

# Strategic risks

## Strategic delivery:

Safe, ethical  
effective treatment

Consistent  
outcomes and  
support

Improving standards  
through intelligence

## Details:

Meeting	Audit and Governance Committee
Agenda item	14
Paper number	[AGC (13/06/2017) 554 PR]
Meeting date	13 June 2017
Author	Paula Robinson, Head of Planning and Governance

## 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

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## 1. Strategic risk register

### Latest review

- 1.1. CMG reviewed a draft of the new risk register at its meeting on 17 May. Following the launch of our new strategy for 2017-2020, the risks have been considered afresh.
- 1.2. We recognised that there are a number of core (but high level) risks that constitute risks to the delivery of the strategy as a whole (financial risks, legal challenge, cyber-security, people risks, and change), while other risks relate to specific elements of the strategy. We believe this is a valid and useful distinction, and have grouped the new risks accordingly.
- 1.3. We have also revised the format for recording risks, making more prominent the risk itself and the tolerance level. Many of the risk sources and controls listed in the previous edition of the risk register are still applicable, and have therefore been carried across. We have added a new section on risk interdependencies with other ALBs or the DH. And we have moved all the methodological material to the back of the report.
- 1.4. CMG's initial comments on the new risk register are summarised towards the end of the annex, in the 'reviews and revisions' section.
- 1.5. Since several risks are new, the usual graphical overview of residual risks plotted against risk tolerances has been omitted this time. We will resume this from the next meeting.
- 1.6. Two of the seven risks are currently above tolerance.
- 1.7. For the time being we have a total of five generic risks and two strategy-specific risks. I would expect the new risk register to develop over the next few reviews, and the Committee's comments and observations will help to shape it further.

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## 2. Recommendation

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

# Strategic risk register 2017/18

## Risk summary: high to low residual risks

Risk area	Strategy link*	Residual risk	Status	Trend**
LC1: Legal challenge	Generic risk – whole strategy	<b>15 – High</b>	Above tolerance	↔↔↔↔↑
OC1: Organisational change	Generic risk – whole strategy	<b>12 – High</b>	Above tolerance	-↑
C1: Capability	Generic risk – whole strategy	<b>12 – High</b>	At tolerance	↔↑↔↔↔
FV1: Financial viability	Generic risk – whole strategy	<b>9 – Medium</b>	At tolerance	↔↔↔↔↔
CS1: Cyber security	Generic risk – whole strategy	<b>6 – Medium</b>	At tolerance	<b>New</b>
RE1: Regulatory effectiveness	Improving standards through intelligence	<b>6 – Medium</b>	At tolerance	<b>New</b>
ME1: Effective communications	Safe, ethical effective treatment Consistent outcomes and support	<b>6 – Medium</b>	At tolerance	<b>New</b>

\* 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:

Old risk register 2014-2017: Authority 16 November ⇒ CMG 23 November/AGC 7 December ⇒ CMG 8 February

New risk register 2017-2020: CMG 17 May 2017

(Some risks are new or recent, as at May 2017, and therefore do not yet show four trend points.)

**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	9	9	9 - Medium
<b>Tolerance threshold:</b>					<b>9 - Medium</b>

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

### Commentary

#### At tolerance.

As of May 2017 we are within budget. It is too early to forecast what our position will be at the key quarter-end. Detailed analysis work on treatment fee income will commence in Q3 of this financial year.

Causes / sources	Mitigations	Timescale / owner
Our annual income can vary significantly as: <ul style="list-style-type: none"> <li>- Our income is linked directly to level of treatment activity in licensed establishments</li> <li>- Forecasting treatment numbers is complex</li> <li>- We rely on our data submission system to notify us of billable cycles.</li> </ul>	Activity levels are tracked and change is discussed at CMG, who would consider what work to deprioritise and reduce expenditure.	Monthly (on-going) – Richard Sydee
	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
	Worked planned in 2017/18 to better understand the likely future trends in treatment cycle activity.	Being planned – 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 IfQ project board and monthly budget meetings with finance.	Ongoing – Richard Sydee or Morounke Akingbola
	Cash flow forecast updated.	Monthly (ongoing) – Morounke Akingbola
<b>Risk interdependencies (ALBs / DH)</b>	<b>Control arrangements</b>	<b>Owner</b>
<b>DH:</b> 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
<b>DH:</b> 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 (ongoing) – 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
4	4	16 – High	4	3	12 - High
<b>Tolerance threshold:</b>					<b>12 - High</b>

Risk area	Risk owner	Links to which strategic objectives?	Trend
<b>Capability</b> C1: Knowledge and capability	Peter Thompson, Chief Executive	Whole strategy	↔ ↑ ↔ ↔

Commentary
<p><b>At tolerance.</b></p> <p>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.</p> <p>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 IfQ related work ongoing until September. Turnover is also variable, and so this risk will be retained on the risk register, and will continue to receive ongoing management attention.</p>

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 – Rachel Hopkins/Peter Thompson
	Organisational knowledge captured via documentation, 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
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. Task and Finish Groups working on ideas for improvements.	Survey and staff conference 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.	Additional member of staff dedicated to handling such enquiries. IfQ delivery means there is still pressure on team capacity.	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 – 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.	
	Planning prioritising IfQ/data submission project delivery, and therefore strategy delivery, within our limited resources.	In place until project ends (Autumn 2017) – 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 are unlikely to be many.  New licensing processes are in place, ready for first use (decision trees etc.).	Issue for further consideration – Juliet Tizzard
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.	IT team working to identify and resolve the issues, with staff encouraged to continue to send support tickets. External expert commissioned to assist.  Continued use of external venues with appropriate facilities.  Use of mailboxes to provide an alternative channel when Skype calls are not received (however there are also some problems with these too).	In progress – Dave Moysen and Nick Jones
<b>Risk interdependencies (ALBs / DH)</b>	<b>Control arrangements</b>	<b>Owner</b>
<b>Government/DH:</b> 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	4	3	12 - High
<b>Tolerance threshold:</b>					<b>9 - Medium</b>

Risk area	Risk owner	Links to which strategic objectives?	Trend
<b>Organisational change</b> OC1: Change-related instability	Peter Thompson, Chief Executive	Whole strategy	↑ (Added in February 2017)

Commentary
<b>Above tolerance.</b>

Causes / sources	Mitigations	Timescale / owner
<p>The change period may lead to dips in morale, commitment, discretionary effort and goodwill.</p> <p>There are likely to be differential impacts as different changes affect different groups of staff at different times.</p> <p>Risks are to the delivery of current work, including IfQ, and possibly technical or business continuity risks.</p>	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 – Rachel Hopkins
	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 – Rachel Hopkins
	Good decision-making and risk management mechanisms in place. Knowledge retention via good records management practice, SOPs and documentation.	In place – Peter Thompson
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, to support new ways of working development	In place for coming year – Rachel Hopkins
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, negatively impacting on the relationship between staff and members.	Communicate the changes clearly to Authority members so that they understand when staff are particularly under pressure, and that they will have 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.	To be implemented – Peter Thompson

<p>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.</p>	<p>Ensure a settling in period where staff are inducted and learn, and teams develop new ways of working. Formal training and development provided where required.</p> <p>Knowledge management via records management and documentation.</p>	<p>To be implemented – Peter Thompson</p>
<p>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.</p>	<p>Change management will be prioritised so that bedding down occurs and is effective, and does not take an unduly long time.</p>	<p>To be implemented – Peter Thompson</p>
	<p>Continuing programme of leadership development for Heads and SMT.</p>	<p>Being planned – Rachel Hopkins</p>
<p>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.</p>	<p>The model will be kept under review following implementation to ensure it yields the intended benefits.</p>	<p>To be implemented – Peter Thompson</p>
<p><b>Risk interdependencies (ALBs / DH)</b></p>	<p><b>Control arrangements</b></p>	<p><b>Owner</b></p>
<p>-</p>		

**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
<b>Tolerance threshold:</b>					<b>6 - Medium</b>

Risk area	Risk owner	Links to which strategic objectives?	Trend
<b>Cyber security</b> CS1: Security and infrastructure weaknesses	Nick Jones, Director of Compliance and Information	Whole strategy	New (added in April 2017)

### Commentary

#### At tolerance.

The recent cyber-security event 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 recent 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/Dave Moysen
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.  Security consultant providing advice throughout IfQ. At the end of the programme, we will receive documented assurance of security and any steps necessary to maintain that security at a high level.  Penetration testing for the portal and website.  Ongoing security advice is in place for the development of the new data submission systems.	In place - Nick Jones/Dave Moysen  In place – Dave Moysen

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.  Secure working arrangements for Register team, including when working at home.	In place – 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.	In place – Dave Moysen
Register or other data (electronic or paper) becomes corrupted or lost.	Back-ups and warehouse in place to ensure data cannot be lost.  Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality.	In place – Nick Jones/ Dave Moysen
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 – Dave Moysen
	Deliberate internal damage to infrastructure, or data, is controlled for through off-site back-ups and the fact that any malicious tampering would be a criminal act.	In place (March 2015) – 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. Regular testing in place, with follow-up.  New technology options being 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.	In place – Richard Sydee  Update done Dave Moysen – September 2016
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 2017, following planned organisational changes and the conclusion of IfQ.	To follow after organisational re-shaping – 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
<b>Risk interdependencies (ALBs / DH)</b>	<b>Control arrangements</b>	<b>Owner</b>
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	4	20 – Very high	5	3	15 - High
Tolerance threshold:					12 - High

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

### Commentary

#### Above tolerance.

The judgment on consent to legal parenthood in 2015 and subsequent cases have administrative and policy consequences for the HFEA. Further cases were heard in May 2017. The evidence suggest that we are near the end of these historic cases.

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 courts on whether to grant permission to appeal is likely to be heard soon.

A licensing matter is currently being challenged and will be considered by the Appeal Committee shortly. If the decision is endorsed we can expect a judicial review.

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

<p>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).</p> <p>Note: 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.</p>	<p>Legal panel in place, as above.</p>	<p>In place – Peter Thompson</p>
	<p>Maintaining, keeping up to date and publishing licensing SOPs, committee decision trees etc. to ensure we take decisions well.</p> <p>Consistent decision making at licence committees supported by effective tools for committees.</p> <p>Standard licensing pack distributed to members/advisers (refreshed in April 2015).</p>	<p>In place – Paula Robinson</p>
	<p>Well-evidenced recommendations in inspection reports.</p>	<p>In place – Sharon Fensome-Rimmer</p>
<p>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.</p>	<p>Risks considered whenever a new approach or policy is being developed.</p> <p>Business impact target assessments carried out whenever a regulatory change is likely to have a cost consequence for clinics.</p> <p>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.</p> <p>Major changes are consulted on widely.</p>	<p>In place – Juliet Tizzard</p>
<p>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.</p>	<p>Scenario planning is undertaken at the initiation of any likely action.</p>	<p>In place – Peter Thompson</p>
<p>Legal proceedings can be lengthy and resource draining.</p>	<p>Panel in place, as above, enabling us to outsource some elements of the work.</p>	<p>In place – Peter Thompson</p>
	<p>Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise work should this become necessary.</p>	<p>In place – Peter Thompson</p>
<p>Adverse judgments requiring us to alter or intensify our processes, sometimes more than once.</p>	<p>Licensing SOPs, committee decision trees in place.</p>	<p>In place – Paula Robinson</p>



HFEA process failings could create or contribute to legal challenges, or weaken cases that are otherwise sound, or generate additional regulatory sanctions activity (eg, legal parenthood consent).	Licensing SOPs, committee decision trees in place.	In place – 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 – Nick Jones
<b>Risk interdependencies (ALBs / DH)</b>	<b>Control arrangements</b>	<b>Owner</b>
<b>DH:</b> 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
<b>DH:</b> 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 of our regulatory effectiveness being compromised 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
<b>Tolerance threshold:</b>					<b>6 - Medium</b>

Risk area	Risk owner	Links to which strategic objectives?	Trend
<b>Regulatory effectiveness</b> 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	New (added in May 2017)

### Commentary

**At tolerance.**

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 anticipated by August 2017 – 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/Dave Moysen
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.	In place – Dave Moysen
The new Intelligence team is critical to the new model, and will need to develop an information strategy before it will be possible to use the data for regulatory and other purposes.	Recruitment for a Head is in progress now and will soon be complete. The development of the team, and the information strategy, will follow.  The data submission project has been delayed but is now making good progress.	In place – Juliet Tizzard
Benefits of IfQ not maximised and internalised into ways of working.	During IfQ delivery, product owners have been 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.	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.	Experienced inspection team and business support team, at full complement.  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 – Nick Jones  To be developed – Head of Intelligence when recruited – Juliet Tizzard
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 IfQ delivery help to address this risk by extending the release date for the EDI replacement (IfQ release 2).  Mitigation plans for this risk have been agreed as part of planning.	Mitigation in place - Nick Jones
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.	Continuous work with clinics on data quality, including verification processes, steps in the OTR process, regular audit alongside inspections, and emphasis on the need for life-long support for donors, donor-conceived people and parents.	In place – Nick Jones
	Audit programme to check information provision and accuracy.	In place – Nick Jones
	IfQ work has identified data accuracy requirements for different fields as part of migration planning, and will put in place more efficient processes.	In place – Nick Jones
	If subsequent work or data submissions reveal an unpreventable earlier inaccuracy (or an error), we explain this transparently to the recipient of the information, so it is clear to them what the position is and why this differs from the earlier provided data.	In place – Nick Jones
	Data verification work (February 2017) in preparation for Register migration will improve overall data accuracy, and the exercise includes tailored support for individual clinics that are struggling.	In place – Nick Jones
Excessive demand on systems and over-reliance on a few key expert individuals – request overload – leading to errors	<p>PQs, FOIs and OTRs have dedicated expert staff/teams to deal with them.</p> <p>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.</p> <p>PQ SOP revised and log created, to be maintained by Committee and Information Officer/Scientific Policy Manager.</p>	In place – Juliet Tizzard / Paula Robinson
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 / Nick Jones
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.	<p>Communications strategy in place, including more patient feedback.</p> <p>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.</p>	In development – Juliet Tizzard
<b>Risk interdependencies (ALBs / DH)</b>	<b>Control arrangements</b>	<b>Owner</b>
None	-	-

**ME1: There is a risk that we will not get key messages and information to patients and clinics through our new website, so failing to bring about positive change.**

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
3	5	15 High	2	3	6 - Medium
<b>Tolerance threshold:</b>					<b>6 - Medium</b>

Risk area	Risk owner	Links to which strategic objectives?	Trend
<b>Effective communications</b> ME1: Messaging, engagement and information provision	Juliet Tizzard Director of Strategy and Corporate Affairs	<p>Safe, ethical effective treatment: Publish clear information so that patients understand treatments and treatment add ons and feel prepared</p> <p>Safe, ethical effective treatment: Engender high quality research and responsible innovation in clinics.</p> <p>Consistent outcomes and support: Increase consistency in treatment standards, outcomes, value for money and support for donors and patients.</p>	New (added May 2017)

Commentary
<b>At tolerance.</b>

Causes / sources	Mitigations	Timescale / owner
Our ability to provide patient information via the website or CaFC could be compromised by a website failure or failure to launch the new website following GDS assessment.	We have good cyber-security measures to prevent website attacks, and the new content management system is more reliable than the old one.  Detailed preparations are well under way for the next gateway review.	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
Redeveloped website does not meet the needs and expectations of our audience.	User research was done before the website was developed, to properly understand needs and reasons.	In place – Juliet Tizzard
Some information will be derived from data, so depends on risk above being controlled.	See controls listed in RE1, above.	

<b>Risk interdependencies (ALBs / DH)</b>	<b>Control arrangements</b>	<b>Owner</b>
None.		

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## Reviews and revisions

### AGC – March 2017 meeting

AGC commented on the 2014-2017 strategic risk register, and noted that the new version would come to the next meeting. AGC particularly noted the ongoing unpredictability of our PQ and FOI requests, and their complexity.

### CMG – May 2017 meeting

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

The new risk register comprised two types of strategic risk: generic high level risks to the infrastructure and general operation of the HFEA, affecting the whole strategy, and specific risks to elements of the strategy. The generic risks are financial viability, people-related risks, cyber-security and legal risks.

CMG discussed whether to combine the two people-related risks areas of 'Capability' and 'Change'. Although the organisational changes have now been agreed, resulting in some overlap, CMG agreed it was appropriate to retain the separate organisational change risk for a few months, while the new organisational structure is fully implemented.

CMG agreed that beyond the generic category of risk, there were two main risks to delivery of the strategy:

- Regulatory effectiveness – if we are unable to make use of our improved data and intelligence to ensure high quality care, for example through our aim to do more targeted regulatory interventions.
- Messaging, engagement and information provision – if we were unable to use our new website and other channels effectively to convey and promote key messages and information to patients and clinics, for example about treatment add ons or improved support.

CMG agreed that the products of IfQ should now be listed among the controls for these risks, rather than retaining IfQ as a separate risk area. We continue to manage the remaining IfQ delivery risks through the IfQ Programme Board and the IfQ risk log, and will continue to report regularly to AGC and the Authority on risks and progress, until the work has been completed.

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



### **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**

From April 2017 onwards, 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 interdependencies in collaboration with relevant other bodies, and so that we can report easily and transparently on such interdependencies to DH or auditors as required.