

Authority agenda

Date - 1 June 2020

Venue - Teleconference

Agenda item	Time
1. Welcome, apologies and declarations of interest	3.00pm
2. Previous Authority minutes 7 May 2020	3.05pm
3. General update	3.10pm
4. Covid-19/Sector/patient updates	3.25pm
5. Revised license fee model – development and consultation process	3.55pm
6. Strategic risk register	4.15pm
7. Any Other Business	4.35pm
8. Close	4.40pm

Minutes of Authority extraordinary meeting 7 May 2020

Details:

Area(s) of strategy this paper relates to:	Safe, ethical effective treatment/Consistent outcomes and support/Improving standards through intelligence
Agenda item	2
Meeting date	01 June 2020
Author	Debbie Okutubo, Governance Manager

Output:

For information or decision?	For decision
Recommendation	Members are asked to confirm the minutes of the extraordinary Authority meeting held on 7 May 2020 as a true record of the meeting
Resource implications	
Implementation date	
Communication(s)	
Organisational risk	<input checked="" type="checkbox"/> Low <input type="checkbox"/> Medium <input type="checkbox"/> High
Annexes	

Minutes of the extraordinary Authority meeting on 7 May 2020 held via teleconference

Members present	Sally Cheshire Margaret Gilmore Anita Bharucha Anthony Rutherford Emma Cave Anne Lampe	Jonathan Herring Gudrun Moore Ruth Wilde Yacoub Khalaf Ermal Kirby Kate Brian
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Apologies	None
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Staff in attendance	Peter Thompson Clare Ettinghausen Richard Sydee Rachel Cutting	Catherine Drennan Joanne Triggs Paula Robinson Debbie Okutubo
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Members

There were 12 members at the meeting – eight lay members and four professional members.

1. Welcome and apologies

- 1.1. The Chair welcomed everyone present to the extraordinary Authority meeting and noted that the focus of the meeting was the application process for licensed centres to resume treatment and to agree a commencement date from which centres could apply to the HFEA under a revised General Direction 0014.
- 1.2. The Chair advised everyone present that the meeting was being recorded and to ensure that we continued to be a transparent public body, a minute would be issued in draft shortly after the meeting.

2. Minutes of the extraordinary meeting on 30 April 2020

- 2.1. Members agreed that the minutes of the meeting held on 30 April 2020 be signed by the Chair subject to the corrections submitted prior to the meeting.

3. Resuming fertility treatment: implementation

- 3.1. The Chair gave a brief introduction and commented that the proposal for decision was that from 11 May clinics could apply to re-open by providing specified information to their inspector and receiving approval from the inspector to restart treatment. Professional bodies had produced updated guidance and a number of clinics had trialled the self-assessment questionnaire and given useful feedback.
- 3.2. Following the Chair's introduction, the Chief Executive (CE) was invited to outline further details.

- 3.3.** It was noted that the British Fertility Society (BFS) and the Association of Reproductive and Clinical Scientists (ARCS) had released their position statement and we had updated the information to be requested from clinics drawing on that guidance.
- 3.4.** Members were invited to comment. It was noted that the UK strategy remained to only test symptomatic people for Covid-19 and this was a position that was not likely to change. It was suggested that this could cause anxiety as some patients and/or staff who had the virus but remained asymptomatic could still spread the virus.
- 3.5.** Officers responded that individual centres were likely to take different approaches to testing but we could not go against the UK-wide testing strategy. BFS guidance clearly states “if available”.
- 3.6.** Officers further commented that the issues raised were valid but that licensed centres would ultimately decide if they wanted to re-open based on local factors. It would then be up to the HFEA to decide whether centres had evidenced that they met the requirements laid out in the self-assessment tool.
- 3.7.** The Director of Compliance and Information addressed the meeting and stated that the draft self-assessment tool had been sent to 33 licensed centres and 20 had responded with a good mix of respondents.
- 3.8.** In response to a question it was noted that patient safety and staff wellbeing were addressed in the questionnaire.
- 3.9.** The Director of Compliance and Information outlined the proposed application and assessment process. It was for licensed centres to indicate to their inspector that they wished to re-open. Inspectors would then send the person responsible (PR) the self-assessment questionnaire, which sets out the essential requirements that centres need to follow in their treatment commencement strategy. Once the licensed centres responded, the inspectorate would aim for a turnaround period of five days for assessing each response. If approved the centre could then resume treatment.
- 3.10.** If not approved the centre would need to address all areas of concern and re-submit a revised self-assessment for approval.
- 3.11.** Officers clarified that it was a self-assessment tool per clinic and per PR rather than for one per group of clinics.
- 3.12.** Members wanted to know what would be done about ongoing monitoring of compliance with the treatment commencement strategy. Officers responded that centres would be expected to keep up to date with updated guidance and inspectors would be in touch and carry out a desk-based assessment should the need arise. Monitoring of treatment numbers and incidents would continue.
- 3.13.** In response to a question, it was noted that physical inspections had been halted until the end of August 2020 and the situation would need to be reviewed after that, depending on the wider approach to the pandemic across the UK.
- 3.14.** Members requested feedback on progress on how centres were managing at the next meeting.
- 3.15.** There was a concern raised that clinic staff who were shielding or living with vulnerable people would be required to go into their clinics. Officers commented that staff concerns were part of the self-assessment questionnaire and inspectors could ask additional questions on how staff were being kept safe.

- 3.16.** A member noted that their experience was that staff who were shielding or needed to self-isolate were staying at home and given administrative duties where appropriate.
- 3.17.** The Chair commented that there were mixed reactions from clinics, with clinics responding differently but that all clinics would have to be transparent about their practices.
- 3.18.** A member commented that some patients who were keen to resume treatment had now started thinking of the practicalities involved in attending appointments as well as their personal safety.
- 3.19.** The CE commented that should any centre staff feel that they were being asked to do something which they felt uneasy about they could contact the HFEA in a whistle blowing capacity and other channels for feedback would also be made available.
- 3.20.** The Chair commented that HFEA should look into having a dedicated email address for centre staff and patients for feedback. Also, the frequently asked questions (FAQs) section on the website should be updated for patients with further questions on testing, personal protective equipment (PPE) and risk.
- 3.21.** The Chair also suggested that if members had further comments on the self-assessment tool then they should be sent to the Director of Compliance and Information.
- 3.22.** Members were assured that the HFEA could take regulatory action against non-compliance. Incidents and near misses were also captured by us. Also clinics had to notify us if staff or patients tested Covid-19 positive.
- 3.23.** It was noted that in cases where centres do not adhere to guidance the responsibility was that of the PR. It was therefore suggested that the guidance needed to make it clear where liability lay. We also needed to be realistic about the risks we would allow clinics to take which should all be addressed in the letter to the PRs.
- 3.24.** The Head of Legal responded to a question that in terms of litigation it was unlikely that we would face any legal challenge as a regulator for enabling clinics to commence treatment if patients felt it was still unsafe, but it could not be ruled out. She further commented that the self-assessment tool was developed based on UK and international guidance available on safety and good practice and this is what we would rely on if challenged, to support the decision to allow clinics to commence treatment.
- 3.25.** Members commented that centres might want to adapt a policy of having patients read and sign a consent form that stated that relevant risks had been explained to them.
- 3.26.** Some members commented that many centres have been reviewing their protocols and were probably already compliant with the new HFEA guidance. There were further comments that centres were running a business so they would not knowingly open themselves up to litigation. Some clinics were still offering storage facilities and therefore patient safety remained paramount.
- 3.27.** In response to a question, staff suggested that although it was down to individual clinics to decide how best to treat individual patients, it might not be wise for patients with comorbidities to access treatment at present. Similarly, high risk patients and/or extremely vulnerable patients should be cautious about coming forward for treatment during the Covid-19 pandemic. However, where they do, it would be for clinics to decide whether treatment could safely go ahead. Staff also commented that centres need to follow the guidance on the use of treatment add-ons.

- 3.28.** Summing up after asking each individual Authority member for their views, the Chair noted that members approved the issuing of the revised GD0014 to come into force on the 11 May 2020 subject to any issues raised.
- 3.29.** The CE remarked that the covering letter to PRs would state that it was a live situation and as the situation developed so would the guidance.
- 3.30.** The website would be kept updated and patients advised to keep in touch with their centres.
- 3.31.** Lastly, a second open letter to patients would be published by the Chair summarising the outcome of the meeting and that the priority remained the safety of patients and clinic staff.
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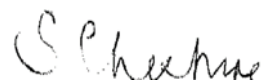
4. Any other business

- 4.1.** The Chair reminded Authority members that they would be contacted about the date of the next Authority meeting which will be around the first week in June, but that the 13 May meeting was cancelled.
- 4.2.** The 2 July Authority meeting will go ahead as scheduled but, similar to this one, future meetings will be shorter and be a virtual meeting covering a mix of business as usual and Covid-19 updates.
- 4.3.** There was also the likelihood of an Authority meeting in August.
- 4.4.** Members were informed that the Government had proposed that the 10-year storage period for gametes and embryos should be extended by two years as a result of the Covid-19 pandemic. Guidance and a new consent form would be issued when the regulations come into force. Members were asked to delegate approval of a revised General Direction 0007 (which lists HFEA consent forms) to the Chair. Members agreed with this delegation.
- 4.5.** It was agreed that an appreciation letter will be sent to all HFEA staff from the Chair on behalf of the Authority members for their hard work to date.
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Chair's signature

I confirm this is a true and accurate record of the meeting.

Signature



Chair: Sally Cheshire

Date: 01 June 2020

Revised license fee model – development and consultation process.

Details about this paper

Area(s) of strategy this paper
relates to:

Meeting:	Authority
Agenda item:	5
Meeting date:	1 June 2020
Author:	Richard Sydee, Director of Resources
Annexes	N/a

Output from this paper

For information or decision?	For decision
Recommendation:	That members agree the modelling and selection criteria set out in sections 3 and 4 of this paper
Resource implications:	N/a
Implementation date:	N/a
Communication(s):	Engagement with Licensed Centres and Patient Groups
Organisational risk:	High

1. Introduction

- 1.1. As agreed with the Authority at its meeting of 29 January 2020 we have commenced work on developing a revised licence fee model to be introduced from April 2021. This paper sets out the initial development and longlisting of potential modelling options and our proposed timetable for development, detailed modelling and consultation on options before presenting a preferred approach to Authority in the autumn of 2020.

2. Background

- 2.1. As with a number of Government regulators across numerous sectors the HFEA is expected to recover the majority of its operating funds (currently 80% of total income, with the remainder from the DHSC in the form of grant-in-aid) through charging fees to the sector it regulates. In doing this the HFEA must look to ensure that it recovers the full cost of regulation through a mechanism that is fair, transparent and that ensures there is no cross subsidisation, for example that Private and Public funded clinics are charged consistently.
- 2.2. Historically it has been felt the cost of regulation is evenly distributed amongst licenced establishments based on the level of activity that they undertake, and that therefore a fee per IVF/DI cycle performed is used as the basis for licence fees.
- 2.3. Until recently we had seen consistent year on year growth in treatment activity across the sector. Since the HFEA last reviewed its fees in April 2016 growth had been approximately 2% per annum, which is broadly in line with inflation across the same period. As a result, the HFEA has been able to hold fees at the 2016 rate for the past 4 years (currently £80per IVF treatment and £37.50 for DUI).
- 2.4. During the 2019/20 business year we saw, for the first time, a reduction in the number of chargeable cycles, leading to drop in income for the HFEA. Further analysis of this data highlighted some key changes:
- within the private sector activity was increasing, but the number of cycles that met the threshold for charging was falling – partly due to changes in clinic practice
 - that although overall activity levels were increasing there was a material drop in activity within NHS clinics.
- 2.5. The Authority discussed this data tail at its meeting in January 2020 and agreed that a licence fees review project should be undertaken to consider whether the current charging mechanism remains a fair and equitable recovery of the cost of regulation or if an alternative model would be more appropriate and ensure a sustainable income for the HFEA's future regulatory activity.
- 2.5. As ever it is important to be clear that HFEA licence fees are charged to licenced establishments and not patients, although some clinics choose to list the activity based licence fee on patient's bills the HFEA does not and will not charge patients.

3. Alternative licence fee models and shortlisting

- 3.1. It was agreed that the existing licence fee model (our "Do nothing" option) should be used as a baseline comparator for modelled proposals.

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- 3.2. The first stage of modelling resulted in 7 new models for the HFEA's licence fee, these are contained at annex A to this paper. Although this list was not exhaustive it was agreed it captured the broad range of options available.
- 3.3. A panel consisting of finance, data & intelligence, policy and compliance colleagues reviewed these proposals and shortlisted 4 options that should move forward to detailed modelling. These are:
- **Introduce new variable charges.** This maintains a full activity-based charging regime but will consider increasing the number of chargeable activities under the licence, this could result in different charges for freeze all, fresh embryo transfer and frozen embryo transfer etc.
 - **Inspection fee +.** The cost of inspection would be recovered in the year of an inspection taking place (a different charge for a renewal and interim inspection). The remainder of HFEA licence fees would be derived from activity levels at each clinic (similar to current approach).
 - **Semi fixed, some differentiation.** A combination of fixed "minimum" annual fee plus an activity-based charge. Fixed charge bandings would be based clinic size in terms of activity (A different fee based on number of IVF cycles e.g. 0 - 99, 100 - 249, 250 - 599, 600 - 999, 1000 - 1499, 1500 - 2249, 2500 +). A further direct activity-based charge would apply per cycle.
 - **Fully fixed, some differentiation.** This would be a single fixed annual fee – with the annual licence fee being based on clinic size (historic activity levels) and weighted against agreed activity bands e.g. Number of IVF cycles - 0 - 99, 100 - 249, 250 - 599, 600 - 999, 1000 - 1499, 1500 - 2249, 2500 +).
- 3.4 Detailed modelling will be undertaken for each of the 5 options (do nothing and the 4 options above) as set out below.

4. Proposed modelling of shortlisted options and stakeholder engagement

- 4.1. The assessment panel considered how the detailed modelling should be undertaken and the criteria that should be applied to assess the validity and impact of each model.
- 4.2. It is proposed that the 20/80 grant-in-aid/fee income remains broadly right and that modelling should be based on an income requirement of £5.5m, which represents consumer price index inflation to the income budget set in 2019/20. Activity levels for the forecast modelling will be based on 2018/19 business year data. Annex B to this paper contains more detail on modelling and selection criteria, but in summary we will identify impact at clinic, regional and national levels and also consider the impact on NHS and private sector provision.
- 4.3. Once our initial modelling is complete, we propose to engage concurrently with clinics through our licensed centres panel (LCP) and our sponsor Department/HM Treasury to obtain feedback on modelled outcomes. We will use a combination of our selection criteria and feedback from clinics and Department colleagues to inform a final decision on a preferred licence fee model from the 2021/22 business year.
- 4.4. We anticipate this work can be completed by late summer 2020. Once a preferred model has been selected, we would then propose undertaking a consultation with patient groups, this would be aimed at providing information on the nature of our proposed changes and how we anticipate

this will impact on patients through treatment costs. As we have stated before HFEA charges are to licenced establishments and not patients, we are keen to ensure that this message is clear and that we provide clarity to patients on how any changes to our fees should be presented by clinics.

- 4.5. Final recommendations on a licence fee model, and proposed licence fee charges for 2021/22, will be presented to the November Authority meeting for approval.

5. For discussion

5.1. Members are asked to:

- consider and agree the proposed modelling options at paragraph 3.3
- provide comment on the proposed approach to modelling, assessment and stakeholder engagement
- agree the proposed timetable for approval of a new fees model in November 2020

Annex A – longlist of licence fee models

Variation to current charging definitions	Make no fundamental change to existing fee regime, consider variation to definition of chargeable IVF cycle
Introduce new variable charges	Maintain current volume-based regime - consider increasing number of charges, with different charges for freeze all, fresh transfer and frozen transfer
Inspection fee +	Cost of inspection covered in year of inspection (Renewal and interim). Remainder of income derived from activity
Semi fixed, some differentiation	Combination of fixed "minimum" annual fee & activity charge - bandings based on activity levels (e.g. 0 - 99, 100 - 249, 250 - 599, 600 - 999, 1000 - 1499, 1500 - 2249, 2500 +). Remainder of income derived from activity charge
Semi fixed, no differentiation	Combination of fixed "minimum" annual fee & activity charge - Agreed % of Income budget / licensed treatment establishments. No consideration of activity levels in fixed element. Remainder of income derived from activity charge
Fully fixed, some differentiation	Fixed annual fee - bandings based on activity levels (e.g. 0 - 99, 100 - 249, 250 - 599, 600 - 999, 1000 - 1499, 1500 - 2249, 2500 +)
Fully fixed, no differentiation	Fixed annual fee - Income budget / licensed treatment establishments. No consideration of activity levels

Annex B – Modelling and selection criteria

Model & analysis

Using the current sector activity forecast model apply the three forecast scenarios (Best, most likely, worst) against selected scenario options

Identify gross activity and payable licence fees at individual clinic levels, identifying material variation with historic charges (% threshold to be agreed - perhaps 5%?)

Identify progressive (over three years) sector (NHS and Private) variations in activity levels and licence fee charges

Identify progressive (over three years) regional variations in activity and charges

Look to identify particular sectors, groups or clinics who might see disproportionate impact (positive or negative - threshold to be agreed - should this be % point or £000?)

Selection criteria

Does this recover costs against the main areas of regulatory effort / risk?

Does this lead to activity cross subsidisation?

Does this lead to sector (NHS and Private) cross subsidisation?

Will this create a barrier to entry or impact on going concerns?

Will this lead to uneven charging to clinics?

Is this transparent to stakeholders?

Does this align with legislation?

How difficult is this to implement? (Scale 1 - 5)

Period of time for which this provides sufficient budget for HFEA

Frequency of fee review regime required

How does this take account of future shifts in activity

How volatile is this in relation to sector activity

How will this be received by Clinics

How will this be received by patients

How will this be perceived by wider stakeholders (DHSC, HMT)

New strategic risk register

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	6
Meeting date:	1 June 2020
Author:	Helen Crutcher, Risk and Business Planning Manager
Annexes	Annex 1 – draft new strategic risk register

Output from this paper

For information or decision?	For information and comment.
Recommendation:	The Authority is asked to note and comment on the latest edition of the strategic risk register.
Resource implications:	In budget.
Implementation date:	Ongoing.
Communication(s):	The risk register is reviewed monthly by the Senior Management Team (SMT) and presented at every Audit and Governance Committee (AGC) meeting. AGC last reviewed the risk register at its meeting on 10 March and will review it again at its meeting on 23 June.
Organisational risk:	Low.

1. Revision of the strategic risk register

- 1.1. The attached revised strategic risk register is still a work in progress. Reviewing it has been an iterative process involving a wide range of staff, including all Heads and Directors.
- 1.2. The review process began with a workshop with the Senior Management Team (SMT), following sign-off of the new strategy by Authority in January. Follow on discussions have taken place, with key risk and mitigation owners and with the whole management team at the Corporate Management Group (CMG) meeting in April.
- 1.3. The primary purpose of the review has been to ensure the register reflects the risks to delivering our strategy and that we focus on ensuring that our risk controls are adequate and effective.
- 1.4. The overarching theme is continuity. We have retained most of the standing high-level risks, though a few of these have been substantially revised to ensure that they are as clear as possible and reflect the changed organisational context. Meanwhile, we have drafted three new risks aligned to the key strategic aims for 2020-2024:
 - RF1 – Regulatory framework (the best care)
 - I1 – Information provision (the right information)
 - P1 – Positioning and influencing (shaping the future)
- 1.5. In March, we presented the outline of the three new risks to AGC, along with an overview of the approach taken to reviewing the register as a whole.
- 1.6. Some of the risks will need more work before we are entirely content with the articulation of the risk itself, the causes and mitigations, the inherent and residual risk scores, and the tolerance level for each risk.

2. Impact of Covid-19

- 2.1. Covid-19 has obviously led to a delay to the launch of the new strategy. It has also required some significant re-planning and live risk management. There is now a separate Coronavirus risk on the risk register, but the impacts cascade across a number of areas of the wider register and are reflected as such.
- 2.2. Although the launch of the strategy may have been delayed, we will continue to manage the new strategic risks, since properly addressing these is also likely to make it easier to commence delivery of the strategy when we are able to launch it. We will keep the risks under review during any future conversations about considering our ongoing strategic approaches.

3. Latest reviews

- 3.1. CMG reviewed the new register for the first time on 22 April. SMT last reviewed the register at its meeting on 20 May. SMT and CMG reviewed all risks, controls and scores.
- 3.2. SMT and CMG's comments are summarised in the commentary for each risk and at the end of the register, which is attached at Annex 1.
- 3.3. Three of the ten risks are above tolerance.

4. Recommendations

4.1. The Authority is asked to:

- Note the above and agree the new strategic risks for the 2020 – 2024 strategy.
- Comment on the strategic risk register.

Draft strategic risk register 2020-2024

Risk summary: high to low residual risks

Risk ID	Strategy link	Residual risk	Status	Trend*
C2: Board capability	Generic risk – whole strategy	16 – High	Above tolerance	↔↔↔↔
FV1: Financial viability	Generic risk – whole strategy	15 – High	Above tolerance	↔↑↔↔
CV1 - Coronavirus	Whole strategy	12 – High	At tolerance	New risk March 2020 -↔↔↔
E1: Relocation of HFEA offices in 2020	Generic risk – whole strategy	9 – Medium	Above tolerance	↔↑↔↔
P1 – Positioning and influencing	Shaping the future (and whole strategy)	9 - Medium	At tolerance	(New risk April) -↔↔
CS1: Cyber security	Generic risk – whole strategy	9 – Medium	At tolerance	↔↔↔↔
C1: Capability	Generic risk – whole strategy	9 – Medium	Below tolerance	↔↔↔↓
RF1 – Regulatory framework	The best care (and whole strategy)	8 - Medium	At tolerance	(New risk April) -↔↔
LC1: Legal challenge	Generic risk – whole strategy	8 – Medium	Below tolerance	↔↔↔↔
I1 – Information provision	The right information	6 - Medium	Below tolerance	(New risk April) -↔↔

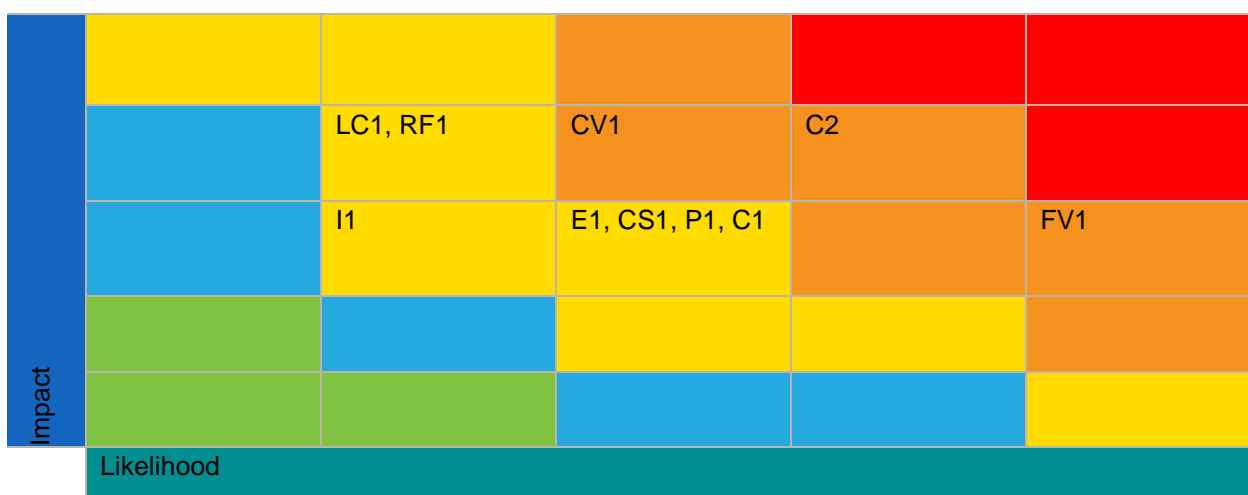
*This column tracks the four most recent reviews by AGC, SMT or the Authority (eg, ↑↔↓↔).

Recent review points are:

For current register: SMT 20 April 2020⇒CMG 22 April 2020 ⇒ SMT 20 May 2020

For previous register: SMT 23 March (Coronavirus risk only)

Summary risk profile – residual risks plotted against each other:



RF1: There is a risk that the regulatory framework in which the HFEA operates is overtaken by developments and becomes not fit for purpose.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
3	5	15	2	4	8 - Medium
Tolerance threshold:					8 - Medium
Status: At tolerance					

Risk area	Risk owner	Links to which strategic objectives?	Trend
Regulatory framework RF1: Responsive and safe regulation	Rachel Cutting, Director of Compliance and Information	The best care and whole strategy	New risk April -↔↔

Commentary

As a regulator, we are by nature at a remove from the care and developments being offered in clinics and we must rely on our regulatory framework to provide sufficient powers to assure the public that treatment and research is safe and ethical.

The result of not having an effective regulatory framework could be significant, the worst case of this risk would be us being without appropriate powers or ability to intervene, and patients being at risk, or not having access to treatment options that should be available to them in a safe and effective way.

Causes / sources	Controls	Timescale / owner of control(s)
We don't have powers in some of the areas where there are or will be changes affecting the fertility sector (for instance artificial intelligence).	We are strengthening or seeking to build connections with relevant partners who do have powers in such areas (for instance, the CMA in relation to pricing of treatments). We have taken external legal advice on AI technology being used in the fertility sector and await the final report to establish our legal position. We are analysing where there are gaps in our regulatory powers so that we may be able to make a case for further powers if these are necessary, whenever these are next reviewed.	In progress - Clare Ettinghausen In progress as at May - Catherine Drennan In progress as at May - Laura Riley, Joanne Anton, Catherine Drennan
We may have ineffective tools, systems, or regulatory interventions available which are	Regular review processes for all regulatory tools such as:	

<p>too rigid and cannot be adapted to changes.</p>	<ul style="list-style-type: none"> • Code of Practice (we are considering the timing of the next review and any risks related to delay). • Compliance and enforcement policy • Licensing SOPs and decision trees <p>To enable us to revise these and prevent them from becoming ineffective or outdated.</p>	<p>In place, last update December 2019 – Laura Riley, Joanne Anton</p> <p>Currently under review as at May – Catherine Drennan, Rachel Cutting</p> <p>In place and review ongoing – Paula Robinson</p>
<p>Change may be too fast for us to adequately respond to if we do not understand the nature of the changes arising. Resulting in us being under-prepared or taking an insufficiently nuanced approach.</p>	<p>We cannot control the rate of change, but we can make sure we are aware of likely changes and make our response as timely as possible by:</p> <ul style="list-style-type: none"> • Annual horizon scanning at SCAAC • maintaining links with key stakeholders including other professional organisations and the licensed centres panel to get a sense of changes they are experiencing or have early sight of. <p>We necessarily have to wait for some changes to be clearer in order to take an effective regulatory position. However, we may choose to take a staged approach when changes are emerging, issuing immediate responses such as a Chair's letter or change to General Directions to address immediate regulatory needs, before strengthening our position with further guidance or regulatory updates.</p>	<p>In place – Laura Riley, Joanne Anton</p> <p>In place - Peter Thompson</p>
<p>We may focus on 'pet projects' or ephemeral interests being influenced by personal preferences or biases.</p>	<p>Strategic aims have been clearly articulated; all projects must be aligned to these aims to ensure that our work is focused on delivering these objectives. We ensure this by consideration at Corporate Management Group.</p>	<p>Ongoing – Peter Thompson</p>
<p>We have limited capacity, which may reduce our ability to respond quickly to new work, since we may need to review and stop doing something else.</p>	<p>Monthly opportunity for reprioritising at CMG when new work arises and weekly SMT meetings for more pressing decisions.</p>	<p>In place – Peter Thompson</p>
<p>We may have a lack of staffing expertise or capability in the areas developments occur in, for instance in AI.</p>	<p>As developments occur, Heads consider what the gaps are in our expertise and whether there is training available to our staff.</p> <p>If a specific skills gap is identified in relation to a new development, we could consider whether it is appropriate or possible to bring in resource from outside, for instance by employing someone temporary or sharing skills with other organisations.</p>	<p>Ongoing - Relevant Head/Director with Yvonne Akinmodun</p>

<p>If RITA (the register information team app – used to review submissions to the Register) is not completed in a timely way, the new data submission system PRISM may not effectively enable us to use data and ensure our regulatory actions are based on the best and most current information.</p>	<p>Launch date of PRISM delayed due to Covid-19, this should enable further work to be undertaken on RITA before PRISM launches.</p>	<p>Ongoing – Dan Howard</p>
<p>We may not have all the right data from the sector (from inspections or the Register) to make informed interventions, for instance on add-ons.</p>	<p>As part of planning the add-ons project we will look at the evidence available and consider whether we can access other information if we do not have this already.</p> <p>We can consider revising our approach on inspection, to ensure that the right information is available (for instance, launching an add-ons audit tool).</p> <p>Process to be established for reviewing data on the Register and adding fields when required.</p>	<p>In place - Laura Riley</p> <p>Audit tool being tested and launched in clinics from Autumn 2020 - Rachel Cutting</p> <p>Within 2020/2021 business year - Dan Howard</p>
<p>We may face barriers to adding fields to the Register, preventing us from collecting the right data to reflect changes in the sector. This might reduce the evidence available to inform regulatory interventions and maintain patient safety as the sector changes.</p>	<p>Process to be established for reviewing data on the Register and adding fields when required.</p>	<p>Within 2020/2021 business year - Dan Howard</p>
<p>Risk interdependencies (ALBs / DHSC)</p>	<p>Control arrangements</p>	<p>Owner</p>
<p>DHSC - If there was a review of our regulatory powers, there would be a strong interdependency with the Department of Health and Social Care.</p>	<p>Early engagement with the Department to ensure that they are aware of HFEA position in relation to any future review of the legislation.</p> <p>For example, provided a considered response to the Department’s storage consent consultation to set out the HFEA position.</p>	<p>Peter Thompson</p>

I1: There is a risk that HFEA becomes an ineffective information provider, jeopardising our ability to improve quality of care and make the right information available to people.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
4	3	12 - high	2	3	6 - Medium
Tolerance threshold:					8 - Medium
Status: Below tolerance					

Risk area	Risk owner	Links to which strategic objectives?	Trend
Information provision I1: short description	Clare Ettinghausen, Director of Strategy and Corporate Affairs	The right information	New risk April -↔↔

Commentary

Information provision is a key part of our regulatory duties and it is a fundamental to us being able to regulate effectively. We provide information to the public, patients, partners, donors, the donor conceived, their families and clinics alike. If we are not seen as relevant then we risk our information not being used which in turn may affect the quality of care, outcomes and options available to those involved in treatment.

Causes / sources	Controls	Status / timescale / owner
People don't find us/our information, meaning we are unable to get clear and unbiased information to patients, donors and others.	Knowledge of key searches and work to improve search engine optimisation to ensure that we will be found. We have a rolling bi-annual cycle to review website content and can revise website content to ensure this is optimised for search if necessary. We undertake activities to raise awareness of our information, such as using social and traditional media. We maintain connections with other organisations to ensure that others link to us appropriately, and so we increase the chance of people finding us.	In place and ongoing - Jo Triggs
We aren't in the places that people look for information meaning they do not find us. In some cases, this is because we have decided not to be, for instance on some social media platforms.	We are developing relationships with key influencers to ensure that we have an indirect presence on social media or forums.	In place and ongoing - Jo Triggs

<p>We might undermine our own role as an information provider by partnering with too many other stakeholders to provide information or doing so in an ad hoc and non-strategic way.</p>	<p>Ensure a stakeholder engagement plan is agreed and revisited frequently.</p> <p>Stakeholder engagement plans considered as part of project planning to ensure this is effective.</p>	<p>Early work done but development needed, future control – Clare Ettinghausen</p> <p>Ongoing – Paula Robinson</p>
<p>We have more competition to get information out to people. For instance, other companies have set up their own clinic comparison sites, or clinics post their own data.</p>	<p>Monitoring of clinic websites at the renewal inspection point to ensure that the data there is accurate and in line with guidance.</p> <p>Ensure we maximise the information on our website and the unique features of our clinic inspection information and patient ratings. Clinics are encouraged to ask patients to use the HFEA patient rating system. We have optimised Choose a Fertility Clinic so that it is one of the top sites that patients will find when searching online.</p>	<p>In place and regularly reviewed - Rachel Cutting, Sharon Fensome Rimmer</p> <p>In place and ongoing - Jo Triggs</p>
<p>There are gaps in key strategic information flows on our website, for instance after treatment, resulting in missed opportunities to share information.</p>	<p>Digital Communications Board with membership from across the organisation in place to discuss information available and identify any gaps and what to do to fill these.</p>	<p>In place and ongoing - Jo Triggs</p>
<p>We don't signpost effectively elsewhere resulting in us trying to reinvent the wheel and stepping on other organisation's toes rather than targeting our resources.</p>	<p>We have an ongoing partnership with NHS.UK to get information to patients early in their fertility journey and signpost them to HFEA guidance and information.</p> <p>Links to other specialist organisations in place as relevant on the website (ie, Fertility Network UK, BICA, BFS, Endometriosis UK etc).</p>	<p>In place and ongoing - Jo Triggs</p>
<p>We may provide too much information, leading to information overload and lack of clarity about what information we provide and how.</p>	<p>Regular review cycle for website ensures that the information provided is relevant.</p>	<p>In place and ongoing - Jo Triggs</p>
<p>We provide inaccurate information to the media or public enquiries.</p>	<p>Regular communication between relevant teams. Information provided in enquiries is checked within teams and by legal or at a more senior level if needed.</p> <p>Briefings when key reports etc are issued to ensure others know the key issues, statistics etc.</p>	<p>In place and ongoing - Jo Triggs, Joanne Anton</p> <p>In place and ongoing – Nora Cooke O'Dowd</p>

<p>Given the advent of increased DNA testing, we no longer hold all the keys on donor data. Donors and donor conceived offspring may not have the information they need to deal with this.</p>	<p>Maintain links with donor organisations to mutually signpost information and increase that chance that this will be available to those in this situation.</p> <p>Developed links with DNA testing organisations to ensure that they provide information to those using direct to consumer tests about the possible implications.</p>	<p>In place and ongoing - Jo Triggs</p> <p>In place and ongoing - Laura Riley</p>
<p>Our OTR workload will increase in 2021/2023 (when children born after anonymity was lifted turn 16 and 18) and we may lack the capability to deal sensitivity with donor issues.</p>	<p>Plans to undertake service redesign work to review resourcing and other requirements for OTR to ensure these are fit for purpose.</p>	<p>Future control – to be undertaken in Q3/4 2020/2021 - Dan Howard</p>
<p>Ineffective media management may mean we don't correct incorrect information available elsewhere or signpost our own.</p>	<p>Good media monitoring service in place that is checked daily to identify items where a decision should be taken about need to correct information or not.</p> <p>We review the contract for our media monitoring service annually to ensure that it is fit for purpose. We would choose an alternate provider if this was not working effectively.</p> <p>Relationship with the media ensures that we are asked for comment and that we have internal processes in place to provide the comment in an effective way.</p>	<p>In place and ongoing - Jo Triggs</p> <p>In place - Jo Triggs</p> <p>Jo Triggs – Last reviewed January 2020</p>
<p>We may not have a coordinated approach to contacting PRs, if we send emails to them in an ad hoc way, meaning that they are overloaded with information or requests, or that they receive inconsistent messages.</p>	<p>While we are managing the impact of Covid-19 on the sector, all communications with clinics are going through Rachel Cutting to ensure a coordinated approach.</p> <p>PRs must ensure that they can discharge their duties and responding to HFEA correspondence is one element of that. To support this, correspondence is also sent to LHs in relation Covid-19.</p> <p>PR email addresses are not readily available to all users, which prevents uncontrolled emailing.</p>	<p>In place – Rachel Cutting</p>
<p>We may not get our information out to clinics if they do not use the clinic portal.</p>	<p>We duplicate essential communications by also sending via email to the centres' PR and LH (for instance, all Covid-19 correspondence).</p> <p>We actively encourage all PRs to make full use of the clinic portal.</p>	<p>In place - Rachel Cutting</p>
<p>Clinic Focus may not go out to the right people in clinics, meaning that they do not receive our information this way.</p>	<p>New PRs are added to the Clinic Focus mailing list when they become the PR, to ensure that they receive this information.</p> <p>Critical information is sent directly to PRs' email addresses and not via Clinic Focus.</p>	<p>SOPs revised April 2020 - Sharon Fensome-Rimmer</p> <p>In place – Rachel Cutting</p>

<p>Risk that key regulatory information will be missed if Clinic Focus, Clinic Portal or emails are not being read.</p>	<p>As above, there is a statutory duty for PRs to stay abreast of updates.</p> <p>We ensure that the Code and other regulatory tools are up to date, so that clinics find the right guidance when they need it regardless of additional communicated updates.</p> <p>We are considering implementing a formal annual catch-up between clinics and an inspector.</p>	<p>In place – Rachel Cutting</p> <p>In place – Laura Riley, Joanne Anton</p> <p>Possible future control, TBC – Rachel Cutting</p>
<p>We don't provide tangible insights for patients in inspection reports to inform their decision making.</p>	<p>Review of inspection reports is underway to identify future improvements to inspection reports.</p> <p>We do provide patient and inspector ratings on CaFC to provide some additional insight into clinics.</p>	<p>In place – Rachel Cutting</p>
<p>Risk interdependencies (ALBs / DHSC)</p>	<p>Control arrangements</p>	<p>Owner</p>
<p>None.</p>		

P1: There is a risk that we don't position ourselves effectively and so cannot influence and regulate optimally for current and future needs.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
4	4	16	3	3	9 - Medium
Tolerance threshold:					9 - Medium
Status: At tolerance					

Risk area	Risk owner	Links to which strategic objectives?	Trend
Positioning and influencing P1: strategic reach and influence	Clare Ettinghausen – Director of Strategy and Corporate Affairs	Shaping the future and whole strategy	New risk April -↔↔

Commentary

This risk is about us being in a position to influence effectively to achieve our strategic aims. If we do not ensure we are, we may not be involved in key debates and developments, others will not present the HFEA perspective, meaning we may be voiceless, or our strategic impact may be limited.

Although we have not yet publicly launched our new strategy, the decisions taken over the next months prior to its launch will have an impact on these strategic risk areas, so we are already beginning to think about these risks and controls in order to manage them effectively.

Causes / sources	Controls	Status/timescale / owner
We may not engage widely enough or have the contacts and reach we need to undertake key work, meaning aspects of the strategy are too big to complete within our resources.	Ensure a stakeholder engagement plan is agreed and revisited frequently. Stakeholder identification undertaken for all projects to ensure that these are clear from the outset of planning, and that we can plan communications, involvement and if necessary, consultations, appropriately.	Early work done but development needed, future control – Clare Ettinghausen In place - Paula Robinson
We may be unable to persuade partner organisations to utilise their powers/influence/resources to achieve shared aims.	Early engagement with such organisations, to build on shared interests and reduce the likelihood of this becoming an issue. For instance, the treatment add-ons working group.	In place - Clare Ettinghausen

The sector may disagree with HFEA about key strategic terms and principles, such as 'ethical care' creating negative publicity for us and reputational damage.	We will clearly communicate our intentions, to ensure that these are not misunderstood or misinterpreted and engage with our established stakeholder groups.	In place - Clare Ettinghausen
The sector may take a different view on the evidence HFEA provides in relation to Add-ons and so we may be ignored.	The working group for the add-ons project will focus on building on earlier consensus and pull together key stakeholders to reduce the likelihood of guidance and evidence being dismissed. SCAAC sharing evidence it receives and having an open dialogue with the sector on add-ons.	Ongoing - Laura Riley
In relation to changes, HFEA and sector interests may be in conflict, damaging our reputation. This may particularly be the case in relation to Covid-19 and the use, variation and, in time, revocation of General Directions 0014 (GD0014).	Decisions taken within the legal framework of the Act and supported by appropriate evidence, which would ensure these are clear and defensible. Framework for decision making around varying or revoking GD0014 drawn up following Authority discussion.	In place - Peter Thompson In place – Rachel Cutting
We may not engage with early adopters or initiators of new treatments/innovations or changes in the sector.	We are investigating holding an annual meeting with key innovators.	Future control - Clare Ettinghausen
Risk interdependencies (ALBs / DHSC)	Control arrangements	Owner
DHSC: The Department may not consider future HFEA regulatory interests or requirements when planning for any future consideration of relevant legislation which could compromise the future regulatory regime.	Early engagement with the Department to ensure that they are aware of HFEA position in relation to any future review of the legislation. Provided a considered response to the Department's storage consent consultation to set out the HFEA position.	Ongoing - Peter Thompson Underway, Spring 2020 - Joanne Anton
Government: Any consideration of the future legislative landscape may become politicised.	There are no preventative controls for this, however, clear and balanced messaging between us, the department and ministers may reduce the impact. Develop improved relationships with MPs and Peers to ensure our views and expertise are taken into account.	Ongoing - Peter Thompson
Government: Consideration of changes to the regulatory framework may be affected by political turbulence (for instance changes of Minister).	There are no preventative controls for this, however, we will ensure that we are prepared to effectively brief any future incumbents to reduce turbulence. We would also do any horizon scanning as the political landscape changed if needed.	Ongoing - Peter Thompson

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
5	5	25–Very High	5	3	15 – High
Tolerance threshold:					9 - Medium
Status: Above tolerance					

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
<p>Due to Covid-19 and the suspension and subsequent control of clinic treatment activities this is a live issue for 2020/2021 since we have limited income for as long as GD0014 (version 2) is in place. Furthermore, although clinics can now resume treatment, even for those that do, it may take some time for activity to return to normal levels which means that our income will be lower than planned.</p> <p>We have sufficient cash reserves to meet all liabilities due until the end of August. We are in discussion with the Department of Health and Social Care to provide additional funding and cash, to ensure that we can operate until normal activity resumes.</p> <p>An initial options appraisal for a fee review project will go to the Authority in June. A consultation and modelling for the new income model will follow, with the intention to launch this in 2021/2022, subject to Authority agreement. This should ensure that the income model is fit for purpose and reflects the changing nature of sector activity, and the set the HFEA up for the future.</p>

Causes / sources	Controls	Timescale / owner
<p>There is uncertainty about the annual recovery of treatment fee income – this may not cover our annual spending.</p> <p>This is no longer a risk – this is a live issue for 2020/2021 as we have reduced income for as long as GD0014 (version 2) is in place and furthermore we expect that as clinics reopen it will take some time for activity to return to normal levels.</p>	<p>Heads see quarterly finance figures and would consider what work to deprioritise or reduce should income fall below projected expenditure.</p> <p>We have a model for forecasting treatment fee income, and this reduces the risk of significant variance, by utilising historic data and future population projections. We will refresh this model quarterly internally and review at least annually with AGC.</p> <p>We are undertaking a fee review project in 2020/2021 to ensure that the income model is fit for purpose and reflects the changing nature of sector activity.</p>	<p>Quarterly, ongoing, with AGC model review at least annually - - Richard Sydee</p> <p>Planning underway – Peter Thompson and Richard Sydee</p>

	We are discussing with the Department of Health and Social Care how this issue will be managed.	
<p>Our monthly income can vary significantly as:</p> <ul style="list-style-type: none"> it is linked directly to level of treatment activity in licensed establishments we rely on our data submission system to notify us of billable cycles. <p>As at May 2020 we have very limited income due to the deployment of GD0014 in response to Covid-19.</p>	<p>Our reserves policy takes account of monthly fluctuations in treatment activity and we have sufficient cash reserves to function normally for a period of two months if there was a steep drop-off in activity. The reserves policy was reviewed by AGC in June 2019.</p> <p>If clinics were not able to submit data and could not be invoiced for more than three months, we would invoice them on historic treatment volumes and reconcile this against actual volumes once the submission issue was resolved and data could be submitted.</p>	<p>Given the Covid-19 related drop in income, we are now actively employing this control – Richard Sydee</p> <p>In place – Richard Sydee</p>
Annual budget setting process lacks information from directorates on variable/additional activity that will impact on planned spend.	<p>Annual budgets are agreed in detail between Finance and Directorates with all planning assumptions noted. Quarterly meetings with Directorates flag any shortfall or further funding requirements.</p> <p>All project business cases are approved through CMG, so any financial consequences of approving work are discussed.</p>	<p>Quarterly meetings (ongoing) – Morounke Akingbola</p> <p>Ongoing – Richard Sydee</p>
<p>Additional funds have been required for the completion of PRISM and the data migration work and this will constrain HFEA finances and may affect other planned and ad hoc work.</p> <p>This may not be sufficient to complete the work if it is delayed due to Covid-19.</p>	<p>The most cost-effective approach was taken to procure external support to reduce costs and the resulting impact.</p> <p>Ongoing monitoring and reporting against control totals to ensure we do not overspend.</p> <p>Funding has now been received from the Department to complete the PRISM programme.</p>	<p>Procurement underway – Richard Sydee</p> <p>Ongoing – Richard Sydee</p>
Inadequate decision-making leads to incorrect financial forecasting and insufficient budget.	<p>Within the finance team there are a series of formalised checks and reviews, including root and branch analyses of financial models and calculations.</p> <p>The organisation plans effectively to ensure enough time and senior resource for assessing core budget assumptions and subsequent decision making.</p>	<p>In place and ongoing - Richard Sydee</p> <p>Quarterly meetings (ongoing) – Morounke Akingbola</p>
Project scope creep leads to increases in costs beyond the levels that have been approved.	<p>Finance staff member present at Programme Board. Periodic review of actual and budgeted spend by Digital Projects Board (formerly IfQ) and monthly budget meetings with finance.</p> <p>Any exceptions to tolerances are discussed at Programme Board and escalated to CMG at</p>	<p>Ongoing – Richard Sydee or Morounke Akingbola</p> <p>Monthly (ongoing) – Olaide Kazeem</p>

	monthly meetings, or sooner, via SMT, if the impact is significant or time critical.	
Failure to comply with Treasury and DHSC spending controls and finance policies and guidance may lead to serious reputational risk and a loss of financial autonomy or goodwill for securing future funding.	<p>The oversight and understanding of the finance team ensures that we do not inadvertently break any rules. The team's professional development is ongoing, and this includes engaging and networking with the wider government finance community.</p> <p>All HFEA finance policies and guidance are compliant with wider government rules. Policies are reviewed annually, or before this if required. Internal oversight of expenditure and approvals provides further assurance (see above mitigations).</p>	<p>Continuous - Richard Sydee</p> <p>Annually and as required – Morounke Akingbola</p>
Risk interdependencies (ALBs / DHSC)	Control arrangements	Owner
DHSC: Covid-19 impacts on HFEA income.	The final contingency for all our financial risks is to seek additional cash and/or funding from the Department and we are in active discussion with the Department about this issue.	Ongoing - Richard Sydee
DHSC: Legal costs materially exceed annual budget because of unforeseen litigation.	<p>Use of reserves, up to appropriate contingency level available at this point in the financial year.</p> <p>The final contingency for all our financial risks would be to seek additional cash and/or funding from the Department.</p>	Monthly – Morounke Akingbola
DHSC: GIA funding could be reduced due to changes in Government/policy.	<p>A good relationship with DHSC Sponsors, who are well informed about our work and our funding model.</p> <p>Annual budget has been agreed with DHSC Finance team. GIA funding has been provisionally agreed through to 2021.</p>	<p>Quarterly accountability meetings (ongoing) – Richard Sydee</p> <p>December/January annually, – Richard Sydee</p>

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	3	3	9- Medium
Tolerance threshold:					12 - High
Status: Below tolerance.					

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

Commentary
<p>This risk and the controls are focused on organisational capability, rather than capacity, though there are obviously some linkages between capability and capacity.</p> <p>For 2019/2020 Turnover was 12.2% (in 2018/19 this was 26.8%). This reduction in turnover suggests that we are currently in a more stable situation and this will naturally strengthen our capabilities as staff develop more experience in their roles. We have also often been able to recruit internally which has assisted in reducing turnover as staff have been able to develop their careers within the HFEA. We have taken active steps to improve retention, focussing on things that we can control like learning and development.</p> <p>AGC receive 6-monthly updates on capability risk to consider our ongoing strategies for the handling of these, to allow them to track progress. Looking further ahead, we need to find ways to tackle the issue of development opportunities, to prevent this risk increasing further. An idea we are keen to explore is whether we can build informal links or networks with other public sector or health bodies, to develop clearer career paths between organisations.</p> <p>We have two Authority member vacancies which create Board capability gaps, these risks are captured in the separate C2 risk, below.</p> <p>Although we have reduced our assessment of this risk score in May 2020, we are aware that ongoing impacts of Covid-19 may affect capability in future months, and we are considering approaches to manage this as the situation develops.</p>

Causes / sources	Mitigations	Status/Timescale / owner

<p>High turnover, sick leave etc., leading to temporary knowledge loss and capability gaps.</p>	<p>Organisational knowledge captured via documentation, handovers and induction notes, and manager engagement.</p> <p>We have developed corporate guidance for all staff for handovers. A checklist for handovers is circulated to managers when staff hand in their notice. This checklist will reduce the risk of variable handover provision.</p>	<p>In place – Yvonne Akinmodun</p> <p>Checklist in use – Yvonne Akinmodun</p>
	<p>Vacancies are addressed speedily, and any needed changes to ways of working or backfill arrangements receive immediate attention.</p> <p>CMG and managers prioritise work appropriately when workload peaks arise.</p> <p>Contingency: In the event of knowledge gaps we would consider alternative resources such as using agency staff if appropriate.</p>	<p>In place – Yvonne Akinmodun</p> <p>In place – Peter Thompson</p> <p>In place – Relevant Director alongside managers</p>
<p>Inability to recruit due to Coronavirus leads to capability gaps in the Policy and other teams.</p>	<p>Reprioritisation of workload due to Coronavirus has led to some work being delayed, which reduces the impact of any capability gaps, especially in the Policy team.</p> <p>Pause in OTR workload to ensure that the service can be effectively manned. Will reopen following recruitment to Manager post.</p> <p>Planning to develop a clear internal methodology for return to BAU workload following Covid-19. This will ensure that capability and capacity is sufficient and effectively managed.</p>	<p>Reprioritisation undertaken April 2020 - Laura Riley and Joanne Anton</p> <p>In place - Dan Howard</p> <p>Future control, being developed as at May - Yvonne Akinmodun</p>
<p>Poor morale could lead to staff leaving, opening up capability gaps.</p>	<p>Communication between managers and staff at regular team and one-to-one meetings allows any morale issues to be identified early and provides an opportunity to determine actions to be taken.</p> <p>The staff intranet enables regular internal communications.</p> <p>Ongoing CMG discussions about wider staff engagement (including surveys) to enable management responses where there are areas of concern.</p> <p>Policies and benefits are in place that support staff to balance work and life (stress management resources, mental health first aiders, PerkBox) promoting staff to feel positive about the wider package offered by the HFEA. This may boost good morale.</p>	<p>In place, ongoing – Peter Thompson</p> <p>In place – Jo Triggs</p> <p>In place but staff survey due May 2020 – Yvonne Akinmodun</p> <p>In place - Peter Thompson</p>

<p>Work unexpectedly arises or increases for which we do not have relevant capabilities.</p>	<p>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 at monthly meetings.</p> <p>Team-level service delivery planning for the next business year, with active involvement of team members. CMG will continue to review planning and delivery. Requirement for this to be in place for each business year.</p> <p>Oversight of projects by both the monthly Programme Board and CMG meetings.</p> <p>Review of project guidance to support early identification of interdependencies and products in projects, to allow for effective planning of resources.</p> <p>Planning and prioritising data submission project delivery, within our limited resources.</p>	<p>In place – Paula Robinson</p> <p>In place – Paula Robinson</p> <p>In place – Paula Robinson</p> <p>Ongoing review in progress 2020-2021– Paula Robinson</p> <p>In place until project ends – Dan Howard</p>
<p>The future office move, may not meet the needs of staff (for instance location), meaning staff decide to leave sooner than this, leading to a significant spike in turnover, resulting in capability gaps.</p>	<p>See separate E1 risk for full assessment of risk causes and controls.</p>	<p>Early engagement with staff and other organisations underway and ongoing – Richard Sydee</p>
<p>Possible capability benefits of colocation with other organisations, arising out of the office move, such as the ability to create career pathways and closer working may not be realised.</p>	<p>Active engagement with other organisations early on.</p> <p>We are collaborating with other relevant regulators to see what more can be done to create career paths and achieve other benefits of working more closely, including mentorship programme.</p>	<p>Ongoing – Richard Sydee</p> <p>Early progress, ongoing – Yvonne Akinmodun</p>
<p>Risk interdependencies (ALBs / DHSC)</p>	<p>Control arrangements</p>	<p>Owner</p>
<p>Government/DHSC</p> <p>The UK leaving the EU may have unexpected operational consequences for the HFEA for which we do not have the relevant capabilities.</p>	<p>We continue to work closely with the Department to ensure that we are prepared and can provide detailed guidance to the sector at the earliest opportunity, to limit any impact on patients. We have provided ongoing updates to the sector.</p> <p>Since December 2018, we have run an EU exit project to ensure that we fully consider implications and are able to build enough knowledge and capability to handle the effects of the UK's exit from the EU. We will progress this project through the transition period.</p> <p>We continue to engage with DHSC and clinics to prepare for EU exit. Actions will depend on the</p>	<p>Communications ongoing – Peter Thompson</p>

	progress of the UK/EU talks. Authority and AGC are also updated at their meetings, as appropriate.	
<p>In-common risk</p> <p>Covid-19 (Coronavirus) may lead to high levels of staff absence leading to capability gaps or need to redeploy staff.</p>	<p>Management discussion of situation as it emerges, to ensure a responsive approach to any developments.</p> <p>We have reviewed our business continuity plan to ensure it is fit for purpose.</p>	<p>Ongoing - Peter Thompson</p>

C2: Failure to appoint new or reappoint current Authority members within an appropriate timescale leads to loss of knowledge and may impact formal decision-making.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
4	5	20 - Very High	4	4	16 - High
Tolerance threshold:					4 - Low
Status: Above tolerance					

Risk area	Risk owner	Links to which strategic objectives?	Trend
Estates C2: Board capability	Peter Thompson Chief Executive	Whole strategy.	↔ ↔ ↔ ↔

Commentary

The HFEA board is unusual as members undertake quasi-judicial decision-making as part of their roles, sitting on licensing and other committees. This means that changes in Board capability and capacity may impact the legal functions of the Authority. We need to maintain sufficient members with sufficient experience to take what can be highly controversial decisions in a robust manner. As such our tolerance threshold for this risk is low.

Out of a current Board membership of 14, we have two vacancies. In addition, two members' terms end on 11 November 2020, bringing the Board membership down to ten. The Chair's term expires on 31 March 2021. Three other senior Authority members' terms also end on that date. If we are not able to recruit to all these positions, the membership would be reduced to six. This would pose a significant challenge to robust statutory decision-making and knowledge management. The extension of the Chair's term to 2021 is helpful, however recruitment is not yet underway for any of these posts.

We are in contact with the Department on how and when recruitment will be handled in the light of Covid-19.

Causes / sources	Mitigations	Status/timescale / owner
As at May 2020, we have two member vacancies. The reduction of available members that is possible by March 2021, including the Chair, would put at risk our ability to meet our statutory responsibilities to licence fertility clinics and research centres and authorise treatment for serious inherited illnesses.	Membership of licensing committees has been actively managed to ensure that formal decision-making can continue unimpeded by the current board vacancies. However, there is no guarantee that this would be possible for future vacancies, especially if there were several at once and bearing in mind that a lay/professional balance must be maintained for some committees.	In place, ongoing - Paula Robinson

<p>The uncertainty about the position of the Chair role may result in a gap in leadership and direction for the Authority.</p> <p>The Chair's term has been extended until March 2021, which gives more time to consider controls, though it only changes the proximity of this risk.</p>	<p>Given the Deputy Chair's current term of office also ends in 2021, our previous controls, for the Deputy Chair to take over on a temporary basis, subject to approval, will no longer be fit for purpose.</p>	<p>Further controls to be considered - Peter Thompson</p>
<p>Any member recruitment may take some time and therefore give rise to further vacancies and capability gaps.</p> <p>The recruitment process is run by DHSC meaning we have limited power to influence this risk source.</p> <p>Historically, decisions on appointments have taken some time which may create additional challenges for planning. Meanwhile, the annual report from the commission for public appointments suggests appointments take on average five months.</p>	<p>The Chair/CEO are in close contact with the Department to agree a recruitment timetable.</p>	<p>In progress, timescale TBC - Peter Thompson</p>
<p>Several current Board members are on their second terms in office, which expire within the same period (six Members of the Board by March 2021, in addition to the two pre-existing vacancies).</p>	<p>We are discussing options with the Department for managing the cycle of appointments, in order to reduce the impact of this.</p>	<p>In progress, ongoing - Peter Thompson</p>
<p>The induction time of new members (including bespoke legal training), particularly those sitting on licensing committees, may lead to a loss of collective knowledge and potentially an impact on the quality of decision-making.</p> <p>Evidence from current members suggests that it may take up to a year for members to feel fully confident.</p>	<p>The Governance team are reviewing recruitment information and member induction to ensure that this will be as smooth as possible once it starts.</p>	<p>In progress, ongoing - Paula Robinson</p>
<p>Induction of new members to licensing and other committees, will require a significant amount of internal staff resource and could reduce the ability of the</p>	<p>We will be mindful of this resource requirement when planning other work, in order to limit the impact of induction on other priorities.</p>	<p>In progress, as timescales become clear - Peter Thompson,</p>

governance and other teams to support effective decision-making.		Paula Robinson
Risk interdependencies (ALBs / DHSC)	Control arrangements	Status/timescale / owner
Government/DHSC The Department is responsible for our Board recruitment but is bound by Cabinet Office guidelines.	CEO letter to DHSC Permanent Secretary on 10 December to clarify this risk interdependency and recommend that member appointments should be added to Departmental risk register.	Raised December 2019 - Peter Thompson
Government/DHSC DHSC is responsible for having an effective arm's length body in place to regulate ART. If it does not ensure this by effectively managing HFEA Board recruitment, it will be breaching its own legal responsibilities.	CEO letter to DHSC Permanent Secretary on 10 December to clarify this risk interdependency and recommend that member appointments should be added to Departmental risk register.	Raised December 2019 - Peter Thompson
Government/DHSC HFEA operates in a sensitive area of public policy, meaning there may be interest from central government in the appointments process. We are unsure of the intended approach of any future government. This may impact any planned approach and risk mitigations and give rise to further risk.	CEO letter to DHSC Permanent Secretary on 10 December to clarify this risk interdependency and recommend that member appointments should be added to Departmental risk register.	Raised December 2019 - Peter Thompson

CS1: There is a risk that the HFEA is subject to a cyber-attack, resulting in data or sensitive information being compromised, or IT services being unavailable.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
5	4	20 – Very high	3	3	9 - Medium
Tolerance threshold:					9 - Medium
Status: At tolerance					

Risk area	Risk owner	Links to which strategic objectives?	Trend
Cyber security CS1: Security and infrastructure weaknesses	Rachel Cutting Director of Compliance and Information	Whole strategy	↔ ↔ ↔ ↔

Commentary
<p>Cyber-attacks and threats are inherently very likely. Our approach to handling these risks effectively includes ensuring we:</p> <ul style="list-style-type: none"> • have an accurate awareness of our exposure to cyber risk • have the right capability and resource to handle it • undertake independent review and testing • are effectively prepared for a cyber security incident • have external connections in place to learn from others. <p>We continue to assess and review the level of national cyber security risk and act as necessary to ensure our security controls are robust and are working effectively.</p> <p>Delays to PRISM delivery necessitate the continued use of EDI in clinics. Many clinics use older server technology to run our EDI gateway within their clinic or organisation resulting in an increased cyber risk while that technology is in use. We are supporting many to upgrade their infrastructure to reduce the likelihood of a cyber incident. The related cyber risk concerns an attack on the clinic’s infrastructure – and all have local logical and physical security controls in place. We are aware of the related cyber risk. All submission data is encrypted in transit. We continue to work with clinics to support the upgrade of their server infrastructure.</p>

Causes / sources	Controls	Timescale / owner
Insufficient board oversight of cyber security risks, resulting in them not being managed effectively.	Routine cyber risk management delegated from Authority to Audit and Governance Committee which receives reports at each meeting on cyber-security and associated internal audit reports to assure the Authority that the internal approach is appropriate and ensure they are aware of the organisation’s exposure to cyber risk (preventative control).	In place – Dan Howard

	<p>The Deputy Chair of the Authority and AGC is the cyber lead who is regularly appraised on actual and perceived cyber risks. These would be discussed with the wider board if necessary (preventative control).</p> <p>Annual cyber security training in place to ensure that Authority are appropriately aware of cyber risks and responsibilities (preventative control).</p>	<p>In place - Peter Thompson</p> <p>Last undertaken January 2020 – Dan Howard</p>
<p>Insufficient executive oversight of cyber security risks, resulting in them not being managed effectively</p>	<p>Cyber security training in place to ensure that all staff are appropriately aware of cyber risks and responsibilities (preventative control).</p> <p>Regular review of cyber / network security policies to ensure they are appropriate and in line with other guidance.</p> <p>We undertake independent review and test our cyber controls, to assure us that these are appropriate (preventative control).</p> <p>Regular review of business continuity plan to ensure that this is fit for purpose for appropriate handling cyber security incidents to minimise their impact (corrective control).</p>	<p>Last undertaken by all staff June 2019. Due June 2020 – Dan Howard</p> <p>Update to go to CMG in June 2020 – Dan Howard</p> <p>In place, review last undertaken March 2019 – Dan Howard</p> <p>In place, review last undertaken May 2019 – Dan Howard</p>
<p>Changes to the digital estate open up potential attack surfaces or new vulnerabilities. Our relationship with clinics is more digital, and patient identifying information or clinic data could therefore be exposed to attack.</p>	<p>Penetration testing of newly developed systems (PRISM, the Register) assure us that development has appropriately considered cyber security.</p> <p>Clear information security guidance to HFEA staff about how identifying information should be shared, especially by the Register team, to reduce the chance of this being vulnerable.</p>	<p>In place and further testing planned before going live – Dan Howard</p> <p>In place – Dan Howard</p>
<p>The IT support function may not provide us with the cyber security resource that we need (ie, emergency support in the case of dealing with attacks)</p>	<p>We have an arrangement with a third-party IT supplier who would be able to assist if we did not have enough internal resource to handle an emergency for any reason.</p>	<p>Contract in place until May 2021 with option to extend until May 2023 – Dan Howard</p>

<p>We may not effectively mitigate emerging or developing cyber security threats if we are not aware of these.</p>	<p>We maintain external linkages with other organisations to learn from others in relation to cyber risk.</p>	<p>Ongoing (such as ALB CIO network) – Dan Howard</p>
<p>We may have technical or system weaknesses which could lead to loss of, or inability to access, sensitive data, including the Register.</p>	<p>We undertake regular penetration testing to identify weaknesses so that we can address these.</p> <p>We have advanced threat protection in place to identify and effectively handle threats.</p> <p>Our third-party IT supplier undertakes daily checks on our server infrastructure to monitor for any errors and to monitor for any security issues or increased threats.</p> <p>We regularly review and if necessary, upgrade software to improve security controls for network and data access, such as Remote Access Service (RAS) software.</p> <p>We regularly review and if necessary, upgrade software to improve security controls for telephony</p>	<p>Ongoing (last test May 2019) – Dan Howard</p> <p>In place – Dan Howard</p> <p>In place – Dan Howard</p> <p>Ongoing (Last review and upgrade to Pulse RAS system April 2020) – Dan Howard</p> <p>Ongoing (Last review and upgrade to Microsoft Teams system April 2020) – Dan Howard</p>
<p>Physical devices used by staff are lost, stolen or otherwise fall into malicious hands, increasing chance of a cyber-attack.</p>	<p>Hardware is encrypted, which would prevent access to data if devices were misplaced. (corrective control)</p> <p>Staff reminded during IT induction about the need to fully shut down devices while outside of secure locations (such as travelling) in order to implement encryption (corrective control).</p>	<p>Ongoing (regular reminders sent to staff with security best practice) – Dan Howard</p>
<p>Remote access connections and hosting via the cloud may create greater opportunity for cyber threats by hostile parties.</p>	<p>All cloud systems in use have appropriate security controls, terms and conditions and certifications (ISO and GCloud) in place.</p> <p>We have an effective permission matrix and password policy.</p> <p>Our web configuration limits the service to 20 requests at any one time.</p> <p>The new Register will be under the tightest security when this is migrated to the cloud.</p>	<p>In place – Dan Howard</p> <p>In place – Dan Howard</p> <p>In place – Dan Howard</p> <p>To be implemented – Dan Howard</p>

<p>The continued use of EDI by clinics during the extended delivery of PRISM means the end of life server version used for the EDI gateway application (which processes data from EDI or 3rd party servers into the HFEA Register) continues to be used. This may therefore be more vulnerable to attack as it becomes unsupported.</p>	<p>Data submitted through the EDI gateway application is encrypted in transit, which reduces the likelihood of sensitive information being accessed. (corrective control)</p>	<p>In place – Dan Howard</p>
<p>Risk interdependencies (ALBs / DHSC)</p>	<p>Control arrangements</p>	<p>Owner</p>
<p>None. Cyber-security is an 'in-common' risk across the Department and its ALBs.</p>		

E1: There is a risk that the HFEA’s office relocation in 2020 leads to disruption to operational activities and delivery of our strategic objectives.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
4	4	16	3	3	9 - Medium
Tolerance threshold:					8 - Medium
Status: Above tolerance					

Risk area	Risk owner	Links to which strategic objectives?	Trend
Estates E1: Relocation of HFEA offices in 2020	Richard Sydee Director of Finance and Resources	Whole strategy.	↔ ↑ ↔ ↔

Commentary
<p>An internal project is in place to prepare for the office move, handle the direct impacts of the move on the organisation and ensure that we actively prepare and mitigate associated risks. This feeds into a larger programme managed by DHSC.</p> <p>We have made progress in reviewing working practices and policies and have launched several of these. Several cross-ALB working groups have been established and are actively defining requirements and solutions and these are feeding into the HFEA internal project.</p> <p>Covid-19 has had significant impacts on the office move and may result in a delay to HFEA being able to move. The overall DHSC programme is currently considering various contingency plans. These will ensure that we are able to continue to operate if the move is delayed. Due to this emerging risk, SMT raised the risk score in April.</p>

Causes / sources	Controls	Status/Timescale / owner
<p>The facilities provided in the Stratford office may not fulfil all HFEA requirements and desired benefits, such as ability to host key corporate meetings.</p> <p>Note: Covid-19 may have altered the requirements of the HFEA.</p>	<p>HFEA requirements were specified up front and feedback given on all proposed designs. Outline plans are in line with HFEA needs and we have staff on the working groups set up to define the detail.</p> <p>We will revisit our requirements and ways of working in the light of the changed circumstances we are in due to Covid-19.</p> <p>If lower-priority requirements are unable to be fulfilled, conversations will take place about alternative arrangements to ensure HFEA delivery is not adversely affected.</p>	<p>Ongoing – Richard Sydee</p> <p>Future control as part of Covid-19 management – Richard Sydee</p> <p>Contingency if required – Richard Sydee</p>

Causes / sources	Controls	Status/Timescale / owner
	Arrangements need to be put in place to ensure that costs and access are shared equitably.	Discussions underway – Richard Sydee
<p>We may be unable to recruit staff as they do not see the HFEA as an attractive central London organisation.</p> <p>Note: Move to Stratford noted in all job adverts. Recruitment data to date suggests we are not seeing an impact on recruitment. We will continue to monitor this to consider whether other mitigations are needed/possible.</p>	<p>We will continue to offer desirable staff benefits and policies, such as flexible working, and have reviewed and updated these to ensure that they support staff recruitment and retention.</p> <p>Other civil service and government departments are also being moved out of central London, so this is less likely to impact recruitment of those moving within the public sector.</p>	Completed (however as per above control we may need to revisit in the light of Covid-19) – Yvonne Akinmodun
<p>Stratford may be a less desirable location for some current staff due to:</p> <ul style="list-style-type: none"> • increased commuting costs • increased commuting times • preference of staff to continue to work in central London for other reasons, <p>leading to lower morale and lower levels of staff retention as staff choose to leave before the move.</p>	<p>Work underway to review the excess fares policy to define the length of time and mechanism to compensate those who will be paying more following the move to Stratford.</p> <p>Efforts taken to understand the impact on individual staff and discuss their concerns with them via staff survey, 1:1s with managers and all staff meetings to inform controls. These have informed the policies developed.</p> <p>Conversely, there will be improvements to the commuting times and costs of some staff, which may improve morale for them and balance the overall effect.</p>	<p>Begun but to be completed Q1 2020/21 (subject to Covid-19 developments) – Yvonne Akinmodun, Richard Sydee</p> <p>Done - Yvonne Akinmodun,</p>
<p>The Stratford office may cost more than the current office, once all facilities and shared elements are considered, leading to opportunity costs.</p> <p>The Finance and procurement strand of the project has been delayed and delivery timeframes are still unclear.</p>	<p>Costs for Redman Place (the Stratford building) will be allocated on a usage basis which will ensure that we do not pay for more than we need or use.</p> <p>The longer, ten-year lease at Redman Place will provide greater financial stability, allowing us to forecast costs over a longer period and adjust other expenditure, and if necessary, fees, accordingly, to ensure that our work and running costs are effectively financed.</p> <p>The accommodation at Redman Place should allow us to reduce some other costs, such as the use of external meeting rooms, as we will have access to larger internal conference space not available at Spring Gardens.</p>	Ongoing but with uncertainty about timing of overarching procurement arrangements - Richard Sydee

Causes / sources	Controls	Status/Timescale / owner
<p>The move to a new office will lead to ways of working changes that we may be unprepared for.</p>	<p>HFEA will be discussing ways of working in the aftermath of Covid-19 and in relation the office move, to ensure that these changes happen by design rather than by default.</p> <p>Policies related to ways of working have been agreed and circulated significantly before the move, to ensure that there is time for these to be in and be accepted ahead of the physical move. Staff have been involved and updated as appropriate.</p>	<p>Timing to be confirmed but beginning Q1 – Richard Sydee</p> <p>Done and to continue as these are reviewed following Covid-19 - Richard Sydee, Yvonne Akinmodun</p>
<p>Owing to the different cultures and working practices of the organisations moving, there may be perceived inequity about the policy changes made.</p>	<p>A formal working group is in place including all the organisations who are moving to Stratford with us, to ensure that messaging around ways of working is consistent across organisations, while reflecting the individual cultures and requirements of these.</p> <p>The ways of working group will communicate on these differences, so that staff understand any differences in practice and that the intention is not to homogenise practices.</p>	<p>Ongoing – Richard Sydee</p> <p>Future control – Richard Sydee</p>
<p>Current staff may not feel involved in the conversations about the move, leading to a feeling of being ‘done to’ and lower morale.</p>	<p>Conversations about ways of working occurring throughout the project, to ensure that the project team and HFEA staff are an active part of the discussions and development of relevant policies and have a chance to raise questions.</p> <p>An open approach is being taken to ensure that information is cascaded effectively, and staff can voice their views and participate. We have a separate area on the intranet and Q&A functionality where all information is being shared.</p> <p>Staff have had the opportunity to visit the site ahead of time so that they feel prepared.</p>	<p>Ongoing – Richard Sydee</p>
<p>The internal move project may be ineffectively managed, leading to oversights, poor dependency management and ineffective use of resources.</p>	<p>Regular reporting to Programme Board and CMG to ensure that effective project processes and approaches are followed.</p> <p>Assurance will be provided by regular reporting to AGC and Authority.</p> <p>The Director of Finance and Resources is Sponsoring the project meaning it has appropriate senior, strategic guidance.</p> <p>A project manager has been allocated from the IT team to ensure there is resource available for day to day management of project tasks. Options are being investigated for ongoing project</p>	<p>In place – Richard Sydee</p>

Causes / sources	Controls	Status/Timescale / owner
	<p>management, to ensure sufficient and effective resourcing of this as the project moves into a more advanced phase of delivery.</p> <p>Other key staff such as HR and representatives from other teams involved in the internal HFEA Project team.</p>	
<p>Necessary changes to IT systems and operations may not work effectively, leading to disruption to HFEA delivery.</p>	<p>Communications between HFEA and other organisations' IT teams to determine IT requirements, allowing more time to resolve these.</p> <p>Infrastructure has largely been migrated to the cloud, which will facilitate the move and reduce related risk to IT systems. It will also mean the HFEA should be able to function even if there are IT issues affecting other systems on-site.</p>	<p>In place - Ongoing - Steve Morris, Dan Howard</p> <p>Ongoing - Steve Morris, Dan Howard</p>
<p>The physical move may cause short-term disruption to HFEA activities and delivery, if necessary resources, such as meeting rooms or physical assets, are not available to staff.</p> <p>We may move to Redman Place later which could increase the chance of this disruption or extend it.</p>	<p>Careful planning of the move to reduce the likelihood of disruption. We will increase our focus on planning as we move closer to the move date and reprioritise as required.</p> <p>Staff would be able to work from home in the short-term if there was disruption to the physical move which would reduce the impact.</p> <p>Implementation of enhanced remote access security arrangements in advance of the move.</p>	<p>Ongoing - Richard Sydee</p> <p>In place – Dan Howard</p> <p>Done - Dan Howard</p>
Risk interdependencies (ALBs / DHSC)	Control arrangements	Owner
<p>British Council – lead on physical build – may not understand or take HFEA needs into account.</p>	<p>DHSC liaising directly with the British Council and managing this relationship on behalf of the other organisations, with feedback through the DHSC project board, on which the Director of Finance and Resources sits.</p>	<p>In place – Richard Sydee, DHSC</p>
<p>DHSC – Lead on the whole overarching project, entering into contracts on behalf of HFEA and others – HFEA requirements may not be considered/met.</p>	<p>Regular external programme meetings attended by the Director of Finance and Resources as HFEA Project Sponsor and other HFEA staff when delegation required.</p>	<p>In place – Richard Sydee</p>
<p>NICE/CQC/HRA/HTA – IT, facilities, ways of working interdependencies.</p>	<p>Regular DHSC programme meeting involving all regulators.</p> <p>Sub-groups with relevant IT and other staff such as HR.</p> <p>Informal relationship management with other organisations' leads.</p>	<p>In place – Richard Sydee, DHSC</p>

LC1: There is a risk that the HFEA is legally challenged given the ethically contested and legally complex issues it regulates.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
4	5	20 – Very high	2	4	8 - Medium
Tolerance threshold:					12 - High
Status: Below tolerance					

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
<p>We accept that in a controversial area of public policy, the HFEA and its decision-making will be legally challenged. Our Act and related regulations are complex, and aspects are open to interpretation, sometimes leading to challenge. There are four fundamental sources of legal risk to the HFEA, it may be due to:</p> <ul style="list-style-type: none"> • execution of compliance and licensing functions (decision making) • the legal framework itself as new technologies and science emerge • policymaking approach/decisions • individual cases and the implementation of the law by clinics (often driven by the impact of the clinic actions on patients). <p>Legal challenge poses two key threats:</p> <ul style="list-style-type: none"> • that resources are substantially diverted • that the HFEA’s reputation is negatively impacted by our participation in litigation. <p>These may each affect our ability to regulate effectively and deliver our strategy and at their most impactful they could undermine the statutory scheme the HFEA is tasked with upholding. Both the likelihood and impact of legal challenge may be reduced, but it cannot be avoided entirely. For these reasons, our tolerance for legal risk is high.</p> <p>We have not been directly involved in any litigation since October 2018.</p>

Causes / sources	Mitigations	Timescale / owner
We may face legal challenge about the way we have executed our core regulatory functions of inspection and licensing. For instance, clinics	Where necessary, we can draw on the expertise of an established panel of legal advisors, whose experience across other sectors can be applied to put the HFEA in the best possible position to defend any challenge.	In place – Peter Thompson

<p>challenging decisions taken about their licence.</p>		
<p>We may be legally challenged if new science or technology emerges that may not be covered by the existing regulatory framework.</p>	<p>Scientific and Clinical Advances Advisory Committee (SCAAC) horizon scanning processes. This provides the organisation with foresight and may provide more time and ability to prepare our response to developments.</p> <p>Case by case decisions on the strategic handling of contentious or new issues in order to reduce the risk of challenge or, in the event of challenge, to put the HFEA in the strongest legal position.</p>	<p>SCAAC horizon scanning meetings annually.</p> <p>In place – Catherine Drennan and Peter Thompson</p>
<p>Our policies may be legally challenged if others see these as a threat or ill-founded.</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.</p>	<p>Evidence-based and transparent policymaking, with risks considered whenever a new approach or policy is being developed.</p> <p>We undertake good record keeping, to allow us to identify and access old versions of guidance, and other key documentation, which may be relevant to cases or enquiries and enable us to see how we have historically interpreted the law and implemented related policy and respond effectively to challenge.</p> <p>Business impact target assessments carried out whenever a regulatory change is likely to have a significant cost consequence for clinics meaning that consideration of impacts and how these will be managed is taken into account as part of the policymaking process.</p> <p>Stakeholder involvement and communications in place during policymaking process (for instance via regular stakeholder meetings) to ensure that clinics and others 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.</p>	<p>In place – Laura Riley/Joanne Anton with appropriate input from Catherine Drennan</p> <p>Ongoing - Laura Riley, Joanne Anton</p> <p>In place – Richard Sydee</p> <p>Ongoing - Laura Riley, Joanne Anton</p>
<p>We may face legal challenges related to clinical implementation of regulation in terms of individual cases (ie, consent-related cases).</p> <p>Ongoing legal parenthood and storage consent failings in clinics and related cases are specific ongoing examples. The case by case nature of the Courts’ approach to matters</p>	<p>We undertake good record keeping, to allow us to identify and access old versions of guidance, and other key documentation, which may be relevant to cases or enquiries and enable us to see how we have historically interpreted the law.</p> <p>Through constructive and proactive engagement with third parties, the in-house legal function serves to anticipate issues of this sort and prevent challenges. This strengthens our ability to find solutions that do not require legal action.</p> <p>Legal panel in place, as above, enabling us to outsource some elements of the work. Scenario planning is undertaken with input from legal</p>	<p>Ongoing – Catherine Drennan</p> <p>In place – Catherine Drennan</p>

<p>means resource demands are unpredictable when these arise.</p>	<p>advisors at the start of any legal challenge. This allows the HFEA to anticipate a range of different potential outcomes and plan resources accordingly.</p> <p>We took advice from a leading barrister on the possible options for handling storage consent cases to ensure we take the best approach when cases arise.</p> <p>Some amendments were made to guidance in the Code of Practice dealing with consent to storage and extension of storage, this was launched in January 2019. This guidance will go some way to supporting clinics to be clearer about the legal requirements. Additional amendments will be made in the next update.</p> <p>Storage consent has been covered in the revision of the PR entry Programme (PREP).</p>	<p>In place – Peter Thompson</p> <p>Done in Q1 2018/19 – Catherine Drennan</p> <p>Revised guidance will be provided where appropriate to clinics – Catherine Drennan</p> <p>PREP launched January 2020 – Catherine Drennan/ Laura Riley, Joanne Anton</p>
<p>Committee decisions or our decision-making processes may be contested. ie, Licensing appeals and/or Judicial Reviews.</p> <p>Challenge of compliance and licensing decisions is a core part of the regulatory framework and we expect these challenges even if decisions are entirely well founded and supported. Controls therefore include measures to ensure consistency and avoid process failings, so we are in the best position for when we are challenged, therefore reducing the impact of such challenges.</p>	<p>Compliance and Enforcement policy and related procedures to ensure that the Compliance team acts consistently according to agreed processes.</p> <p>Well-evidenced recommendations in inspection reports mean that licensing decisions are adequately supported and defensible.</p> <p>The Compliance team monitors the number and complexity of management reviews and stay in close communication with the Head of Legal to ensure that it is clear if legal involvement is required, to allow for appropriate involvement and effective planning of work.</p> <p>Panel of legal advisors in place to advise committees on questions of law and to help achieve consistency of decision-making processes.</p> <p>Measures in place to ensure consistency of advice between the legal advisors from different firms. Including:</p>	<p>In place but a review of the Compliance and Enforcement policy underway, due for completion Autumn 2020 – Rachel Cutting, Catherine Drennan</p> <p>In place – Sharon Fensome-Rimmer</p> <p>In place – Sharon Fensome-Rimmer</p> <p>In place – Peter Thompson</p> <p>Since Spring 2018 and</p>

	<ul style="list-style-type: none"> • Provision of previous committee papers and minutes to the advisor for the following meeting • Annual workshop • Regular email updates to panel to keep them abreast of any changes. <p>Consistent and well taken decisions at licence committees supported by effective tools for committees and licensing team (licensing pack, Standard operating procedures, decision trees etc) which are regularly reviewed.</p>	<p>ongoing – Catherine Drennan</p> <p>In place – Paula Robinson</p>
<p>Any of the key legal risks may escalate into high-profile legal challenges which may result in significant resource diversion and reputational consequences for the HFEA which risk undermining the robustness of the regulatory regime.</p> <p>We are aware of endeavours to put some test storage consent cases to the courts which may make HFEA involvement more likely.</p>	<p>Close working between legal and communications teams to ensure that the constraints of the law and any HFEA decisions are effectively explained to the press and the public.</p> <p>The default HFEA position is to conduct litigation in a way which is not confrontational, personal or aggressive. We have sought to build constructive relationships with legal representatives who practice in the sector and the tone of engagement with them means that challenge is more likely to be focused on matters of law than on the HFEA.</p> <p>Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise workload should this become necessary.</p>	<p>In place – Catherine Drennan, Joanne Triggs</p> <p>In place – Peter Thompson, Catherine Drennan</p> <p>In place – Peter Thompson</p>
Risk interdependencies (ALBs / DHSC)	Control arrangements	Owner
<p>DHSC: HFEA could face unexpected high legal costs or damages which it could not fund. This is an interdependent risk as the Department must ensure the ability to maintain the regulatory regime.</p>	<p>If this risk was to become an issue then discussion with the Department of Health and Social Care 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 DHSC would be involved in resolving it.</p>	<p>In place – Peter Thompson</p>
<p>DHSC: We rely upon the Department for any legislative changes in response to legal risks or impacts.</p>	<p>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.</p> <p>Departmental/ministerial sign-off for key documents such as the Code of Practice in place.</p>	<p>In place – Peter Thompson</p>
<p>DHSC: The Department may be a co-defendant for handling legal risk when cases arise.</p>	<p>We work closely with colleagues at the Department to ensure that the approach of all</p>	<p>In place – Peter Thompson</p>

	parties is clear and is coordinated wherever possible.	
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CV1: There is a risk that we are unable to undertake our statutory functions and strategic delivery because of the impact of the Covid-19 Coronavirus.

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
Status: At tolerance					

Risk area	Risk owner	Links to which strategic objectives?	Trend
Business Continuity CV1: Coronavirus	Peter Thompson Chief Executive	Whole strategy.	New risk March 2020 -↔ ↔ ↔

Commentary

Risk management of these risk causes has necessarily become our organisational priority over the past few weeks. All staff are working from home and an alternative strategy to manage inspections has been put in place until September. Communications to the sector and patients are in place and ongoing. A business continuity group meets regularly to consider risks and ensure an effective response is developed and maintained.

The Coronavirus risk will have a cascading effect across the whole risk register for the foreseeable future. Where there are specific risk causes related to other core risks these are signposted as relevant.

Causes / sources	Controls	Status/Timescale / owner
Risk of providing incorrect, inconsistent or non-responsive advice to clinics or patients as guidance and circumstances change (ie, not updating our information in a timely manner) and this leading to criticism and undermining our authoritative position as regulator.	<p>Business continuity group (including SMT, Communications, HR and IT) meeting frequently to discuss changes or circumstances and planning timely responses to these.</p> <p>Out of hours media monitoring being undertaken, to ensure that we respond to anything occurring at weekends or evenings in a timely manner.</p> <p>Close communication with key sector professional organisations to ensure we are ready to react to any developments led by them (such as guidance updates).</p> <p>Proactive handling of clinic enquiries and close communication with them.</p>	<p>In place, ongoing daily – Richard Sydee</p> <p>In place - SMT and communications team</p> <p>In place and ongoing – Clare Ettinghausen</p> <p>In place and ongoing – Sharon Fensome-Rimmer,</p>

Causes / sources	Controls	Status/Timescale / owner
	<p>Careful monitoring of the need to update information and proactive handling of updates.</p> <p>Public enquiries about Coronavirus are being triaged, with tailored responses in place. Enquirers are being directed to information on our website, to ensure that there is a single source of truth and this is up to date. Enquiries team have additional support from Managers and Directors. We will review our approach regularly to ensure that this is fit for purpose.</p> <p>Close monitoring of media (including social) to identify and respond to any perceived criticism to ensure our position is clear. Regular review of communications activities to ensure they are relevant and effective.</p>	<p>Rachel Cutting</p> <p>Joanne Triggs – in place</p> <p>In place and under regular review – Laura Riley</p> <p>In place – Jo Triggs</p>
<p>Risk of being challenged publicly or legally about the HFEA response, resulting in reputational damage or legal challenge.</p> <p>(This risk also therefore relates directly to LC1 above)</p>	<p>As above – ensuring approach is appropriate.</p> <p>As above – continuing to liaise with professional bodies.</p> <p>We may choose to put out a press release in case of public challenge.</p> <p>Legal advice has been sought to ensure that HFEA actions are in line with legislative powers. Further advice available for future decisions.</p> <p>Ability to further engage legal advisors from our established panel if we are challenged.</p>	<p>In place – Richard Sydee</p> <p>Ongoing - Rachel Cutting</p> <p>If required - Joanne Triggs</p> <p>Done – Peter Thompson</p> <p>If required – Peter Thompson, Catherine Drennan</p>
<p>Gaps in HFEA staffing due to sickness, caring responsibilities etc could result in:</p> <ul style="list-style-type: none"> Not enough inspection staff to complete inspections of clinics 	<p>We have removed the immediate risk source related to the inspection team by changing our approach to inspections until after August.</p> <p>Further discussions required to finalise controls to ensure that we have processes to extend licences to support this decision.</p> <p>We will also need to ensure we have processes and systems in place to be organisationally ready to resume inspections after August.</p>	<p>In place – Rachel Cutting</p> <p>Future control, development underway – Paula Robinson, Sharon Fensome-Rimmer, Rachel Cutting</p>

Causes / sources	Controls	Status/Timescale / owner
<ul style="list-style-type: none"> • Not enough licensing staff to licence clinics • Not enough communications staff to provide timely Coronavirus guidance to the public etc. • Not enough IT staff to effectively support staff remote working. 	<p>Ensuring clarity about working status of all licensing staff so that we understand the likelihood of this risk. We would reallocate work within the licensing team to cover immediate gaps.</p> <p>Considering option to train or reallocate other resource to support the licensing team if required.</p> <p>Planned work to ensure more staff are able to access and change website content.</p> <p>Exploring how contracted external IT support company can provide additional cover to add extra resilience for the IT support team and offer first- and second-line support.</p>	<p>In place - Paula Robinson</p> <p>Developing – further discussions required – Paula Robinson</p> <p>Future control, outstanding needs to be developed - Jo Triggs</p> <p>Underway, not in place yet – Dan Howard</p>
<p>Clinics stop activity during the epidemic and so we are unable to inspect them within the necessary statutory timeframes.</p>	<p>Extending of licences (noted above) should remove this risk by ensuring that the licence status of clinics is maintained.</p>	<p>In place - Paula Robinson</p>
<p>Ineffective oversight of those clinics that are continuing to practice as clinics may not abide by professional body and HFEA guidance.</p> <p>Since GD0014 version 2 was issued, clinics have been able to reopen where it is safe to do so. Meanwhile, HFEA do not plan to restart physical inspections until September. This creates a potential oversight gap.</p>	<p>We have put in place a new General Direction for clinics to follow. Clinics who do not follow General Direction 14 would be subject to serious regulatory action.</p> <p>Inspection team are in active communication with all of their clinics to ensure oversight and understanding of risks. Activity of centres is being monitored through the register submission system.</p> <p>Effective desk-based approach to oversight of clinics. Those clinics (who have resumed treatment services and/or are open) where Interim inspections were due during the period of no inspections will still be asked to complete the Self-Assessment Questionnaire, in the same way that they would have done before an inspection. This gives us oversight of all areas of practice.</p>	<p>In place – Rachel Cutting</p> <p>In place – Sharon Fensome-Rimmer</p> <p>Approach agreed and in place – Sharon Fensome-Rimmer, Rachel Cutting</p>
<p>Public transport may be unreliable or significantly reduced, preventing us travelling to inspections, clinic visits or other meetings and events.</p>	<p>Pausing inspections, external events being cancelled and move to homeworking for all HFEA staff, largely removes this risk in the medium term as we will not need to travel.</p>	<p>In place – Richard Sydee</p>

Causes / sources	Controls	Status/Timescale / owner
Inability to run representations hearing due to restrictions/inability of staff/others to meet.	Plan in place to run this via teleconference. Finer points of arrangements being agreed.	In place and developing – Paula Robinson
Precipitous decrease in funding likely due to large reductions in treatment undertaken because of Coronavirus. Note: this risk may be both short and longer-term if clinics close down as a result.	As per FV1 risk - We have sufficient cash reserves to function normally for a period of several months if there was a steep drop-off in activity (contingency). The final contingency would be to seek additional cash and/or funding from the Department, and we are in conversation with them about the likely impact on us (further contingency)	In place – Richard Sydee Ongoing discussions as impact becomes clearer – Richard Sydee
Hardware for the Register runs at Spring Gardens and we may not have access to this for a long period of time if a full lockdown was imposed on London.	Regular back-up of the Register is stored securely off-site, meaning we would be able to roll-back to an old version if anything happened to the hardware. Exploring further implications of this with IT staff to ensure that the Register would be secure, and we have plans in place for all eventualities.	In place – Dan Howard Discussions underway – Richard Sydee
Lack of access to necessary IT equipment (for instance when Surface Pros need replacing) because we are working from home.	Our IT team has ordered equipment and is storing this securely outside of the office to ensure that this is available if we need it. We would post this to staff's home addresses.	In place - Dan Howard
We are unable to get hold of the kit that we need due to possible supply chain or procurement issues due to Coronavirus.	We ordered equipment well ahead of time to ensure that this is available if we need it. If this became an issue, we may need to consider reallocating kit to available staff and priority areas of work (contingency plan).	In place - Dan Howard More planning required to define this contingency – Richard Sydee
We have had to cancel events and meetings and cannot run them as planned which may delay some strategic delivery.	Conversations ongoing with Authority and Corporate Management about options for management of individual risk impacts and review key milestones where needed. Routine stakeholder meetings occurring virtually and revised arrangements to allow for virtual meetings and committees.	In place – Peter Thompson
Negative effects on staff wellbeing (both health and safety and mental health) caused by extended working from home (WFH), may mean	Provided equipment for staff who have to WFH without suitable arrangements in place.	In place – Richard Sydee

Causes / sources	Controls	Status/Timescale / owner
that they are unable to work effectively, reducing overall staff capacity.	<p>Mental Health resources provided to staff, such as employee assistance programme and links to other organisations' resources.</p> <p>Mental Health First Aiders in place to increase awareness of need to care for mental health. Available to discuss mental health concerns confidentially with staff.</p> <p>Regular check-ins in place between staff and managers at all levels, to support staff, monitor effectiveness of controls and identify need for any corrective actions. Additional support for Managers in place. Corrective actions could include discussions about workload, equipment, reallocation of work or resource dependent on circumstance.</p>	<p>In place – Yvonne Akinmodun</p> <p>In place – Yvonne Akinmodun</p> <p>In place and ongoing – Yvonne Akinmodun</p>
Risk that we miss posted financial correspondence (ie, invoices etc) and are unable to act on these effectively which could potentially result in services being withdrawn.	<p>While the office remains open, we have an arrangement to securely store, collect and distribute post. Though we would need to reconsider this control should the office be closed.</p> <p>Updated website info to ask people to contact us via email and phone.</p> <p>We have notified all suppliers about the change in arrangements. Although this is unlikely to stop all post as some have automated systems.</p>	<p>In place – Richard Sydee</p> <p>In place – Jo Triggs</p> <p>In place – Morounke Akingbola</p>
Risk that we miss physical correspondence related to OTR requests, resulting in delayed responses, negative impact on individual applicants and rework needed to handle this.	<p>Decision to suspend OTR service has mitigated much of this risk. In addition, as above - arrangements in place to securely store, collect and forward post.</p> <p>Digital method for submission of requests (DocuSign) should reduce this risk.</p> <p>Clear communications to applicants about digital submission of requests being the preferred approach.</p>	<p>In place – Richard Sydee</p> <p>In place – Dan Howard</p> <p>In place – Donor Information Manager</p>
Risk that we miss other miscellaneous post.	Most other post is lower risk, but as above - arrangements in place to securely store, collect and forward post.	In place – Richard Sydee
Risk interdependencies (ALBs / DHSC)	Control arrangements	Owner
In common risk		
DHSC: HFEA costs exceed annual income because of reduced treatment volumes.	<p>Use of cash reserves, up to appropriate contingency level available.</p> <p>The final contingency would be to seek additional cash and/or funding from the Department.</p>	Richard Sydee

Reviews and revisions

20/05/2020 - SMT review – May 2020

SMT reviewed all risks, controls and scores and made the following points:

- RF1 – SMT noted that the Head of Planning and Governance had proposed that the inherent risk was actually higher (the controls already in place were bringing the residual likelihood down). SMT agreed with this change.
- C1 – SMT noted that the Head of HR had reviewed this risk and suggested that given the current reduced level of turnover this risk was now below tolerance. SMT agreed with this and noted that we would need to monitor this carefully as things could change in future months following Covid-19.
- CV1 - A few updates were needed to the Covid-19 risk to reflect recent developments in controls.

22/04/2020 - CMG review of draft register – April 2020

CMG reviewed all risks, controls and scores and made the following points:

- They agreed the scores seemed appropriate and the new strategic risks captured the core risk to the new strategy.
- Members agreed to further review to ensure controls in their areas were correct.

20/04/2020 - SMT review of draft register – April 2020

This was the first time that SMT had reviewed the revised Strategic risk register. SMT reviewed all risks, controls and scores and made the following points:

- RF1, I1 and P1 - Further review was needed of the new strategic risks, although SMT agreed outline scores and next steps for further review in advance of Authority consideration.
- FV1 – Needed a full review with the Director of Finance and resources in the light of Covid-19 impacts, but SMT raised the risk score in the light of these.
- C1 – Should be reviewed with Head of HR.
- C2 – Minor update related to confirmation of Chair’s term extension, no effect on the score.
- LC1 – SMT noted this had been updated with the Chief Executive and Head of Legal and gave additional clarity. We would need to consider whether possibility of Covid-19 related challenge increased the score further, but SMT did not raise it at this time.
- CS1 – Reframed to remove information governance which had been conflated with the cyber risk. Needed review by CIO before going to Authority.
- E1 – Needed a full review with the Director of Finance and resources in the light of Covid-19 impacts but SMT raised the risk score in the light of these.
- CV1 – SMT would review this to ensure that it reflected the current position.

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				

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

We explicitly consider whether any HFEA strategic risks or controls have a potential impact for, or interdependency with, the Department or any other ALBs. There is a distinct section beneath each risk to record any such interdependencies, so 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 DHSC or auditors as required.

Contingency actions

When putting mitigations in place to ensure that the risk stays within the established tolerance threshold, the organisation must achieve balance between the costs and resources involved in limiting the risk, compared to the cost of the risk translating into an issue. In some circumstances it may be possible to have contingency plans in case mitigations fail, or, if a risk goes over tolerance it may be necessary to consider additional controls.

When a risk exceeds its tolerance threshold, or when the risk translates into a live issue, we will discuss and agree further mitigations to be taken in the form of an action plan. This should be done at the relevant managerial level and may be escalated if appropriate.