

## Minutes of the Audit and Governance Committee meeting on 30 April 2025 held virtually

Members present	Catharine Seddon, Chair Tom Fowler Alex Kafetz, Deputy Chair Anne Marie Miller
Staff in attendance	Peter Thompson, Chief Executive Clare Ettinghausen, Director of Strategy & Corporate Affairs Rachel Cutting, Director of Compliance & Information Tom Skrinar, Director of Finance & Resources Rachel Cooper, Senior Legal Adviser Kevin Hudson, PRISM Programme Manager Alison Margrave, Board Governance Manager
Staff observing	Morounke Akingbola, Head of Finance Sophie Tuhey, Head of Planning and Governance Shabbir Qureshi, Risk and Business Planning Manager Kathleen Sarsfield-Watson, Communications Manager
Apologies	Steve Pugh, Department of Health and Social Care (DHSC) Kath Bainbridge, Department of Health and Social Care (DHSC)

### 1. Digital Projects/PRISM update April 2025

- 1.1. The Chair welcomed everyone to the meeting and noted that it had been called to consider issues relating to the publication of the Interim and Full CaFC.
- 1.2. The Chair noted that apologies had been received from our sponsor team at the Department of Health and Social Care.
- 1.3. The Chair asked members whether there were any declarations of interest concerning the topic to be discussed. There were none declared.
- 1.4. The Chair proposed how the meeting would be structured: the committee would receive updates on developments from the Chief Executive, PRISM Programme Manager and Senior Legal Adviser since the AGC meetings in December 2024 and March 2025. Then the committee could consider each section of the paper before them.
- 1.5. The Chief Executive thanked the committee for accommodating the additional meeting. The Chief Executive reminded the AGC that in October 2024 the committee had asked that options for the publication of CaFC be brought to their next meeting as they were concerned that delays in publication were not in the best interest of patients.
- 1.6. In December 2024 the committee had received a paper from the PRISM Programme Manager and after consideration had agreed to:
  - publish an Interim CaFC with headline success rates earlier than would otherwise be achieved if waiting for the full set of data to be verified;

- continue work on missing thaw linkages for the Full CaFC;
- publish the Full CaFC (for treatments up to the end of 2023) by the end of June 2025
- publish the full CaFC (for treatments up to the end of 2024) by the end of December 2025 (and to include only treatments from 2022 onwards); and
- Address data verification for EDI data submitted in the years 2020 and 2021 via a retrospective data verification exercise after the 2024 Full CaFC is published. This will also include addressing the 22,500 missing thaw linkages that are in the Register relating to years earlier than 2020.

**1.7.** Continuing, the Chief Executive reminded the committee that during its 4 March 2025 meeting members were advised of the relevant updates about the Interim CaFC including:

- That a letter from the Chief Executive to Persons Responsible (PRs) had been issued on 17 December 2024 setting out the plan for 2025, the scope of the Interim CaFC and confirming that the detailed data until 2018 would remain available on the website. (A summary of this information was included in the December 2024 edition of Clinic Focus).
- That a decision of the Executive on 23 January had agreed the detailed methodology that would be used to calculate success rates for the Interim CaFC, specifically the proposed birth per embryo transferred success rate that amalgamates all IVF treatments (the composite rate).
- That the PRISM programme manager wrote to all clinics on 29 January 2025, setting out the detailed process by which they would receive their Interim CaFC calculation.
- That sign off for the Interim CaFC commenced on 18 February 2025 and the statistics that were on the calculation sheets were sent to each clinic.
- That a decision was taken to publish a caveat with regard to clinics with higher-than-average levels of donor egg treatments.
- That ongoing work was being undertaken to address the remaining missing thaw linkages for the Full CaFC publication.

**1.8.** The Chief Executive informed committee members that since the March 2025 AGC meeting the HFEA had received correspondence about a potential judicial review of its decision to publish an Interim CaFC using the composite rate.

**1.9.** The Chair thanked the Chief Executive and asked the PRISM Programme Manager to provide an update on the verification process.

**1.10.** The PRISM Programme Manager informed the committee that the calculation sheets for the Interim CaFC were issued to the clinics in early March and 77 clinics signed off their data in the following eight weeks. Of the remaining 13 clinics, one clinic had declined to sign off as the HFEA was proposing to report only one headline rate. The PRISM Programme Manager stated that the other clinics are still in the process of reviewing their data and the HFEA staff will continue to engage with them.

**1.11.** The PRISM Programme Manager informed the committee that three clinics will not be included in the Interim CaFC publication as they have not submitted enough information on PRISM. The clinics had been advised of this fact and were provided with partial calculations for information only.

- 1.12.** The Chair thanked the PRISM Programme Manager and asked the Senior Legal Adviser to provide an update to the committee.
- 1.13.** The Senior Legal Adviser confirmed that as the Chief Executive had stated earlier the HFEA had received correspondence about a potential judicial review of its decision to publish an Interim CaFC using a new methodology, specifically a success rate that amalgamates all IVF treatments (the composite rate). The substantive challenge being made by the claimant is that the proposed metric would be misleading for patients.
- 1.14.** Although the HFEA does not accept this premise, the Senior Legal Adviser stated that to allay concerns raised by the potential claimant, the HFEA had proposed publishing an additional births per embryo transferred success rate for women having fresh stimulated IVF using their own eggs only (which is the current headline rate used for CaFC) and to add an additional caveat about the success rates published in order to assist patients in their interpretation of the data.
- 1.15.** Given the concerns raised by the claimant, the HFEA had conducted a short survey to gauge the views of clinics on publication (see section 2 of the paper) and the purpose of this meeting is for the AGC to consider the evidence and make a decision on whether to approve the recommendation to publish the Interim CaFC using the headline metrics now being proposed and with the caveats suggested.
- 1.16.** The Chair thanked the Senior Legal Adviser and opened the floor for comments from the committee members on the first section of the paper.
- 1.17.** In response to a question the PRISM Programme Manager confirmed that the new CaFC data would only be published once each clinic had signed off their data via their verification process. If the data is not signed off, then the 2018 data would remain in place for that clinic. The Chief Executive confirmed that this had been the general practice in previous CaFC updates.
- 1.18.** A member commented that if a clinic's old data (2018) showed a higher success rate than their new data they could decide not to sign off the verification process. The Chief Executive stated that historically clinics have decided it is better to be included in the update than not.
- 1.19.** A member asked what would happen if those clinics who have not yet signed off their data did so after the Interim CaFC had been published. The PRISM Programme Manager responded that if the remaining clinics were to sign off their data once the first publication had taken place, then it would not be too onerous a task to update the data, clinic by clinic, with only a short delay.
- 1.20.** In response to a question the Chief Executive confirmed that the HFEA's sponsor team are aware of the potential legal challenge. He confirmed that the HFEA has a communication plan in place for whenever publication might take place.
- 1.21.** The Chair thanked the committee members for their questions on the first section of the paper and asked that they now look at section two of the paper, which would be split into three parts: the survey results, the proposed metrics and subsequent decision on the appropriate metrics to be published for the Interim CaFC and whether to reference PGT-A data and donor egg data in the caveats.
- 1.22.** Committee members noted, as detailed in the paper, that the HFEA had conducted a brief survey of clinics (via letter to PRs dated 28 March 2025) outlining the proposed headline rate metrics to be published for the Interim CaFC and asking clinics to confirm whether they were in favour of the

Interim CaFC using those metrics or whether they preferred delaying publication until a Full CaFC is possible.

- 1.23.** Committee members noted that 68% of all licensed clinics had responded by the close of survey on 11 April 2025 and the results were as follows:
- 79% of respondents (49 clinics) were in favour of the interim CaFC publication with the proposed metrics. Several respondents cited patient interest in updated data being published as soon as possible as the main reason for supporting interim publication.
  - 19% of respondents (12 clinics) preferred publication of the full CaFC only. No reasons were given for opposing interim publication.
  - 1 clinic was happy either way.
- 1.24.** Committee members agreed that the results of this survey showed that there is a clear, strong majority support for pushing ahead with an Interim CaFC.
- 1.25.** In response to a question, the PRISM Programme Manager confirmed that the survey results were presented on a one-vote-per-clinic basis and no weighting of votes due to the size of the clinic had been applied.
- 1.26.** The Chief Executive commented that the aim of the survey was to establish the sectors' view on the merits of publishing an Interim CaFC with limited metrics.
- 1.27.** The Chair then asked the committee to turn their attention to the issue of the composite rate as calculated (i.e. including PGT-A data, donor egg data etc), but to support patients in being able to interpret this data by adding some further information in the introductory text for all clinics and caveats on pages where a clinic's PGT-A and/or donor egg rate is higher than the national average.
- 1.28.** The Director of Compliance and Information provided further information about the use of PGT-A.
- 1.29.** Members felt it was appropriate to include PGT-A data with a suitable caveat for the reasons set out in the paper. A member suggested that a link to the HFEA's rating for the PGT-A add-on should also be included.
- 1.30.** In response to a question, the Director of Compliance and Information confirmed that the HFEA would make use of the expertise of Authority members (including the Chair of the Scientific and Clinical Advances Advisory Committee) in finalising the wording of any caveats.
- 1.31.** The committee agreed that it is in the public's interest to have up-to-date information provided but stressed that the language in any surrounding caveats must be capable of being understood by lay persons.
- 1.32.** The Chief Executive provided further explanation of the proposed metrics for the Interim CaFC ie that this will include publishing three headline rates (the composite headline rate, the 'fresh only' headline rate and the multiple birth rate). Alongside this data will be caveats, to assist patients in their interpretation of the data.
- 1.33.** The Chair thanked the committee for their comments and asked them to now consider section three of the paper regarding the recommendation for the Interim CaFC.
- 1.34.** Members were supportive of the metrics proposed for the Interim CaFC noting that public interest and patient benefit remains paramount in the decision-making process.

- 1.35.** In response to a question, the Director of Strategy and Corporate Affairs provided further details about the proposed communications plan for both the Interim and Full CaFC, including updates to the FAQs section on the HFEA website.
- 1.36.** In response to a question, the Director of Strategy and Corporate Affairs informed members that the success of the communications will be assessed by monitoring the number and theme of enquiries received and if required, the FAQs would be amended further.
- 1.37.** The Chair asked the committee whether they were content with the recommendation regarding the Interim CaFC. The committee agreed the recommendation noting:
- that as a national regulator it is necessary and appropriate for the HFEA to publish up-to-date data on the website as quickly as possible pursuant to its statutory duty under s.8(1)(c) of the Human Fertilisation and Embryology Act 2008.
  - the committee believe that it is in the public and patients' interest to have an authoritative source of data to help inform choice.
  - the committee is satisfied that all clinics have been treated equally and fairly.
  - there is strong support from the sector for the Interim CaFC Publication.
  - the committee is satisfied with the evidence provided to them for the use of the metrics for the Interim CaFC.
  - that caveats will be provided against the data explaining that various practices affect success rates and that those clinics who do more than the average number of PGT-A or donor egg cycles make it difficult to compare against the UK average and other clinics.
- 1.38.** The Committee agreed the recommendation to proceed with the Interim CaFC as soon as possible, based on the proposed metrics, i.e. publishing three headline rates (the composite headline rate, the 'fresh only' headline rate and the multiple birth rate) and including the caveats that various practices can affect success rates such as the proportion of donor egg treatments or PGT-A cycles carried out by clinics for the reasons set out by the Chair and in the paper. In addition, for clinics where the number of donor egg treatments and/or PGT-A cycles is above the national average, a note should be added advising patients that this can make it more difficult to compare those clinic's rates against the UK average and those of other individual clinics.
- 1.39.** The Chair thanked the committee for their discussion on the Interim CaFC and asked the PRISM Programme Manager for an update on the proposed Full CaFC publication, focusing on what has changed since the March 2025 AGC Meeting.
- 1.40.** The PRISM Programme Manager stated that learning from the Interim CaFC verification process suggests that rather than undertake two separate verification exercises for the Full CaFC as planned (in June for 2023 treatments and December for 2024 treatments), it would be more efficient to undertake one Full CaFC, likely to be published in Autumn 2025. The PRISM Programme Manager explained that this is because in order to properly calculate births per egg collection three years of data is needed – 2022, 2023 and 2024 – and if 2023 and 2024 were verified separately it would mean verifying 2023 data twice, first against pregnancies and then against live births.
- 1.41.** The committee noted that:
- the proposal would ease resource implications for both the sector and the HFEA and would therefore reduce regulatory burden.

- the proposal would only incur a small delay against the original timeline for publication of 2023 data.
- the HFEA proposes to conduct a form of consultation in 2025 to consider the appropriate metrics prior to publication of the Full CaFC in the Autumn. Additionally, once CaFC is properly re-established, the HFEA plans to undertake a wider piece of work, in line with its business plan, to establish appropriate metrics for future CaFC publications.

**1.42.** The Chair drew the discussion to a close and asked the committee if they were ready to take a decision on the recommendation before them. The committee agreed the recommendation to have one Full CaFC publication for both 2023 and 2024 in Autumn 2025, rather than the previous plan for the two separate publications.

**1.43.** The Chief Executive thanked the committee and informed them of the next steps.

### Decisions

**1.44.** The Committee agreed the recommendation to proceed with the Interim CaFC as soon as possible, based on the proposed metrics, i.e. publishing three headline rates (the composite headline rate, the 'fresh only' headline rate and the multiple birth rate) and including the caveats, that various practices can affect success rates such as the proportion of donor egg treatments or PGT-A cycles carried out by clinics. In addition, for clinics where the number of donor egg treatments and/or PGT-A cycles is above the national average, a note should be added advising patients that this can make it more difficult to compare that clinic's rate against the UK average and those of other individual clinics.

**1.45.** The committee agreed the recommendation to have one Full CaFC publication for both 2023 and 2024 in Autumn 2025, rather than the previous plan for the two separate publications.

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## **2. Any other business**

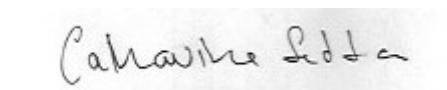
**2.1.** The committee were reminded that the next AGC meeting was in person at 2 Redman Place on 17 June 2025.

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### **Chair's signature**

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

Signature



Chair: Catharine Seddon

Date: 12 May 2025