Strategic risks

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Audit and Governance Committee		
Agenda item	11		
Paper number	[AGC (05/12/2017) 581 HC]		
Meeting date	5 December 2017		
Author	Helen Crutcher, Risk and Business Planning Manager		
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 received the risk register at its meeting on 15 November.

1.2. CMG reviewed the risk register at its meeting on 22 November. CMG reviewed all risks, controls and scores.

1.3. CMG and Authority's comments are summarised at the end of the risk register, which is attached at Annex A. The annex also includes a graphical overview of residual risk scores plotted against risk tolerances.

1.4. One of the seven risks is currently above tolerance.

Additions to the register

1.5. AGC should note that we have now added statements on risk tolerance and appetite in the background information of the report. This sets out our general position in relation to addressing the tolerance levels of particular risks.

1.6. We have also been reviewing the risk policy in the light of previous AGC and initial feedback from an advisory internal audit report, which is currently being finalised. The policy will reflect the statements on risk appetite and tolerance and it will clearly set out our approach for dealing with over-tolerance risks. This is partly about reviewing the adequacy of mitigations but also about clearly explaining the rationale if there are periods when we may be unable to bring a risk down to our desired tolerance level.

1.7. The revised policy will be discussed and agreed at the Corporate Management Group meeting in February. We will relaunch the policy following agreement.

2. Recommendation

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

Latest review date – 22/11/2017

Strategic risk register 2017/18

Risk summary: high to low residual risks

Risk area	Strategy link*	Residual risk	Status	Trend**
C1: Capability	Generic risk – whole strategy	**16 – High**	Above tolerance	⇧⇔⇔⇔
LC1: Legal challenge	Generic risk – whole strategy	**12 – High**	At tolerance	⇩⇔⇔⇔
OC1: Organisational change	Generic risk – whole strategy	**9 – Medium**	At tolerance	⇔⇔⇩⇔
FV1: Financial viability	Generic risk – whole strategy	**9 – Medium**	At tolerance	⇔⇔⇔⇔
CS1: Cyber security	Generic risk – whole strategy	**6 – Medium**	At tolerance	⇔⇔⇔⇔
RE1: Regulatory effectiveness	Improving standards through intelligence	**6 – Medium**	At tolerance	⇔⇔⇔⇔
ME1: Effective communications	Safe, ethical effective treatment Consistent outcomes and support	**6 – Medium**	At tolerance	⇔⇔⇔⇔

* Strategic objectives 2017-2020:

Safe, ethical effective treatment: Ensure that all clinics provide consistently high quality and safe treatment

Safe, ethical effective treatment: Publish clear information so that patients understand treatments and treatment add ons and feel prepared

Safe, ethical effective treatment: Engender high quality research and responsible innovation in clinics

Consistent outcomes and support: Improve access to treatment

Consistent outcomes and support: Increase consistency in treatment standards, outcomes, value for money and support for donors and patients

Improving standards through intelligence: use our data and feedback from patients to provide a sharper focus in our regulatory work and improve the information we produce

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

Risk register 2017-2020: CMG 6 September ⇨ AGC 3 October ⇨ Authority 15 November ⇨ CMG 22 November

FV1: There is a risk that the HFEA has insufficient financial resources to fund its regulatory activity and strategic aims.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	4	16 - High	**3**	**3**	**9 - Medium**
Tolerance threshold:					**9 - Medium**

Risk area	Risk owner	Links to which strategic objectives?	Trend
Financial viability FV1: Income and expenditure	Richard Sydee, Director of Finance and Resources	Whole strategy	⇔⇔⇔⇔

Commentary
At tolerance. As of Q2, we are showing a surplus against budget which is due to the steady increase in our treatment fee income and the slow expenditure activity of which unfilled vacancies are a major part. Our forecast for the year is likely to be a surplus subject to any new legal issues and assuming spend on the data submission and migration projects is maintained. The work that is currently in progress to produce a model for forecasting treatment fee income may mean that the residual risk will be able to be reduced, but this will not be clear until the model is finalised and agreed by the Authority in early 2018. A paper will go the Authority in January. A deep-dive review of this risk is planned in the light of the outcomes of this and this will be reflected in the next update to AGC in March.

Causes / sources	Mitigations	Timescale / owner
Our annual income can vary significantly as: - Our income is linked directly to level of treatment activity in licensed establishments - Forecasting treatment numbers is complex - We rely on our data submission system to notify us of billable cycles.	Activity levels are tracked and significant changes are discussed at CMG, who would consider what work to deprioritise and reduce expenditure.	Monthly (on-going) – Richard Sydee
	Fees Group enables dialogue with sector about appropriate fee levels.	Ongoing – Richard Sydee
	We have sufficient reserves to function normally for a period if there was a steep drop-off in activity, or clinics were not able to submit data and could not be invoiced. If this happened, resolving it would be high priority, and the roll-out of the new data submission system will be planned carefully.	In place – Richard Sydee/Nick Jones
	Work on the drivers of treatment fees to better understand the likely future trends in treatment cycle activity.	Begun in Q2. Ongoing – Richard Sydee

Annual budget setting process lacks information from directorates on variable/additional activity that will impact on planned spend.	Annual budgets are agreed in detail between Finance and Directorates with all planning assumptions noted. Quarterly meetings with Directorates flags any shortfall or further funding requirements.	Quarterly meetings (on-going) – Morounke Akingbola
Project scope creep.	Senior Finance staff present at Programme Board. Periodic review of actual and budgeted spend by Digital Projects Board (formerly IfQ) and monthly budget meetings with finance.	Ongoing – Richard Sydee or Morounke Akingbola
	Cash flow forecast updated.	Monthly (on-going) – Morounke Akingbola
Risk interdependencies (ALBs / DH)	**Control arrangements**	**Owner**
DH: Legal costs materially exceed annual budget because of unforeseen litigation.	Use of reserves, up to contingency level available. DH kept abreast of current situation and are a final source of additional funding if required.	Monthly – Morounke Akingbola
DH: GIA funding could be reduced due to changes in Government/policy.	A good relationship with DH Sponsors, who are well informed about our work and our funding model.	Accountability quarterly meetings (on-going) – Richard Sydee
	Annual budget agreed with DH Finance team alongside draft business plan submission. GIA funding has been provisionally agreed through to 2020.	December annually – Richard Sydee
	Detailed budgets for 2017/18 have been agreed with Directors. DH has previously agreed our resource envelope.	In place – Morounke Akingbola

C1: There is a risk that the HFEA experiences unforeseen knowledge and capability gaps, threatening delivery of the strategy.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
5	4	20 – Very high	**4**	**4**	**16 - High**
Tolerance threshold:					**12 - High**

Risk area	Risk owner	Links to which strategic objectives?	Trend
Capability C1: Knowledge and capability	Peter Thompson, Chief Executive	Whole strategy	⇧⇔⇔⇔

Commentary

Above tolerance.

This risk and the controls are focused on business as usual capability, rather than capacity, though there are obviously some linkages between capability and capacity.

Since we are a small organisation, with little intrinsic resilience, it seems prudent to retain a low tolerance level. We are currently in a period of turnover and internal churn, with some knowledge gaps, and data submission and migration work ongoing. As a result, the tolerance level for this risk was raised from 6 to 12 at CMG in May. And in September, CMG raised the risk level in recognition of the additional impact of organisational change.

Action plan

Heads and managers are proactively treating this risk by ensuring that handovers are as full and thorough as possible and ensuring that recruitment happens as quickly as possible. Our Interim Head of HR, Yvonne Akinmodun, has been working on the new people strategy and this was discussed with Heads and SMT at a leadership away day in November.

Alongside this, an improved system for formalised knowledge capture and handover is being scoped. A formalised corporate process should go further to ensuring that all staff know what is required and that handovers are of a high quality. These further actions should help to mitigate this risk and bring it back within tolerance, although these are not yet fully in place. We should be able to reassess the effectiveness of these mitigations in early 2018.

Causes / sources	Mitigations	Timescale / owner
High turnover, sick leave etc., leading to temporary knowledge loss and capability gaps.	Staff have access to Civil Service Learning (CSL); expectation is five working days per year of learning and development for each member of staff. Staff are encouraged to identify personal development opportunities with their manager, through the PDP process, making good use of CSL.	In place – Yvonne Akinmodun (Interim Head of HR)/Peter Thompson

	Organisational knowledge captured via documentation, handovers and induction notes, and manager engagement.	In place – Yvonne Akinmodun
	Vacancies are addressed speedily, and any needed changes to ways of working or backfill arrangements receive immediate attention.	In place – Peter Thompson
Poor morale leading to decreased effectiveness and performance failures.	Engagement with the issue by managers through team and one-to-one meetings to obtain feedback and identify actions to be taken.	In place – Peter Thompson
	Implementation of staff survey outcomes, followed up after December 2016 staff conference (follow-up staff conference held on 10 July 2017). Task and Finish Groups submitted ideas for improvements, which are being included in the people strategy for 2017-2020.	Survey and staff conferences 2016 done – Rachel Hopkins Follow-up plan and communications in place – Peter Thompson
Particular staff changes could lead to specific knowledge loss and low performance.	CMG and managers prioritise work appropriately when workload peaks arise.	In place – Peter Thompson
	Policies and processes to treat staff fairly and consistently, particularly in scenarios where people are or could be ‘at risk’.	In place – Peter Thompson
Insufficient Register team resource to deal properly with OTR enquiries.	The team is now at full capacity (headcount) and this risk is reducing over time as the new member of staff gets up to speed.	In place – Nick Jones
Increased workload either because work takes longer than expected or reactive diversions arise.	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
	Oversight of projects by both Programme Board and CMG, to ensure that projects end through due process (or closed, if necessary).	In place – Paula Robinson
	Learning from Agile methodology to ensure we always have a clear ‘definition of done’ in place, and that we record when products/outputs have met the ‘done’ criteria and are deemed complete.	Partially in place – agile approach to be brought into project processes under new project governance framework – by early 2018/19

		Paula Robinson
	Early emphasis on team-level service delivery planning for the next business year, with active involvement of team members. CMG will continue to review planning and delivery.	In place – Paula Robinson
	Planning and prioritising data submission project delivery, and therefore strategy delivery, within our limited resources.	In place until project ends in Spring 2018 – Paula Robinson
Possible future increase in capacity and capability needed to process mitochondrial donation applications.	Starting to be considered now, but will not be known for sure until later, so no controls can yet be put in place. Only one clinic licensed to provide these treatments, applications unlikely to be many at first. New licensing processes for mitochondrial donation are in place (decision trees etc). One Licence Committee variation agreed, and the first Statutory Approvals Committee decision was at August 2017 meeting. As at November three patient applications had been considered.	Issue for further consideration – Director of Strategy and Corporate Affairs
Technical issues with our communications systems since our office move in 2016. This leads to poor service (missed calls, poor quality Skype meetings), reputational impacts, additional costs (meetings having to be held externally), and potentially to complaints.	The IT team has been working to identify and resolve the issues, with staff encouraged to continue to send support tickets. In summer 2017 an external expert was commissioned to assist and the system subsequently displayed improvements, although a number of issues have continued to affect the system and so a new company is now sought for further review and assurance. Continued use of external venues with appropriate facilities. As of November 2017, the switchboard has been replaced. This may prevent some of the Skype issues that have been reported, though we will monitor the effectiveness of this over the coming months.	In progress – Nick Jones Since he started in Sept 2017, Dan Howard, the CIO has been monitoring these issues and focussing on ensuring effective controls.
Risk interdependencies (ALBs / DH)	**Control arrangements**	**Owner**
Government/DH: The government may implement further cuts across all ALBs, resulting in further staffing reductions. This would lead to the HFEA having to reduce its workload in some way.	We were proactive in reducing headcount and other costs to minimal levels over a number of years. We have also been reviewed extensively (including the McCracken review and Triennial Review).	In place – Peter Thompson

OC1: There is a risk that the implementation of organisational changes results in instability, loss of capability and capacity, and delays in the delivery of the strategy.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	4	16 – High	**3**	**3**	**9 - Medium**
Tolerance threshold:					**9 - Medium**

Risk area	**Risk owner**	**Links to which strategic objectives?**	**Trend**
Organisational change OC1: Change-related instability	Peter Thompson, Chief Executive	Whole strategy	⇔⇔⇩⇔

Commentary
At tolerance. For some months, this risk was above tolerance and its impact was closely related to the C1, Capability risk. In November, with the agreement of the Authority, this risk was reduced back to tolerance. This was done in the light of the fact that almost all the agreed voluntary redundancies had taken place and most of the recruitment is complete. The Authority also agreed that this strategic risk could be removed at the end of the business year, at which point all of the planned voluntary redundancies will have taken place along with most of the remaining recruitment. Any outstanding risk sources would be considered at that time, to ensure that they are captured in the relevant operational risk logs or under the Capability strategic risk, as relevant.

Causes / sources	**Mitigations**	**Timescale / owner**
The change period may lead to dips in morale, commitment, discretionary effort and goodwill. There are likely to be differential impacts as different changes affect different groups of staff at different times. Risks are to the delivery of current work, including IfQ, and possibly technical or business continuity risks.	Clear published process, with documentation.	In place – Peter Thompson
	Consultation, discussion and communication, with opportunity to comment, and being responsive and empathetic about staff concerns. Staff informed of likely developments and next steps and, when applicable, of personal role impacts and choices.	Completed – Peter Thompson
	Relatively short timeline for decision making, so that uncertainty does not linger.	In place – Peter Thompson
	HR policies and processes are in place to enable us to manage any individual situations that arise.	In place – Yvonne Akinmodun

	Employee assistance programme (EAP) support accessible by all.	In place – Peter Thompson
Organisational change combined with other pressures for particular teams could lead to specific areas of knowledge loss lasting some months (pending recruitment to fill any gaps).	Policies and processes to ensure we treat staff fairly and consistently, particularly those 'at risk'. We will seek to slot staff who are at risk into other roles (suitable alternative employment).	In place – Peter Thompson
	Well established recruitment processes, which can be followed quickly in the event of unplanned establishment leavers.	In place – Yvonne Akinmodun
	Good decision-making and risk management mechanisms in place. Knowledge retention via good records management practice, SOPs and documentation.	In place – Peter Thompson
Potential impact on our ability to complete IfQ on time.	Ability to use more contract staff if need be.	In place – Peter Thompson
Implementing the new structure involves significant additional work across several teams to embed it so that the benefits are realised. There will also be result in some internal churn.	Business plan discussions acknowledging that work in teams doing IfQ or organisational change should not be overloaded.	In place – Paula Robinson
	CMG able to change priorities or timescales if necessary, to ensure that change is managed well.	In place – Paula Robinson
	Organisational development activity will continue, including summer awayday (10 July 2017), to support new ways of working development. A leadership awayday (November 2017) and another all staff awayday will happen in January 2018.	In place for 2017 and planned for 2018 – Yvonne Akinmodun
Additional pressure on SMT, HR and Heads, arising from the need to manage different impacts and responses in a sensitive way, while also implementing formal processes and continuing to ensure that work is delivered throughout the change period.	Recognition that change management requires extra attention and work, which can have knock-on effects on other planned work and on capacity overall. Ability to reprioritise other work if necessary.	In place – Peter Thompson
	Time being set aside by managers to discuss the changes with staff as needed, with messaging about change repeated via different channels to ensure that communications are received and understood.	In place – Peter Thompson
	SMT/CMG additional informal meetings arranged to enable mutual support of managers, to help people retain personal resilience and be better able to support their teams.	In place – Paula Robinson
Level of service to Authority members may suffer while the changes are implemented,	Communicate the changes clearly to Authority members so that they understand when staff are particularly under pressure, and that they will have	In place, with some implementation

negatively impacting on the relationship between staff and members.	reduced capacity. Inform Members when staff are new in post, to understand that those staff need the opportunity to learn and to get up to speed.	ongoing – Peter Thompson
Once the changes have been implemented, a number of staff will simultaneously be new in post. This carries a higher than normal risk of internal incidents and timeline slippages while people learn and teams adapt.	Recognition that a settling in period where staff are inducted and learn, and teams develop new ways of working is necessary. Formal training and development provided where required. Knowledge management via records management and documentation.	To be implemented, Yvonne Akinmodun will review onboarding methods – Peter Thompson
Bedding down the new structure will necessarily involve some team building time, developing new processes, staff away days to discuss new ways of working, etc. This will be challenging given small organisational capacity and ongoing delivery of business as usual.	Change management will be prioritised, where possible, so that bedding down occurs and is effective, and does not take an unduly long time.	To be implemented – Peter Thompson
	Continuing programme of leadership development for Heads and SMT.	Development day planned in November – Yvonne Akinmodun
The new model may not achieve the desired benefits, or transition to the new model could take too long, with staff losing faith in the model.	The model will be kept under review following implementation to ensure it yields the intended benefits.	A review of the new model will be presented to the Authority in May 2018 – Peter Thompson
Risk interdependencies (ALBs / DH)	**Control arrangements**	**Owner**
-		

CS1: There is a risk that the HFEA has unsuspected system vulnerabilities that could be exploited, jeopardising sensitive information and involving significant cost to resolve.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
5	4	20 – Very high	**3**	**2**	**6 - Medium**
Tolerance threshold:					**6 - Medium**

Risk area	Risk owner	Links to which strategic objectives?	Trend
Cyber security CS1: Security and infrastructure weaknesses	Nick Jones, Director of Compliance and Information	Whole strategy	⇔⇔⇔⇔

Commentary
At tolerance. The cyber-security event earlier in 2017, affecting the NHS and other organisations demonstrates that there is no room for complacency. However recent audits and our own assessments indicate that the HFEA is well protected. We were not affected by the 2017 incident.

Causes / sources	Mitigations	Timescale / owner
Insufficient governance or board oversight of cyber security risks (relating to awareness of exposure, capability and resource, independent review and testing, incident preparedness, external linkages to learn from others).	AGC receives regular information on cyber-security and associated internal audit reports. Internal audit report (2017) gave a 'moderate' rating, and recommendations are being actioned. Detailed information on our security arrangements is available in other documents. A business continuity plan is in place.	In place - Nick Jones/Dan Howard
Recent system infrastructure changes open up potential attack surfaces or new vulnerabilities. Our relationship with clinics is now more digital than ever before, and patient data or clinic information could therefore be exposed to attack.	All key IfQ products were subject to external expert advice and penetration testing, with recommendations implemented.	In place - Nick Jones/Dan Howard
	A security consultant provided advice throughout IfQ. At the end of the programme, we have received documented assurance of security and the steps necessary to maintain that security at a high level. Penetration testing for the portal and website (completed and passed).	In place – Dan Howard

	Ongoing security advice is in place for the development of the new data submission systems.	
We could become more dependent on external advice and support, with the risk that we cannot identify or fix problems quickly.	Budget available to commission external support when needed.	In place – Nick Jones
Confidentiality breach of Register data.	Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality. We know we need to refresh this obligation. Secure working arrangements for Register team, including when working at home.	In place, but corporate oversight of completion of security training is being reviewed – Peter Thompson
Loss of Register or other data by staff or through lack of encryption.	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. CIO will review these arrangements and can do so alongside a review of the arrangements for implementing the new GDPR requirements.	In place – Dan Howard
Register or other data (electronic or paper) becomes corrupted or lost.	Back-ups and warehouse in place to ensure data cannot be lost. Regular monitoring takes place to ensure our data backup regime and controls are effective. Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality.	In place – Nick Jones In place, but the corporate system for oversight is being reviewed by Dec 2017 – Dan Howard/Nick Jones
Infrastructure turns out to be insecure, or we lose connection and cannot access our data.	IT strategy agreed, including a thorough investigation prior to the move to the Cloud, with security and reliability factors considered.	In place – Dan Howard
	Deliberate internal damage to infrastructure, or data, is controlled for through off-site back-ups and the fact that any malicious tampering would be a criminal act.	In place – Nick Jones
Business continuity issue (whether caused by cyber-attack or an event affecting access to Spring Gardens).	Business continuity plan and staff site in place. Improved testing of the BCP information cascade to all staff was undertaken in September 2017 as well as a tabletop test and testing with Authority members.	In place and ongoing – Nick Jones Update done Dave Moysen

	New technology options need to be further explored, to enable us to restore critical on premise systems into a cloud environment if our premises become unavailable for a period. Records management systems to be reviewed in 2017/18. During an outage, staff cannot access TRIM, our current records management system. As above, we need to consider this in relation to GDPR project.	(former Head of IT) – September 2016 A revised BCP was considered by CMG in November and will be finalised shortly – Dan Howard
Poor records management or failure of the document management system.	A comprehensive review of our records management practices and document management system (TRIM) will be conducted in 2018/19, following planned organisational changes and the conclusion of IfQ.	To follow in 2018/19 business year – Peter Thompson
Cloud-related risks.	Detailed controls set out in 2017 internal audit report on this area. We have in place remote access for users, appropriate security controls, supply chain security measures, appropriate terms and conditions with Microsoft Azure, Microsoft ISO 27018 certification for cloud privacy, GCloud certification compliance by Azure, a permission matrix and password policy, a web configuration limiting the service to 20 requests at any one time, good physical and logical security in Azure, good back-up options for SQL databases on Azure, and other measures.	In place – Nick Jones
Risk interdependencies (ALBs / DH)	**Control arrangements**	**Owner**
None. Cyber-security is an 'in-common' risk across the Department and its ALBs.		

LC1: There is a risk that the HFEA is legally challenged in such a way that resources are significantly diverted from strategic delivery.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
5	5	25 – Very high	**3**	**4**	**12 - High**
Tolerance threshold:					**12 - High**

Risk area	Risk owner	Links to which strategic objectives?	Trend
Legal challenge LC 1: Resource diversion	Peter Thompson, Chief Executive	Safe, ethical effective treatment: Ensure that all clinics provide consistently high quality and safe treatment	⇩⇔⇔⇔

Commentary
At tolerance. The judgment on consent to legal parenthood in 2015 and subsequent cases, which include cases where errors have been made as recently as 2016/17, have administrative and policy consequences for the HFEA, and potentially reputational consequences too if we are criticised in judgments. The number of new and upcoming cases has reduced, however, recent cases suggest that learning has not been embedded in every clinic. This raises the question of whether further guidance or training is required in clinics. The most recent judgment is somewhat critical of how the HFEA chose to address certain issues and the guidance it provided to clinics. A judicial review hearing of one discrete element of the IfQ CaFC project was held in December 2016 and January 2017. The HFEA won this case. A decision by the Court of Appeal on whether permission to appeal will be granted is still awaited. This is entirely in the hands of the Court as far as timescales go. A licensing matter was considered by the Appeals Committee in October. The matter was settled by way of consent and having disposed of the appeal the judicial review claim which had been launched concurrently with the appeal became redundant and will be withdrawn. Following the consent order, the executive will be undertaking a piece of work looking at options for the regulation and inspection of groups of clinics.

Causes / sources	Mitigations	Timescale / owner
Assisted reproduction is complex and controversial and the Act and regulations are not beyond interpretation, leading to a need for court decisions.	Panel of legal advisors at our disposal for advice, as well as in-house Head of Legal.	In place – Peter Thompson
	Evidence-based and transparent policy-making and horizon scanning processes.	In place – Hannah Verdin

	Case by case decisions regarding what to argue in court cases, so as to clarify the position.	In place – Peter Thompson
Decisions or our decision-making processes may be contested. Policy changes may also be used as a basis for challenge (Licensing appeals and/or JRs). Note: New guide to licensing and inspection rating on CaFC may mean that more clinics make representations against licensing decisions.	Panel of legal advisors in place, as above.	In place – Peter Thompson
	Maintaining, keeping up to date and publishing licensing SOPs, committee decision trees etc. to ensure we take decisions well. Consistent decision making at licence committees supported by effective tools for committees. Standard licensing pack distributed to members/advisers (refreshed in April 2015).	In place, further work underway on licensing SOPs – Paula Robinson
	Well-evidenced recommendations in inspection reports.	In place – Sharon Fensome-Rimmer
Moving to a bolder strategic stance, eg on add ons or value for money, could result in claims that we are adversely affecting some clinics' business model or acting beyond our powers. Any changes could be perceived as a threat – not necessarily ultimately resulting in legal action, but still entailing diversion of effort.	Risks considered whenever a new approach or policy is being developed. Business impact target assessments carried out whenever a regulatory change is likely to have a cost consequence for clinics. Stakeholder involvement and communications in place to ensure that clinics can feed in views before decisions are taken, and that there is awareness and buy-in in advance of any changes. Major changes are consulted on widely.	In place – Juliet Tizzard
Subjectivity of judgments means we often cannot know which way a ruling will go, and the extent to which costs and other resource demands may result from a case.	Scenario planning is undertaken at the initiation of any likely action.	In place – Peter Thompson
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 being improved and updated, committee decision trees in place.	In progress and in place – Paula Robinson
HFEA process failings could create or contribute to legal	Licensing SOPs being improved and updated, committee decision trees in place.	In progress and in place –

challenges, or weaken cases that are otherwise sound, or generate additional regulatory sanctions activity (eg, legal parenthood consent).		Paula Robinson
	Up to date compliance and enforcement policy and related procedures.	In place – Nick Jones / Sharon Fensome-Rimmer
	Seeking robust assurance from the sector regarding parenthood consent issues, and detailed plan to address identified cases and anomalies.	In progress and ongoing – Nick Jones
Risk interdependencies (ALBs / DH)	**Control arrangements**	**Owner**
DH: 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 an interdependent risk because DH would be involved in resolving it.	In place – Peter Thompson
DH: Legislative interdependency.	Our regular communications channels with the Department would ensure we were aware of any planned change at the earliest stage. Joint working arrangements would then be put in place as needed, depending on the scale of the change. If necessary, this would include agreeing any associated implementation budget. The Department are aware of the complexity of our Act and the fact that aspects of it are open to interpretation, sometimes leading to challenge. Sign-off for key documents such as the Code of Practice in place.	In place – Peter Thompson

RE1: There is a risk that planned enhancements to our regulatory effectiveness are not realised, in the event that we are unable to make use of our improved data and intelligence to ensure high quality care.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	4	16	**2**	**3**	**6 – Medium**
Tolerance threshold:					**6 - Medium**

Risk area	**Risk owner**	**Links to which strategic objectives?**	**Trend**
Regulatory effective-ness RE 1: Inability to translate data into quality	Nick Jones, Director of Compliance and Information	Improving standards through intelligence: use our data and feedback from patients to provide a sharper focus in our regulatory work and improve the information we produce	⇔⇔⇔⇔

Commentary
At tolerance. Resource strains, reflected elsewhere in this risk register, have at times affected our ability to progress the data submission project and migration activities.

Causes / sources	**Mitigations**	**Timescale / owner**
IfQ has taken longer than planned, and there will be some ongoing development work needed.	The data submission project is well planned and under way after initial delays. Data cleansing is being done to improve the quality of the data in the Register. The new Register has been designed to be easier to extract data from for analytical purposes.	Completion of data submission project March 2018 – Nick Jones
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/Dan Howard
We could later discover a barrier to meeting a new reporting need, or find that an unanticipated level of accuracy is required, involving 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. Though there has been a reduction in desktop support, there are mitigations in place to ensure day to day support, however, we are running a risk due to lack of resilience.	In place – Dan Howard
The new Intelligence team is critical to the new model, and needs to draft an information strategy before it will be possible to use the data for regulatory and other purposes.	Head of Intelligence started in September. The development of the team, and the information strategy, will follow. An Information Strategy will be produced by the new Intelligence team, to ensure that data analysis and associated internal mechanisms are in place.	In place – Juliet Tizzard In development (review by CMG in January 2018) – Caylin Joski-Jethi
Benefits of IfQ not maximised and internalised into ways of working.	During IfQ delivery, product owners were in place, and a communications plan. The changes were developed involving the right staff expertise (as well as contractors) and part of the purpose of this was to ensure that the changes are culturally embraced and embedded into new ways of working. The data submission project has been delayed but is now making good progress. Inevitably, this will impact the timeframe of benefit realisation delivery on a range of fronts.	In place (from June 2015) – Nick Jones
Insufficient capability and capacity in the Compliance team to enable them to act promptly in response to the additional data that will be available.	Largely experienced inspection team. Business support is now at full complement. Recruitment process underway for final additions to inspection team. Although not all systems are in place in relation to providing data to inspectors eg, patient feedback, workarounds are in place which are working.	In place – Nick Jones
Organisational change could take too much time to embed, the necessary culture shift may not be achieved, or new structure not accepted, with an accompanying risk to our ability to make full use of our data and intelligence as intended by the new organisational model.	Organisational re-shaping in progress, to set the right staffing structure and capabilities in place to ensure we can realise IfQ's benefits. This includes the establishment of an Intelligence team.	New organisational model in place – Peter Thompson
Regulatory monitoring may be disrupted if Electronic Patient Record System (EPRS) providers are not able to submit data to the new register structure until their software has been updated.	Earlier agreements to extend part of 'IfQ' delivery help to address this risk by extending the release date for the EDI replacement (Data submission project). Mitigation plans for this risk have been agreed as part of planning.	Mitigation in place - Nick Jones

Monitoring failure.	Outstanding recommendations from inspection reports are tracked and followed up by the team.	In place – Sharon Fensome-Rimmer
Data accuracy in Register submissions.	Data migration efforts are being privileged over data quality currently (Aug 2017) this is an accepted risk. The Register team has introduced a triage system to deal with clinic queries systematically. Completion of verification processes, steps in the OTR process, regular audit alongside inspections.	In place – Nick Jones
	Audit programme to check information provision and accuracy.	In place – Nick Jones
	There are data accuracy requirements for different fields as part of migration planning, and will put in place more efficient processes.	In place – Nick Jones
	If subsequent work or data submissions reveal an unpreventable earlier inaccuracy (or an error), we explain this transparently to the recipient of the information, so it is clear to them what the position is and why this differs from the earlier provided data.	In place – Nick Jones
	Data verification work (February 2017) in preparation for Register migration has improved overall data accuracy, and the exercise included tailored support for individual clinics that were struggling.	In place – Nick Jones
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. We have systems for checking consistency of answers and the flexibility to push PQ deadlines if necessary. FOI requests are refused when there are grounds for this. PQ SOP revised and log created, to be maintained by Committee and Information Officer/Scientific Policy Manager.	In place – Juliet Tizzard / Caylin Joski-Jethi
Insufficient understanding of our data and/or of the topic or question, leading to misinterpretation or error.	As above – expert staff with the appropriate knowledge and understanding in place.	In place – Juliet Tizzard / Caylin Joski-Jethi
Risk that we do not get enough patient feedback to be useful / usable as soft intelligence for use in regulatory and other processes, or to give feedback of value to clinics.	Communications strategy in place, including more patient feedback. Part of the information strategy will focus on making best use of the information gleaned from patients, and converting our mix of soft and hard data into real outcomes and improvements.	In place and to be developed – Juliet Tizzard

Risk interdependencies (ALBs / DH)	Control arrangements	Owner
None	-	-

ME1: There is a risk that patients and our other stakeholders do not receive the right information and guidance, so we miss opportunities to bring about positive change.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
3	4	12 High	**2**	**3**	**6 - Medium**
Tolerance threshold:					**6 - Medium**

Risk area	Risk owner	Links to which strategic objectives?	Trend
Effective communications ME1: Messaging, engagement and information provision	Juliet Tizzard Director of Strategy and Corporate Affairs	Safe, ethical effective treatment: Publish clear information so that patients understand treatments and treatment add ons and feel prepared Safe, ethical effective treatment: Engender high quality research and responsible innovation in clinics. Consistent outcomes and support: Increase consistency in treatment standards, outcomes, value for money and support for donors and patients.	⇔⇔⇔⇔

Commentary
At tolerance.

Causes / sources	Mitigations	Timescale / owner
Our ability to provide patient information via the website or CaFC could be compromised by a website failure.	We have good cyber-security measures to prevent website attacks, and the new content management system is more reliable than the old one.	In place – Juliet Tizzard
Some of our strategy relies on persuading clinics to do things better. This is harder to put across effectively, or to achieve firm outcomes from.	Communications strategy in place, including social media and other channels as well as making full use of our new website. Stakeholder meetings with the sector in place to help us to underline key campaign messages.	In place – Juliet Tizzard
Our information does not meet the needs or expectations of our audience.	Ongoing user testing and feedback about the information on the website allows us to properly understand user needs. We have internal processes in place which meet the Information Standard.	In place – Juliet Tizzard
We are not able to reach the right people with the right message at the right time.	Partnering with NHS Choices to get information to patients early in their fertility journey. Planning for campaigns and projects includes consideration of communications channels.	In place and developing – Jo Triggs

	Extended use of social media to get to the right audiences.	
Some information will be derived from data, so depends on risk above being controlled.	See controls listed in RE1, above.	
Risk interdependencies (ALBs / DH)	**Control arrangements**	**Owner**
NHS Choices site and our site contain links to one another.	We maintain a relationship with the NHS Choices team.	

Reviews and revisions

Following the AGC meeting on 3 October, we have commenced a review of the risk policy and this will be reconsidered at CMG risk meeting on 22 November. We have also ensured that there is more discussion about how above tolerance risks are being managed in the summary of each risk.

In relation to AGC's comments regarding cyber security, the CIO is ensuring that all staff have completed their cyber security training by end December 2017. The executive will raise any cyber security issues to the Authority member responsible and ensure that she is updated on developments in this area.

Authority feedback – November 2017 meeting (15/11/2017)

Authority noted the report. The following point was raised:

- Authority agreed with the executive's reassessment of the organisational change risk. The residual risk has come down slightly following successful recruitments and the near completion of all planned redundancies. This meant that the risk is at tolerance. It will be removed as a separate risk once all of the organisational changes have been completed, by the end of the business year.

CMG review – November 2017 meeting (22/11/2017)

CMG reviewed the strategic risk register and made the following points in discussion:

- Members discussed the feedback from AGC about being clear about mitigations and handling of above tolerance risks and noted that we are going further to reflect action plans in the register. CMG noted the addition of a statement of risk tolerance and appetite to make the approach clearer.
- CMG discussed the C1 capability risk at length and focussed on the additional mitigations that were planned to bring this risk back to within tolerance. CMG heard that the people strategy should help with this. This would be discussed by CMG at the leadership awayday on 29 November. Alongside this, CMG heard that the Head of HR is reviewing organisational knowledge transfer methods and is preparing a corporate handover template and process. This would bolster current handover processes. The new intranet will help with signposting new staff to information, although this will not be in place as a mitigation for a number of months.
- CMG discussed the Skype issues which are ongoing and received an update from the CIO about progress on the mitigations. The CIO has been providing regular updates to the senior management team on these issues and further external resource has been identified to do additional analysis.
- When discussing the organisational change risk, CMG considered the status of organisational change recruitment and the fact that some recruitments had been harder than expected. Following discussion, it became clear that only a couple of roles were remaining, and in each case a new approach was being considered to recruiting, which should produce results. This reassured CMG that the residual score of this risk had not been reduced prematurely.
- On cyber security, members heard that staff had been reminded to complete training by end Dec 2017. A process for ongoing corporate-level oversight is being investigated but this needs to be finalised. Managers should already have oversight over the completion of mandatory training by their teams.
- Members questioned whether the likelihood of the legal risk was less than currently indicated, given that no new matters had arisen. Members agreed that it was too early to say this, but by the next CMG risk meeting in February we may wish to reassess this.

Criteria for inclusion of risks

Whether the risk results in a potentially serious impact on delivery of the HFEA's strategy or purpose.

Whether it is possible for the HFEA to do anything to control the risk (so external risks such as weather events are not included).

Rank

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

Risk trend

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

Risk scoring system

We use the five-point rating system when assigning a rating to 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				

Risk appetite and tolerance

Risk appetite and tolerance are two different but related terms. We define risk appetite as the willingness of the HFEA to take risk. As a regulator, our risk appetite will be naturally conservative and for most of our history this has been low. Risk appetite is a general statement of the organisation's overall attitude to risk and is unlike to change, unless the organisation's role or environment changes dramatically.

Risk tolerance on the other hand is the willingness of the HFEA to accept and deal with risk in relation to specific goals or outcomes. Risk tolerance will vary according to the perceived importance of particular risks and the timing (it may be more open to risk at different points in time). The HFEA may be prepared to tolerate comparatively large risks in some areas and little in others. Tolerance thresholds are set for each risk and they are considered with all other aspects of the risk each time the risk register is reviewed

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 introduces some element of control, even if no other mitigating action were ever taken, and even with no particular risks in mind. Therefore, for our estimation of inherent risk to be meaningful, we define inherent risk as:

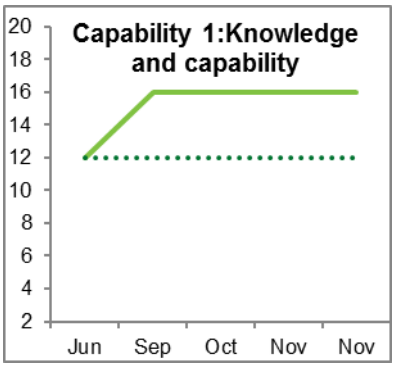
'the exposure arising from a specific risk before any additional action has been taken to manage it, over and above pre-existing ongoing organisational systems and processes.'

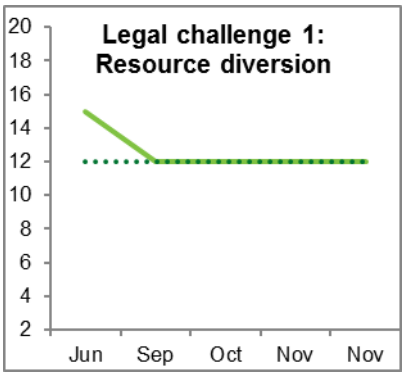
System-wide risk interdependencies

As of April 2017, we explicitly consider whether any HFEA strategic risks or controls have a potential impact for, or interdependency with, the Department or any other ALBs. A distinct section to record any such interdependencies beneath each risk has been added to the risk register, so as to be sure we identify and manage risk interdepencies in collaboration with relevant other bodies, and so that we can report easily and transparently on such interdependencies to DH or auditors as required.

Tolerance vs Residual Risk:

High and above tolerance risks





Lower level / in tolerance risks