Implementation of Audit Recommendations – Progress Report

Strategic delivery	**Setting standards**	☐	**Increasing and informing choice**	☐	**Demonstrating efficiency economy and value**	☒	
Meeting	Audit and Governance Committee						
Agenda item	10						
Paper number	[AGC (16/03/2016) 492 WEC]						
Meeting date	Wednesday, 16 March 2016						
Author	Wilhelmina Crown						
For information or decision?	Decision						
Recommendation	AGC is requested to review the enclosed progress updates and to comment as appropriate.						
Resource implications	As noted in the enclosed summary of outstanding audit recommendations						
Implementation	As noted in the enclosed summary of outstanding audit recommendations						
Communication	CMG						
Organisational risk	As noted in the enclosed summary						
Annexes	Annex 1: Summary of Recommendations						

1. Report

1.1. This report presents an update to the audit recommendations paper presented to this committee in December 2015.

1.2. New recommendations agreed by this committee in December 2015 have been added whilst those agreed as completed removed.

1.3. Recommendations are classified as high (H - red), medium (M - amber) and low (L - green) priority.

1.4. Six new recommendations were received with one requiring no further action and the remaining identified as low risk.

1.5. Recent updates received from Action Managers are recorded under a December 2015 heading in this document.

1.6. All recommendations are noted as completed with none outstanding.

1.7. Progress with the implementation of all audit recommendations will be provided to future AGC and CMG Risk meetings on a quarterly basis

2. Recommendation

AGC is requested to review the enclosed summary of recommendations and updated management responses.

Annex 1: Summary of Recommendations

Recommendation Source	**Status / Actions**	2015/16	Total
Internal – *DH Internal Audit*	*Complete*	*5*	***5***
COUNT		***5***	***5***

FINDING/*RISK*	Recommendation	Agreed actions / Progress Made	Owner/Completion date
2015/16 – INTERNAL AUDIT CYCLE			
HFEA INCIDENT HANDLING			
1. Risk Management	**The Risk Matrix in the policy is not entirely reflective of the incident grading in practice**		
Incidents reported to HFEA are graded A (red), B (yellow) and C (green) according to their severity and likelihood of recurrence. This is depicted in the policy by way of the following Risk Matrix:  Likelihood → / Severity ↓ Almost certain 5 | Likely 4 | Possible 3 | Unlikely 2 | Rare 1 Severe 5: 25 | 20 | 15 | 10 | 5 Major 4: 20 | 16 | 12 | 8 | 4 Moderate 3: 15 | 12 | 9 | 6 | 3 Minor 2: 10 | 8 | 6 | 4 | 2 Insignificant 1: 5 | 4 | 3 | 2 | 1 When we reviewed the grading of our sample of 25 incidents, the gradings applied appeared reasonable to us under the framework but in some cases did not fully align with the matrix. For instance, a severe incident is usually rare and might rightly be graded A, but per the matrix rare incidents are all coloured green regardless of their severity. Similarly, mild to moderate OHSS (Ovarian Hyper stimulation Syndrome) is a known and fairly common side effect of fertility treatment and is graded C in practice, but per the matrix it might be argued to be Grade B as whilst the severity is minor the likelihood is likely or possible. *There may be uncertainty as to the grading of incidents, which could lead to an inconsistent response and potential for challenge.* *In practice, the limited number of staff involved in the process means coding is likely to be consistent, but could be open to question by someone referring to the matrix.*	The risk matrix should be reviewed to see whether it can be updated to better reflect the balance between severity and likelihood of recurrence.	***Review risk matrix. It has been revised to reflect the balance between severity and likelihood of recurrence. Waiting for sign off by the Chief Inspector to be completed by 31 December 2015***. **December 2015 update**: Signed off by Chief Inspector - December 2015 **Recommendation Complete**	**Chief Inspector** **31 December 2015** **COMPLETE**
2. Policies and Procedures	**Key Policies and Procedures are overdue for review**		
We noted that a number of key policies and procedures are under review having not been updated for some time: • The SOP for Managing Patient Complaints and that for Managing A grade Adverse Incidents have not been updated since August 2012; • The SOP for Managing B and C grade Incidents has not been updated since November 2011; and • The Compliance and Enforcement Policy has not been updated since October 2011. The version published on the HFEA website states that it is due for review in April 2013. We noted that within the existing policies there are some references to certain systems and processes that are no longer applicable or relevant. However, we recognise that this has been identified by management and that these policies and procedures are already undergoing review.	Management should ensure that the ongoing review of policies and procedures is completed and revised versions formalised and issued. The updates should take account of the findings from this review. The wording around when	***SOP review. In process for completion 31 December 2015*** **December 2015 update**: SOP review and revision completed. **Recommendation Complete**	**Clinical Governance Lead** **31 December 2015** **COMPLETE**

FINDING/*RISK*	Recommendation	Agreed actions / Progress Made	Owner/Complet -ion date
We also noted that the narrative for the Grade A category states that an inspection is required for these incidents but we understand that HFEA does not always need to undertake an investigation itself, for instance if it can obtain assurance from external investigations. *Staff may not be fully aware of the required process for managing incidents and complaints. This could lead to HFEA's response being inappropriate or ineffective.* *Lapses in process may be more likely to arise if there is staff turnover or if roles have to be reassigned during a period of absence of a key individual.* *There could be uncertainty as to whether investigation by the HFEA is required in circumstances where there is a severe incident but other bodies are undertaking their own investigations.*	an investigation should be undertaken should be reviewed to better describe when HFEA would undertake its own investigation and when it might rely on the results of investigations by others.		
3. Closure of formal complaints	**Rationale for closure of one complaint in our sample was not formally documented.**		
We reviewed a sample of five formal complaints and in one instance there was evidence that the complainant was not wholly satisfied with the final correspondence. The SOP indicates that where the complainant is not satisfied, HFEA should advise them that they may request a review by the Head of Clinical Governance within 10 working days of notification of the outcome of the initial consideration. However, in this instance the complaint was closed on the system without any further follow up. The final correspondence from the complainant noted that they did understand that there was nothing further the HFEA could do, but that they remained dissatisfied with their treatment and the service at the particular clinic. The Clinical Governance Lead/Inspector stated that HFEA could have written another letter re-iterating that there is nothing further they could do, but in this case it was felt that it would have only induced further unnecessary correspondence. This rationale for closing the complaint, however, was not documented. *There is a risk of inconsistency, which could lead to challenge and reputational harm if complaints are not fully dealt with in line with the SOP.* *HFEA may find it harder to demonstrate full compliance with the SOP if the rationale for decisions is not formally recorded on the system.*	As best practice, when closing complaints on the system, a rationale should to be documented for closure if it is noted that the complainant is fully satisfied with the response.	***Further information on how to handle an unhappy complainant now added to the complaint handling SOP. Rolled into the SOP update to be completed by the end of December 2015.*** **December 2015 update**: Completed as part of SOP review and revision **Recommendation Complete**	**Clinical Governance Lead** **31 December 2015** **COMPLETE**
4. Performance reporting	**Performance reporting of incidents and complaints to management is not documented.**		
It was confirmed by the Clinical Governance Lead/Inspector that the number of incidents and complaints are reported to, and discussed within, management. This is usually done within her monthly one to one meetings with the Chief Inspector. The numbers and trends are also discussed with Director of Compliance from time to time. However, these meetings are not documented and there are no formal reports so there is limited evidence that management has considered the number and type of incidents and complaints and assessed whether any particular response may be required.	Some formalisation of brief reporting of the number of incidents and complaints and of any relevant trends or other matters should be	***Quarterly meetings now in calendar. The Clinical Governance Lead and the Chief Inspector will meet in December to set the standing agenda and use this first meeting as a "look back" over 2014.***	**Clinical Governance Lead & Chief** **31 December 2015**

FINDING/*RISK*	Recommendation	Agreed actions / Progress Made	Owner/Complet -ion date
In due course, the numbers are summarised within the Annual Report, which states the number and trends of the reported incidents and details any Grade A incidents along with the key learning outcomes are published on the HFEA website. *If the numbers and the resulting trends of incidents and complaints are not appropriately analysed and monitored on a timely basis management may fail to identify potential issues that may have warranted action. If action is not taken where required, then there is increased risk of issues recurring or of policies and procedures not being developed to improve services.*	considered formalised. This could perhaps be done on a quarterly basis.	**December 2015 update:** Completed – first meeting held in December 2015 **Recommendation Complete**	**COMPLETE**
5. Survey Results	**Performance reporting of incidents and complaints to management is not documented.**		
While the response rate to the survey was low there are some comments that HFEA management may wish to reflect on in terms of enhancements to incident reporting. Please refer to Section 5 of this report for the full survey results. As mentioned in section 1.7 above, the survey was issued with the Clinic Focus paper in September 2015 which is sent to all clinics (approximately 130) and has a total of around 500 subscribers. Unfortunately there were only eight responses which means the results must be treated with caution *Where stakeholders do not see any change a as a result of comments made from such surveys, engagement levels may fall.* *Not acknowledging appreciation to those who responded to the wider population of subscribers might miss an opportunity to encourage more people to respond to any future surveys.*	Send out a thank you communication regarding the survey to the full population and a brief summary of any changes that are planned to be taken as a result of the comments made.	***A brief thank you will be sent out in the December edition of Clinic Focus. Clinic Focus is sent to over 120 clinics and 500 individual subscribers. Due to the very low volume of responses (8) – no meaningful information was gleaned to make any changes to the current system. Therefore a brief thank you to those that participated will be mentioned in Clinic Focus.*** **December 2015 update**: Brief thank you held over until February's edition – urgent contents took priority for December and January. **Recommendation Complete**	**Clinical Governance Lead** **31 December 2015** **COMPLETE**

Audit and Governance Committee Forward Plan

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Audit & Governance Committee Forward Plan		
Agenda item	12		
Paper number	AGC (16/03/2016) 493		
Meeting date	16 March 2016		
Author	Sue Gallone, Director of Finance & Resources		
Output:			
For information or decision?	Decision		
Recommendation	The Committee is asked to review and make any further suggestions and comments and agree the plan.		
Resource implications	None		
Implementation date	N/A		
Organisational risk	☒ Low	☐ Medium	☐ High
	Not to have a plan risks incomplete assurance, inadequate coverage or unavailability key officers or information		
Annexes	N/A		

Audit & Governance Committee Forward Plan

AGC Items Date:	15 June 2016	21 Sept 2016	7 December 2016	Mar 2017
Following Authority Date:	6 July 2016	16 November 2016	January 2017	May 2017
Meeting 'Theme/s'	Annual Reports, Information Governance, People	Strategy & Corporate Affairs, AGC review	Register and Compliance, Business Continuity	Finance and Resources
Reporting Officers	Peter Thompson	Juliet Tizzard	Nick Jones	Sue Gallone
High Level Risk Register	Yes	Yes	Yes	Yes
Information for Quality (IfQ) Programme	Yes	Yes		
Annual Report & Accounts (inc Annual Governance Statement)	Approval			
External audit (NAO) strategy & work	Audit Completion Report	Audit Planning Report	Update	Interim Feedback
Information Assurance & Security	Yes			
Internal Audit Recommendations Follow-up	Yes	Yes	Yes	Yes
Internal Audit	Plan, Results, annual opinion	Update	Update	Early Results, approve draft plan
Whistle Blowing, fraud (report of any incidents)	Update as necessary	Update as necessary	Update as necessary	Update as necessary
Contracts & Procurement including SLA management	Update as necessary	Update as necessary	Update as necessary	Update as necessary
HR, People Planning & Processes	Yes			

AGC Items Date:	15 June 2016	21 Sept 2016	7 December 2016	Mar 2017
Strategy & Corporate Affairs management		Yes		
Regulatory & Register management			Yes	
Resilience & Business Continuity Management			Yes	
Finance and Resources management				Yes
Reserves policy		Yes		
Review of AGC activities & effectiveness, terms of reference			Yes	
AGC Forward Plan	Yes	Yes	Yes	Yes
Session for Members and auditors	Yes	Yes	Yes	Yes
Other one-off items				