

## **Minutes of the Audit and Governance Committee meeting on 1 October 2024 held virtually (Teams)**

Members present	Catharine Seddon, Chair Julia Chain Alex Kafetz, Deputy Chair Anne-Marie Millar
External Advisers	Dean Gibbs, KPMG – External Audit lead Nick Dovan, National Audit Office (NAO) – External Auditor Jo Charlton, Head of Internal Audit (Internal Auditor) – GIAA
Apologies	Steve Pugh, Department of Health and Social Care Farhia Yusuf, Department of Health and Social Care
Observers	Adrian Thompson, Board Apprentice Bernice Ash, Committee Officer
Staff in attendance	Peter Thompson, Chief Executive Tom Skrinar, Director of Finance and Resources Clare Ettinghausen, Director of Strategy and Corporate Affairs Rachel Cuttings, Director of Compliance and Information Morounke Akingbola, Head of Finance Paula Robinson, Head of Planning and Governance Shabbir Qureshi, Risk and Business Planning Manager Martin Cranefield, Head of IT (items 9 and 10) Neil McComb, Head of Information (item 10) Kevin Hudson, PRISM Programme Manager (item 9) Alison Margrave, Board Governance Manager

### **1. Welcome, apologies and declaration of interest**

- 1.1.** The Chair welcomed everyone to the meeting and said that Jo Charlton (Head of Internal Audit GIAA) and Nick Dovan (External Auditor NAO) would be joining later. A warm welcome was extended to the observers.
- 1.2.** Apologies of absence were received from Steve Pugh (DHSC) and Farhia Yusuf (DHSC).
- 1.3.** The Chair asked members if there were any declaration of interest, and none were declared.

### **2. Minutes of the meeting held on 26 June 2024**

- 2.1.** The Chair introduced the minutes from the previous meeting which had been circulated to the members.
- 2.2.** The minutes of the meeting held on 26 June 2024 were agreed as a true record and could be signed by the Chair.

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### **3. Action Log**

- 3.1.** The Head of Finance presented this item.
- 3.2.** The Head of Finance informed the committee that the requirement of item 5.18 from October 2023 and item 5.12 from December 2023 regarding formalising more effectively the process to close off audit recommendations could be closed. She referred to the paper submitted to the committee under agenda item 5 regarding guidance to HFEA staff for internal audit relationships and expectations.
- 3.3.** The Head of Finance informed the committee that the requirement of item 5.7 from December 2023 regarding provision of evidence to GIAA regarding KPIs should be kept open as GIAA had not yet managed to review all the evidence that the HFEA had submitted.
- 3.4.** The Head of Finance informed the committee that requirement of items 6.15 and 7.14 from June 2024 could be closed, as the Annual Report and Accounts were laid before recess.

#### Decision

- 3.5.** Members agreed the proposed amendments to the action log.

#### Action

- 3.6.** Board Governance Manager to update the action log as agreed by the committee.

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### **4. Internal audit report results and annual opinion**

- 4.1.** The Head of Internal Audit – GIAA presented this item and introduced the four papers that were presented to the committee.
- 4.2.** The committee were informed that delivery of the 2024/25 Audit Plan is progressing well, with 40% of the plan now delivered to at least draft report stage, with a further 20% of the plan at planning and scoping stage. It was noted that the planning and scoping work was now in place for the audit on Opening the Register (OTR).
- 4.3.** The Head of Internal Audit stated that there are 27 outstanding audit recommendations and whilst the HFEA had provided additional evidence for some of these, GIAA had raised several questions about this evidence.
- 4.4.** In response to a question the Head of Internal Audit stated that the team at GIAA had been affected by long-term sick leave so the process for reviewing evidence is taking longer than normal. It was noted that the narrative which the HFEA provides when submitting evidence has improved although the scheduling of submitting evidence was concentrated around preparation for these meetings.
- 4.5.** The Head of Planning and Governance commented that the HFEA's ability to provide the required evidence had also been affected by sick leave and annual leave, but for some items there was no further evidence which could be submitted in which case if, after review, GIAA could not agree to closing the recommendation, then the committee would be asked to accept the risk.
- 4.6.** In response to a question about available resources the Chief Executive stated that a number of these recommendation have been outstanding for a period of time, which suggested that the risk

is not critical. The Head of Internal Audit responded that they still related to a risk so it would need to be documented that management are prepared to accept these risks.

- 4.7.** The Head of Internal Audit informed the committee that since its last meeting the final report had been issued on the Data Security and Protection Toolkit (DSPT) audit with a limited assurance. 37% of outstanding audit recommendations relate to DSPT, many from previous years, and the Head of Internal Audit questioned whether the HFEA had a strategy to complete these recommendations and prepare for the next changes to DSPT.
- 4.8.** The Director of Finance and Resources responded that all risks are being managed but that in some cases evidence provided does not completely satisfy the audit recommendation. With the changes to DSPT and eventual replacement by the Cyber Assessment Framework (CAF) the outstanding recommendations may need to be reviewed for relevance, and some accepted at risk.
- 4.9.** In response to the committee expressing disappointment with the overall rating assigned at the conclusion of the audit the Head of Internal Audit commented on the process for completing the DSPT audit which afforded no discretion to the auditor: specific requirements had to be recorded as in place or not.
- 4.10.** The committee reflect that DSPT had been designed for the NHS and had then been implemented for the wider health sector without any consideration for the size or type of the organisations now having to implement it. The committee noted that whilst some NHS trusts have a high DSPT assurance rating they have been subject to data breaches, whereas the HFEA has not been subject to a data breach.
- 4.11.** The Head of Internal Audit commented that NHSE are running various webinars on the changes to DSPT, and it might be beneficial to participate in these so that the HFEA could prepare for the changes in advance.
- 4.12.** In response to a question, the Head of Internal Audit commented on the proposed direction of travel indicators and noted that consideration is being given as to whether these will be implemented in the 2025/26 audit documents.
- 4.13.** The Chair drew the discussion to a close and brought members' attention to the GIAA supplementary pack highlighting the cross-government insights into AI, counter fraud update and resources available to members.

### Decision

- 4.14.** Members noted the internal audit update report, DSPT final report and the final annual opinion report 2023/24.

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## **5. Progress with current audit recommendations**

- 5.1.** The Head of Finance introduced this agenda item.
- 5.2.** The committee discussed whether the Authority had the resources to close recommendations.
- 5.3.** The Chair asked that management review all long outstanding recommendations and bring proposals to the next meeting on those that they intend to accept at risk rather than propose to postpone target dates again.

- 5.4.** The Chair further asked that future proposed target dates be aligned with the dates of preparing papers for the Audit and Governance Committee, rather than for the meeting date itself, in order to secure timely closure of all outstanding recommendations.
- 5.5.** In response to a question, the Head of Finance confirmed that it is anticipated that the risks relating to KPIs could be closed before December due to the new evidence submitted to GIAA.

#### Internal Audit relationships and expectations (Rules of Engagement)

- 5.6.** The Director of Finance and Resources introduced the paper which provides guidance for Directors and Heads undergoing internal audits on rules of engagement with GIAA. He informed the committee that the Head of Internal Audit had attended a recent Corporate Management Group meeting where this paper had been discussed and agreed.
- 5.7.** The Director of Finance and Resources acknowledged that it had been tricky to progress audit recommendations over the summer period due to staff sickness and leave, but suggested that these rules of engagement provide a good basis for the HFEA and GIAA to work together.
- 5.8.** The Head of Internal Audit asked that the following be added to the rules of engagement:
- Regular cycle of submitting evidence which aligns to implementation dates
  - The HFEA to recognise how to manage and action ownership changes, so that new owners see previous relevant audit reports.
- 5.9.** The Chair asked that the rules of engagement document should also add clarification of how and where discussions/agreements between the HFEA and GIAA should be recorded.
- 5.10.** The committee were encouraged that the paper should lead to improved ways of working with GIAA in ensuring audit recommendations are closed off in a timely fashion.

#### Decision

- 5.11.** The committee agreed that management should review all long outstanding recommendations and bring proposals to the next meeting on those that they intend to accept at risk. Future target dates to be aligned with the dates of preparing papers for the Audit and Governance Committee.
- 5.12.** The committee noted the rules of engagement guidance for internal audits with the addition of the extra items agreed at the meeting.

#### Action

- 5.13.** Management to review outstanding audit recommendations and bring proposals to the December meeting.

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## **6. External audit report**

- 6.1.** The External Audit Lead, KPMG, informed the committee that the accounts and annual report were closed and laid in Parliament before recess. Planning work for the preparation of the 2024/25 accounts was underway and would be formally reported to the committee at its next meeting.
- 6.2.** A member commented that the process for the preparation of the accounts and annual report worked well and questioned whether there are any key items of risk which had already been identified in the planning work for the 2024/25 accounts.

- 6.3.** The External Audit Lead, KPMG, responded that PRISM would continue to be a risk that would need to be monitored to consider the level of provision required for duplicate invoices and management's approach to determining this for the year. This could continue to be an area of increased challenge around duplicates and the recognition of revenue in year. The potential need for impairment of PRISM would also continue to be challenged by the auditors.

#### Decision

- 6.4.** The committee noted the verbal report.

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## 7. Strategic risk

### Strategic risk register

- 7.1.** The Risk and Business Planning Manager introduced the paper and reminded members that the risk strategy, which was agreed in December 2023, allowed for the strategic risk register to be updated bi-annually in May and December. At other times it could be updated if the risks had been escalated following the process in the strategy.
- 7.2.** The Risk and Business Planning Manager informed the committee of the recent changes to the strategic risk register as identified in the paper.
- 7.3.** Prior to the main review in December, the committee discussed each section:
- Commercial – the committee commented that the risk name does not fully reflect the commentary.
  - Governance – no comments.
  - Information 1 – the committee questioned whether the definition of this risk is still correct in its current form.
  - Information 2 – the committee discussed pace of delivery and whether the rapid increase in direct to consumer DNA testing would pose a significant risk to OTR.
  - People 2 – the committee were informed that the four new Authority members would be announced later this month and that the six Authority members whose first term concludes in 2025 would be reappointed.
  - Reputational – the committee discussed the HFEA's proactive approach to transparency in its work; and the potential risks from the CQC and Ofsted publications regarding scrutiny of health regulation.
  - Security – the committee discussed the capacity of the current team, the increased government reporting requirement and the potential to apply for additional IT funding.

### Horizon scanning

- 7.4.** The Chair informed the committee that this agenda item is for members to raise topics which could affect the HFEA in the future but are not yet reflected in the strategic risk register.
- 7.5.** The Chair questioned whether the HFEA was exploring and being mindful of the direction of travel of regulators who are looking at the use of AI. AI could bring both opportunities and risk and she asked whether the HFEA was giving this topic sufficient consideration.
- 7.6.** The Chief Executive responded that the HFEA is doing what it can with the resources it has available to it. A project considering the use of AI in clinics is currently in progress and the horizon

scanning function is also monitoring this topic. He commented that the use of AI in clinics as well as more generally in regulation will also be included in the HFEA's next three-year strategy.

- 7.7.** The Director of Strategy and Corporate affairs stated that members of staff regularly attend forums and conferences where this topic is discussed, and she spoke about a recent Institute of Regulation meeting.
- 7.8.** The Director of Finance and Resources stated that the procurement to replace Epicentre will also provide improved infrastructure to support how the HFEA manages its data and spoke about the importance of this to ensure that the HFEA could take advantage of the opportunities which AI might provide in future.
- 7.9.** The Head of Internal Audit GIAA informed the committee that they can put HFEA in touch with colleagues with AI expertise in GIAA if required.
- 7.10.** The Chair asked management whether they had been able to consider if there was any connection between whistleblowing reports and non-compliances identified by the HFEA's inspection process and whether external whistleblowing could be a useful deep dive discussion topic for October 2025.
- 7.11.** The Chief Executive stated that each external case of whistleblowing is investigated and that there is not a general connection between whistleblowing and non-compliance.
- 7.12.** The Director of Compliance and Information reiterated that each case of whistleblowing is taken very seriously with a robust procedure led by the Chief Inspector. The committee were informed that a lot of cases are not upheld as they are personnel/HR complaints rather than regulatory non-compliances.
- 7.13.** The Director of Compliance and Information spoke of the openness and transparency of the sector generally and that clinic staff at all levels do approach the HFEA. Members were informed of the whistleblowing cards that each inspector leaves at licensed premises during an inspection and the increase in the number of whistleblowing reports.
- 7.14.** Members discussed that, generally, clinic staff are more confident to whistle blow to regulators when they work for a trustworthy organisation, so members were reassured that the number of whistleblowing incidents to the HFEA is increasing. Members discussed the recently published independent reports on CQC and Ofsted and the wider implications of these reports for health regulators.
- 7.15.** The Chair drew the discussion to a conclusion noting the desire to add this topic to the deep dive list for October 2025.

### Decision

- 7.16.** Members noted the strategic risk register and that a deep dive on external whistleblowing reports (both for clinics and for the HFEA's inspection process) should be added to the list for October 2025.

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## **8. Deep Dive discussion – near misses**

- 8.1.** The Risk and Business Planning Manager presented the paper and informed members that the HFEA risk management strategy outlines the internal incidents reporting procedure. The aim of

the incidents system is to enable the HFEA to understand and learn from reported internal adverse events.

- 8.2.** The Risk and Business Planning Manager explained the reporting procedure stating that an online reporting form is available on the HFEA intranet. In response to a question, he confirmed that the online reporting function has made it easier for staff to report incidents and there is a level of confidence in the reporting system.
- 8.3.** The Risk and Business Planning Manager referred to the table detailing incident reporting since 2019 and stated that the quantity of incidents reported is not large. The process for dealing with lessons learnt from the near misses was explained with members being informed that processes and standard operating procedures were updated quickly, as required, to minimise the reoccurrence of the incident.
- 8.4.** The committee discussed whether it was possible to highlight lessons learnt learning whilst accepting that, as a small organisation, it would be important to avoid introducing a blame culture by drawing attention to particular incidents. The committee nonetheless wondered whether there might be ways to highlight broad lessons learnt to staff to ensure continuous engagement with the requirements for reporting incidents.
- 8.5.** The Risk and Business Planning Manager responded that it was possible to look at themes of incidents and this could be reported on the HFEA intranet once the required page had been set up.
- 8.6.** In response to a question the Director of Strategy and Corporate Affairs confirmed that there had been one incident several years ago which was reported to the Information Commissioner, but it had been rejected as it did not meet their criteria. Members were also informed that the Information Commissioner was complimentary on how the HFEA had handled the incident at the time.

### Decision

- 8.7.** The committee noted the paper on near misses and the mitigations in place to reduce the likelihood of near misses.

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## 9. Digital projects

### PRISM update

- 9.1.** The Programme Manager presented the paper and informed members of the technical challenges experienced in recent months which impact on the proposed publication dates for CaFC.
- 9.2.** The Programme Manager explained the issues relating to the production of a verification report on thaws as detailed in the paper. Continuing, he stated that for the current report, the missing storage links have been decoupled but that for future reports this will need to be addressed.
- 9.3.** The Programme Manager updated the committee on those clinics on special support noting the positions for both ARGC and CRGH as detailed in the paper.
- 9.4.** The Programme Manager stated that as set out in the paper the team no longer think it possible to publish the 2023 CaFC in 2024. This was obviously disappointing, but he stressed that it is vital to get the verification reports right, particularly as the HFEA will be relying on these to assure itself of the quality of register data in the future.



- 9.5.** Members were informed that the programme team are currently envisaging a scenario where the 2023 CaFC is finalised during the first half of 2025, but where the 2024 CaFC verification is begun on time in March 2025 with a view to publishing the 2024 CaFC later in 2025.
- 9.6.** In response to a question about resourcing, the Programme Manager stated that it would be a distraction to the team to recruit now to the second data analyst post. That role requires a specific skill set and understanding of the fertility sector, and would require considerable induction, taking time away from the primary data analyst.
- 9.7.** The Chief Executive reiterated that whilst more resources would be an asset to the overall project, it would not assist the resolution of the current phase of work. Once the project has moved on then extra resourcing would be considered.
- 9.8.** In response to a question, the Programme Manager explained the support that had been given to clinics to assist them in progressing the verification of their data.
- 9.9.** The committee discussed the progress of clinics, noting that some are more advanced than others.
- 9.10.** In response to a question, the Director of Finance and Resources stated that the thaw errors do not have an impact on estimated billings. The External Auditor from NAO informed the committee that the auditor's perspective on this risk would be clarified in the audit planning report which would be presented at the next meeting.
- 9.11.** A member questioned whether there would be any reputational risk to the HFEA due to the delay in planned publication and slippage in the overall project timelines.
- 9.12.** The Chief Executive responded that this strategic communication issue had been taken to the Authority the week beforehand and the Authority had decided that given the delay, it would like some text added to the CAFC webpages alerting potential patients to the delay, the work underway to fix the problem and to warn against making treatment decisions on old data. This text is currently being prepared and will be added to the website when finalised.
- 9.13.** A member commented that it was important to keep updating the communication dialogue with those organisations that use the HFEA's data.
- 9.14.** In response to a question, the Programme Manager stated that data entry and accuracy for those clinics using PRISM is very good but there are still some challenges for those clinics using API systems with some pockets of difficulty which need to be resolved.
- 9.15.** The Chair drew the discussion to a conclusion asking that the Programme Manager bring to the December meeting a report detailing contingency plans and options available given the progress made during the period between the two meetings.

### Epicentre replacement

- 9.16.** The Head of IT informed members of the work being undertaken with the DHSC procurement team with regards to the epicentre replacement. Over 40 companies had registered to view the tender documents and over 200 clarification questions had been received. Some of these questions had been easy to respond to and others more complex.
- 9.17.** The committee was informed that due to the number of clarification questions received it had been agreed to extend the tender deadline by 4 weeks. The revised timeline and the internal processes which would be used to review all bids received were explained to the committee.



- 9.18.** The Director of Finance and Resources stated that the DHSC Finance Team are aware of the revised timeline and proposed dates for expenditure, and he would continue to liaise with them to ensure that they are kept apprised of the project.

#### Decision

- 9.19.** The committee noted:

- That the CaFC update has not progressed as hoped.
- Particular challenges around the production of the thaws report, but that a successful outcome for this issue is expected to be available in October.
- The publication of the thaws report will represent publication of 82% of all CaFC exceptions, thereafter there is 5% of PRISM exceptions and 13% of EDI exceptions outstanding.
- The HFEA is providing increased support to clinics for addressing exceptions and this showed results in July but not August.
- The expectation that the 2023 CaFC will complete during the first half of 2025, and that the 2024 CaFC data should be published later that same year.

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## 10. Resilience, cyber security & business continuity

- 10.1.** The Head of IT informed members that due to the changes in DSPT the NHS Cyber Improvement Team had ring-fenced funding which could be made available to health ALBs and the HFEA would be considering applying under this fund.
- 10.2.** Members were informed that the HFEA had participated in the NHSE webinars on the changes to DSPT.

#### DSPT and GIAA audit 2023/24

- 10.3.** The Head of Information introduced the paper and informed the committee that after submission of the HFEA's improvement plan to NHSE its ranking was raised to 'Approaching standards'. Whilst the GIAA audit of this submission found the HFEA performance to be 'unsatisfactory' and is clearly disappointing, this classification does not take account of the significant improvements made by the HFEA over the past year as detailed in the paper. There are some aspects which cannot be achieved until the Epicentre replacement is in place.
- 10.4.** The HFEA's approach to address only the mandatory requirements was explained, and members were informed that there 108 mandatory requirements for 2023/24. The GIAA audit of the submission looked at 45 different DSPT requirements.
- 10.5.** The Head of Information spoke about the changes to DSPT and eventual replacement by the Cyber Assessment Framework (CAF) and commented that it is not yet clear what this change will mean in terms of workload for the HFEA team. Work has already commenced on identifying key systems for CAF.
- 10.6.** The Chair thanked the Head of Information for this paper which put into context the GIAA DSPT Final Report. It was clear that improvements have been made and the committee was encouraged that early planning work for CAF is being undertaken.

#### Decision

- 10.7.** The committee noted the report with thanks to the Head of IT and Head of Information.

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## **11. Fraud Risk Assessment**

- 11.1.** The Head of Finance introduced the paper and stated that the fraud risk assessment is an additional tool used to identify areas of business susceptible to risk. This register is reviewed quarterly and presented to the Corporate Management Group for review prior to submission to this committee.
- 11.2.** The Head of Finance asked members whether there were any additional risks that they wanted to add to this assessment.
- 11.3.** The committee discussed the risks included in the assessment and concluded that for a small organisation, such as the HFEA, the risks included in the assessment were comprehensive and there was nothing further to add.
- 11.4.** In response to a question the Head of Finance confirmed that some controls, especially those in Finance, are tested regularly and the Fraud Action Plan could be amended to reflect this. It is anticipated that in the future discussions will be held with the other directors regarding the potential of testing controls.

### Decision

- 11.5.** Subject to the amendment regarding the testing of Finance Controls (minute 11.4 refers) the committee agreed the Fraud Risk Assessment as presented to the meeting.

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## **12. Reserves Policy**

- 12.1.** The Director of Finance and Resources introduced the paper. He informed the committee that there were no fundamental changes to the policy but that a review of the HFEA's annual costs had resulted in increases to the level of contingency required.
- 12.2.** In response to a question the Director of Finance and Resources referred to the management accounts which are issued as part of the performance report to the Authority and published on the HFEA's website.
- 12.3.** In response to a question, the Head of Finance stated that there were no big peaks or troughs in income and as stated in the proposed policy, a cash flow forecast is prepared at the start of the financial year which takes account of when receipts are expected, and payments are to be made. Furthermore, the HFEA's healthy cash reserve levels negate any cashflow risks.
- 12.4.** In response to a question regarding the contingency period the Chair reminded members that this had been raised previously and NAO had confirmed that a contingency of two months' running costs was satisfactory.

### Decision

- 12.5.** The committee approved the reserves policy with a revised reserve level of £1.42m which is made up of working capital of £500,000, contingency level of £892,000 and other commitments of £50,000.

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### 13. Governmental Functional Standards (GFS)

- 13.1.** The Director of Finance and Resources informed the committee that the Corporate Management Group had agreed a formal structured approach to monitoring and assuring functional standards, and that all initial assessments (of the 'shall' statements in the core GFS documents) have now been completed. Annual reviews will happen in Q4, and all of the existing self-assessment tools, that are designed to support continuous improvement, will need to be completed and signed off by the relevant Director prior to this review (likely to be in January 2025).
- 13.2.** The Director of Finance and Resources stated that he would present a more detailed update report on the HFEA's GFS approach to the next Audit and Governance Committee meeting.

#### Decision

- 13.3.** The committee noted the verbal report.

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### 14. AGC forward plan

- 14.1.** The Head of Finance introduced the paper which provides the forward plan for a full year of meetings.
- 14.2.** The Chair asked that a row for "Dear Accounting Officer" letters be added, so that when they are received by the HFEA they are then reported to the committee. The committee noted that the list of horizon scanning topics is to be updated to include whistleblowing with a potential date of October 2025.

#### Decision

- 14.3.** With these amendments the committee noted the forward plan.

#### Action

- 14.4.** Board Governance Manager to update the forward plan.

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### 15. Items for noting

- 15.1.** Whistle-blowing
- Members were advised that there were no whistle-blowing incidents.
- 15.2.** Gifts and Hospitality
- Members noted the updated gifts and hospitality register.
- 15.3.** Contracts and Procurement
- Members noted that there were no contracts or procurements signed off since the last AGC meeting.

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### 16. Any other business

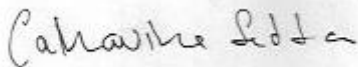
- 16.1.** The committee discussed the decision to host this meeting virtually and agreed that it had worked well.

- 16.2.** The Chair reminded the committee that the December meeting would be held in person with a training session in the afternoon. The Chair provided information about the training session on assurance mapping for a small health ALB and thanked GIAA for providing the trainer.
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### Chair's signature

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

Signature

A handwritten signature in black ink that reads "Catharine Seddon". The signature is written in a cursive style and is centered within a light gray rectangular box.

Chair: Catharine Seddon

Date: 6 December 2024