e. a risk that is not expected to represent a material misstatement in the year but we would like to keep in view in our audit work (details on page 10):

- HFEA's judicial review case

Our team

The details of the key audit staff who will complete this audit are:

- George Smiles, Engagement Director
- Sarah Edwards, Engagement Manager
- Payal Patel, Engagement Lead for audit and will complete the on-site work.

[1] A matter is material if its omission or misstatement would reasonably influence the decisions of users of the financial statements. The assessment of what is material is a matter of the auditor's professional judgement and includes consideration of both the amount and the nature of the misstatement. Further information on materiality is included on page 6.

When do we plan to complete this work?

Timetable

The timetable comprises an interim visit week commencing 23 January 2017 for 1 week and a further second interim visit week commencing 13 March 2017 for 1 week and a final visit commencing 30 May 2015 for 2 weeks with certification planned for start of July 2017. Further details are provided in the table below.

Date	Activity
September/ October 2016	**Planning:** review HFEA's operations, assess risk for our audit and evaluate the control framework.
January 2017	**Interim audit work:** test expenditure and income.
February 2017	**Update to audit committee on interim work**.
30 May 2017	**Receipt of 1st draft account**
May 2017	**Final audit work:** test expenditure and income and significant balances and disclosures.
June 2017	**ISA 240 report including management letter:** compromising audit completion report and management letter to be presented to the audit committee.
July 2017	**Certification:** seek representations and C&AG issues opinion.

Fees

The fee for the audit is £28,000 (PY £27,500).

Completion of our audit in line with the timetable and fee is dependent upon HFEA:

- delivering a complete Annual Report and Accounts of sufficient quality, subject to appropriate internal review on the date agreed;
- delivering good quality supporting evidence and explanations within the agreed timetable;
- making staff available during the audit.

If significant issues arise and we are required to perform additional work this may result in a change in our fee. We will discuss this with you before carrying out additional work.

Our audit approach

Our assessment of materiality

Materiality	The concept of materiality recognises that financial statements are rarely absolutely correct, and that an audit is designed to provide reasonable, rather than absolute, assurance that the financial statements are free from material misstatement or irregularity. For the purposes of determining whether the financial statements are free from material misstatement or irregularity we consider whether: 1. the magnitude of misstatement; or 2. the nature and cause of misstatements (e.g. because of the sensitivity of specific disclosure or regularity requirements) would influence the users of the accounts. In line with generally accepted practice, we have set our quantitative materiality threshold based on our judgement of a range of factors including historic error and level of expenditure. Other elements of the financial statements that we consider to be more sensitive to users of the accounts will be assessed using a lower qualitative materiality threshold. These elements include the remuneration report disclosures; the losses and special payments note; our audit fee. We apply the concept of materiality in planning and performing our audit and in evaluating the effect of misstatements on our audit and on the financial statements. As the audit progresses our assessment of both quantitative and qualitative materiality may change.
Error reporting threshold	For reporting purposes, we will treat any misstatements below £2,500 as “trivial” and therefore not requiring consideration by the Audit Committee. Please note that this is a separate threshold to our consideration of materiality as described above. It is materiality, not the error reporting threshold, which is used in forming our audit opinion.

Our audit approach

Other matters

Independence	We comply with relevant ethical requirements regarding independence and have developed important safeguards and procedures in order to ensure our independence and objectivity. Information on NAO quality standards and independence can be found on the NAO website: http://www.nao.org.uk/about-us/role-2/what-we-do/audit-quality/audit-quality/ We will reconfirm our independence and objectivity to the Audit Committee following the completion of the audit.
Management of personal data	During the course of our audit we have access to personal data to support our audit testing. We have established processes to hold this data securely within encrypted files and to destroy it where relevant at the conclusion of our audit. We confirm that we have discharged those responsibilities communicated to you in the NAO's Statement on Management of Personal Data at the NAO. The statement on the Management of Personal Data is available on the NAO website: http://www.nao.org.uk/freedom-of-information/publication-scheme/how-we-make-decisions/our-policies-and-procedures/policies-and-procedures-for-conducting-our-business/
Using the work of internal audit	We liaise closely with internal audit through the audit process and seek to take assurance from their work where their objectives cover areas of joint interest. Following our review of internal audit's plans we will consider the outcome of the planned report for the Information for Quality capital expenditure project.

Significant financial statement risks (1)

Management override of controls (ISA 240)

Key features

- Under International Standards on Auditing (UK and Ireland) 240 The Auditor's responsibilities relating to fraud in audit of financial statements there is a presumed risk of management override of controls in all organisations, We are required to assess the risk of material misstatements arising from management override, in particular in relation to significant or unusual transactions, bias in accounting estimates and journals.

Change from prior year

Same approach to meet ISA 240 requirements

Audit response

Substantive

- Review of significant transactions;
- Journal sample testing
- Consider the assumptions underpinning each of the key estimates in the accounts (i.e. provisions and impairments).

Significant financial statement risks (2)

Revenue Recognition

Key features

- Under International Standards on Auditing (UK and Ireland) 240 The Auditor's responsibilities relating to fraud in audit of financial statements there is a presumed risk of fraud in revenue recognition, albeit rebuttable in all entities. As HFEA's main income stream is treatment fees from clinics; there is a risk that not all treatment income is reported to HFEA.

Change from prior year

Same approach to meet ISA 240 requirements

Audit response

Substantive and controls testing

- A substantive analytical procedure will be performed by using the invoices sent to clinics.
- We will be assessing the work that the Compliance Audit team carry out on their visits to clinics. This is the control we will seek to rely for income, in order to provide us with assurance that the data provided by the clinics to HFEA is complete and accurate.

Risk factors

Risk factors represent developments or ongoing issues in HFEA that are potential risks to the financial statements or the C&AG's audit opinion. They differ from significant risks as they do not currently require a specific audit response other than already covered by our standard audit approach.

HFEA's judicial review case

HFEA is subject to a judicial review relating to the IfQ project. A risk exists, depending on the outcome of the JR that the IfQ project may be delayed which could increase costs relating to this project and , more widely, may damage HFEA's reputation. We await the outcome of the JR.

Other Matters

These are issues that we do not anticipate giving rise to a risk to the financial statements or the C&AG's opinion but may have an impact on HFEA.

Information for Quality expenditure

HFEA need to ensure that any expenditure relating to IfQ that is capitalised in year meets the recognition criteria as set out on IAS 38 intangible assets.

New Finance Director

The new FD has recently taken up post and, as with any change of personnel at a senior level, there is a loss of corporate knowledge particularly when a long-standing member of staff leaves. We will consider the actions that HFEA takes to ensure that there is no consequential adverse impact on the operation of the overall controls environment following this change in personnel.

Brexit

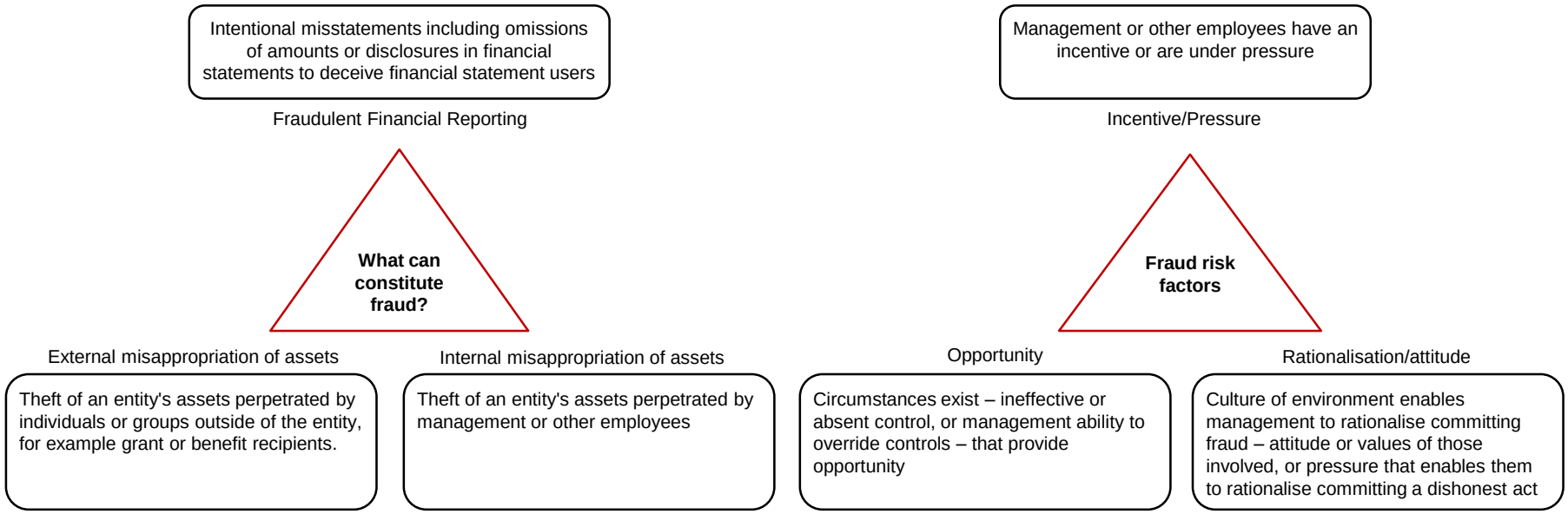
All EU laws to be transposed into UK law, and so we do not expect this to affect our audit. However due to the recent announcement on timing that Article 50 is to be triggered in March 2017, management will need to consider any impacts on the Financial Statements and disclosures after March 2017.

Follow up to recommendations we made in the previous year

Title	Area	What was the recommendation?	Response/Progress	Status
Capitalisation of expenditure	**Intangible Assets**	**Management need to ensure they only capitalise what is permitted under Accounting Standards IAS 38. This consideration should be ongoing, for instance the treatment of maintenance/ enhancement of systems,**	HFEA are in the process of conducting a piece of work on the IfQ expenditure and hope that this will be completed by the time the NAO attend for their interim visit.	Ongoing

Appendix 1 - Fraud matters

ISA 240 (UK&I) 'The auditor's responsibility to consider fraud in an audit of financial statements' requires us, as your auditors, to make inquiries and obtain an understanding of the oversight exercised by those charged with governance.



ISA inquiries

Our inquiries relate to your oversight responsibility for:

- Management's assessment of the risk that the financial statements may be materially misstated owing to fraud, including the nature, extent and frequency of such assessments;
- Management's process for identifying and responding to the risks of fraud, including any specific risks of fraud that management has identified or that has been brought to its attention;
- Management's communication to the Audit Committee (and others charged with governance) on its processes for identifying and responding to the risks of fraud; and
- Management's communication, if any, to its employees on its views about business practices and ethical behaviour.

We are also required to ask whether you have any knowledge of any actual, suspected or alleged fraud.

Audit approach

We have planned our audit of the financial statements so that we have a reasonable expectation of identifying material misstatements and irregularity (including those resulting from fraud). Our audit, however, should not be relied upon to identify all misstatements or irregularities. The primary responsibility for preventing and detecting fraud rests with management.

We will incorporate an element of unpredictability as part of our approach to address fraud risk. This could include, for example, completing procedures at locations which have not previously been subject to audit or adjusting the timing of some procedures.

We will report to the Assurance and Risk Committee where we have identified fraud, obtained any information that indicates a fraud may exist or where we consider there to be any other matters related to fraud that should be discussed with those charged with governance.

Appendix 2: Future accounting standards (not specifically relevant to HFEA, for information only)

IFRS 9: *Financial instruments*

Effective from 2018-19

IASB project summary

Replacing IAS 39, IFRS 9 aims to simplify financial instrument accounting and more closely align accounting and practices with how instruments are used in the business. Specifically:

- **classification and measurement** rules have been adapted to incorporate a more principles-based model with fewer categories – with measurement at fair value except for some debt instruments depending on characteristics;
- **impairments** due to changes in credit quality will result in earlier remeasurement, on an 'expected loss' basis; and
- **hedge accounting** will become more principles-based, with the elimination of the 80-125% effectiveness test and a greater reliance on assessing the purpose of transactions within businesses' risk management strategies.

IFRS 15: *Revenue from Contracts with Customers*

Effective from 2018-19

IASB project summary

IFRS 15 aims to replace a significant amount of existing guidance and reduce inconsistencies by setting a new principles-based Standard.
The step by step process in IFRS 15 involves identifying contractual performance obligations, allocating the transaction price to those obligations, and recognising revenue only when those obligations are satisfied. Impact for most central government clients will be limited.

IFRS 16: *Leases*

Effective from 2019-20

IASB project summary

2013 exposure draft (now superseded by issued Standard)

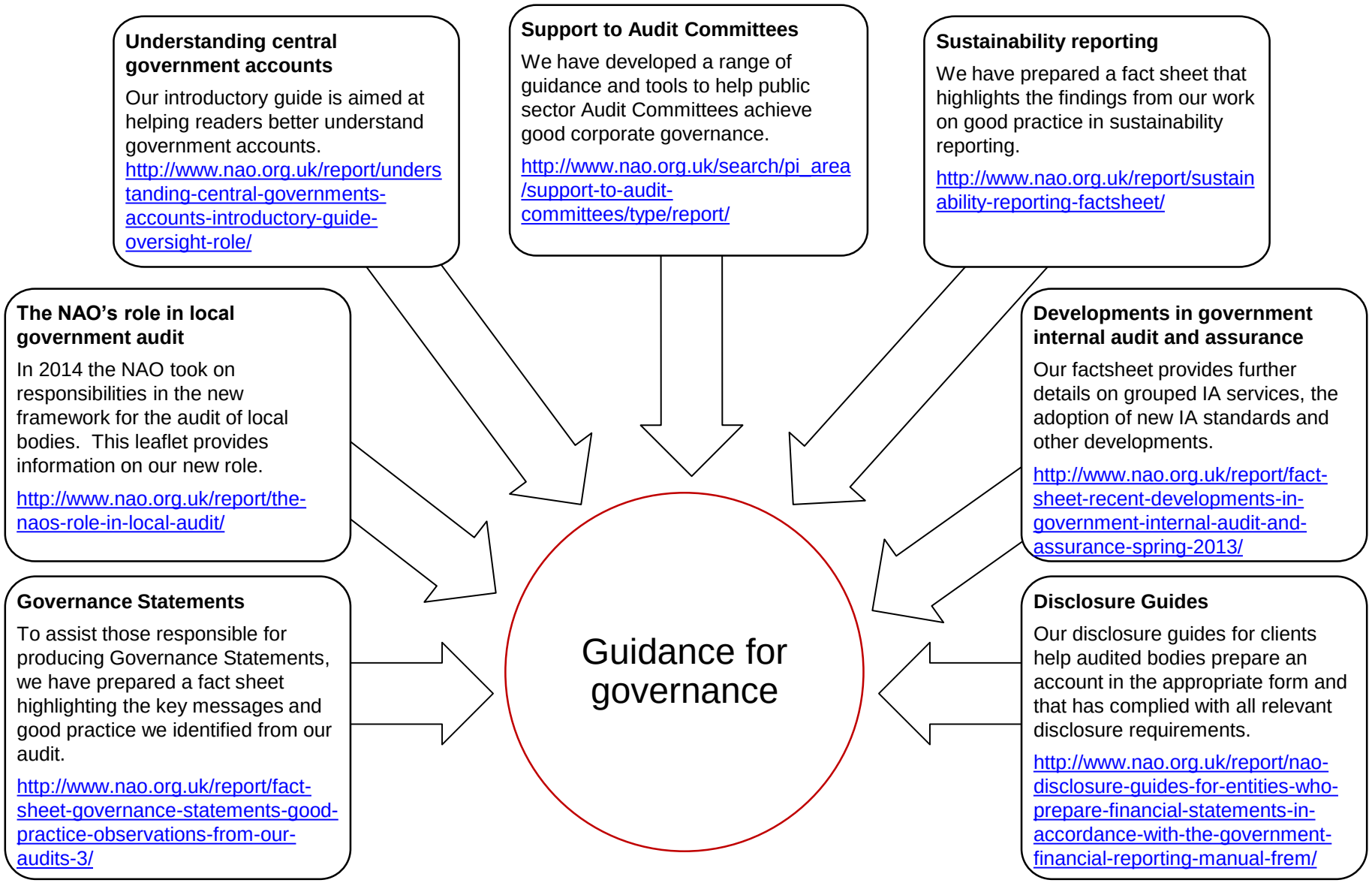
Decisions remain for HM Treasury on if or how to interpret/adapt this Standard for FReM bodies, and what allowances to make for transitional relief.

IFRS 16 eliminates the operating/finance lease distinction and imposes a single model geared towards the recognition of all but low-value or short term (<12m) leases. The proposals arise partly from the IASB's view that:

- disclosures around operating lease commitments have lacked prominence and tended towards understatement; and
- even in leases where the underlying asset is not acquired for its whole useful life, the lessee nevertheless acquires an economic right to its use, along with obligations to make good on minimum lease payments.

These will now be recognised on the Balance Sheet as a **'right of use'** asset and **lease liability**. The lease liability will be measured at initial recognition as the value of future lease payments, with the asset additionally including any initial direct costs incurred by the lessee, plus an estimate of any dismantling/restoration costs. Subsequent measurement of both asset and liability will need to respond to any changes in lease terms, and the accounting for the asset can be on a *cost less depreciation and impairment* model or a *revaluation (*fair value) model.
Successful transition will depend on organisations pro-actively capturing additional information about leases – new and existing – which they expect to remain in place at 1 April 2019, especially regarding future minimum lease payments. Organisations should also ensure systems for capturing cost information are fit for purpose, can respond to changes in lease terms and the presence of any variable (e.g. RPI-based) lease terms where forecasts will need to be updated annually based on prevailing indices.

Appendix 3: Guidance for Governance (not all relevant for HFEA)



Appendix 4 - Key messages from our wider work

Cross Government Fraud Landscape Review **(February 2016)**	The UK government detected fraud figure of 0.02% of expenditure is significantly lower than some estimates of 3-5% in the EU and US. While comparisons should be treated with caution, this suggests there could be significant fraud and error which is unreported or undetected and losses which are not being adequately addressed. Concludes that, overall, the Government lacks a clear understanding of the scale of the fraud problem and departments vary in their ability to identify and address fraud risks. The data that does exist is patchy, inconsistent and of variable quality. The most comprehensive data relates to areas of known risk – tax credit and benefit fraud – but information across the rest of government is clearly incomplete. It is difficult to formulate solutions if the scale and nature of the problem is unknown. www.nao.org.uk/report/fraud-landscape-review
The Commissioning of Specialised Services in the NHS **(April 2016)**	NHS England's spending on the 146 specialised services it offers has increased at a much greater rate than other parts of the NHS. There is no overarching service strategy and increasing demand for effective but expensive new drugs is adding to existing financial pressures. Governance arrangements for specialised commissioning are ineffective and there are concerns over the transparency of decision making. Concludes that if NHS England is unable to control spending on specialised services this will affect its ability to resource other services, such as primary care. Without consistent information from all providers on costs, access to services and outcomes, it cannot manage the ongoing pressure on its budget for specialised services, make effective strategic decisions or gain assurance that its objectives are being met. www.nao.org.uk/report/the-commissioning-of-specialised-services-in-the-nhs

Appendix 4 - Key messages from our wider work

Departments' oversight of arm's-length bodies: a comparative study **(July 2016)**	We looked at and compared how four departments oversee and manage the relationships with their arm's-length bodies (ALBs). These departments are BIS (now BEIS), MoJ, Defra and DCMS. There is no single list of ALBs across government nor a common understanding of when ALBs should be used or what type of ALB is most appropriate for particular circumstances. Although the Cabinet Office is building on its Public Bodies Reform Programme and taking further steps to address these shortfalls, the prevailing inconsistency hampers a coherent approach to overseeing ALBs that is consistent with their purpose. To get the best from ALBs we recommend the Cabinet Office works with departments to improve understanding of the costs and benefits of different approaches, and develop and implement a guiding framework for effective oversight. We propose a principles-based approach. We do not argue for a one size fits all approach, but it's clear that the broad range of approaches cannot all be equally good at getting value from ALBs. www.nao.org.uk/report/departments-oversight-of-arms-length-bodies-a-comparative-study
Protecting information across government **(September 2016)**	Protecting information while re-designing public services and introducing new technology to support them is a complex challenge for government. The responsibility for protecting information held by government from unauthorised access or loss must increasingly be balanced with the need to make information available to other organisations, users and citizens via new digital services. We considered the effectiveness of government in managing the risk of information loss, including cost, breach reporting and deployment of the right skills. We found that some departments have made significant improvements in information governance, but most have not given it the same attention as other forms of governance. We also found that few departments have the skills and expertise to risk manage their information by themselves and will continue to depend on effective support from the centre of government. But at present too many bodies, with overlapping responsibilities, operate in the centre of government, confusing departments about where to go for advice. Although the new National Cyber Security Centre (NCSC) will bring together much of government's cyber expertise, wider reforms will be necessary to further enhance the protection of information. www.nao.org.uk/report/protecting-information-across-government/

Appendix 5: Quality assurance in NAO audits