Audit and Governance Committee meeting

Date: 30 April 2025 – 2.30pm

Venue: Virtual meeting via Teams

Agenda item	Time
1. Welcome, apologies and declarations of interest	2.30pm
2. Digital Projects/PRISM update April 2025 (KH) For decision	2.35pm
3. Close	

Digital Projects/PRISM Update April 2025

Details about this paper

Area(s) of strategy this paper relates to:	Regulating a changing environment / Supporting scientific and medical innovation
Meeting:	AGC
Agenda item:	1
Meeting date:	30 April 2025
Author:	Kevin Hudson, PRISM programme manager Rachel Cooper, Senior Legal Adviser
Annexes	None

Output from this paper

For information or decision?	For Advice and Decisions
Recommendation:	To publish Interim CaFC using the headline rates outlined in this paper To complete the full CaFC for 2023 and 2024 together, which may delay the first set of full CaFC publication
Resource implications:	
Implementation date:	If approved, publication of the interim CaFC in May 2025
Communication(s):	Letter to PRs to advise of decision and deadline for submissions
Organisational risk:	Medium

1. Background

1.1. This paper focuses on the developments in PRISM and plans for data publication on Choose a Fertility Clinic (CaFC). It follows previous discussions about the PRISM project at AGC meetings and members are referred to papers and minutes of those meetings for further detail and background.

1.2. The plan agreed at the December 2024 AGC meeting, was 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 to 2023 by the end of June 2025 and the full CaFC for treatments to 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.

1.3. On 4 March, the AGC was advised of the relevant updates about the Interim CaFC including:

- Letter from Peter Thompson to PRs on 17 December on the plan for 2025, the scope of the interim CaFC and confirming that the detailed data until 2018 would remain available. (A summary of this information was included in the December edition of Clinic Focus).
- Decision of the executives on 23 January to agree the detailed methodologies that would be used to calculate success rates for the Interim CaFC.
- PRISM programme communication to all clinics on 29 January, about the detailed process by which they will receive their interim CaFC calculation.
- Sign off for the Interim CaFC commenced on 18 February 2025 and the statistics that were on the calculation sheets sent to each clinic.
- Decision to publish a caveat with regard to clinics with higher-than-average levels of donor egg treatments.

1.4. Regarding the full CaFC, the AGC were updated on 4 March about the remaining missing thaw linkages and the work being undertaken to address these.

1.5. Following the issuing of calculation sheets for Interim CaFC to 90 clinics, 77 clinics subsequently signed off their data in the following eight weeks. Most did this by checking the HFEA activity totals and calculated success rates against their own, but for 19 clinics that requested more detail, we provided a list of the cycles involved in our calculation which they then were able to check in more detail before confirming their figures.

1.6. Of the remaining 13 clinics, one clinic declined to sign off because we were reporting only one headline rate. The other clinics are still in the process of reviewing their data and we will engage with them again after any decision has been made by AGC. There were three clinics where we were are unable to provide interim CaFC calculation sheets because they had not submitted enough information on PRISM and in these cases we advised them of this fact and

provided partial calculations for information only. These clinics will not be included in the Interim publication.

2. Survey on Interim CaFC

2.1. The HFEA 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 decision as to the metrics for the Interim publication was informed by a paper drafted by the PRISM programme manager on 17 January 2025 which is provided under separate cover (the January Paper).

2.2. The HFEA does not accept that the concerns raised by the potential claimant are justified. However, in order to allay these concerns, the HFEA agreed to publish, in addition to the composite rate, a second success rate of births per embryo transferred for women having fresh, stimulated IVF using their own eggs only (which is the current headline rate used for the CaFC).

2.3. In addition, the HFEA conducted a brief survey of clinics (via a letter to PRs dated 28 March) outlining the proposed headline rate metrics to be published for the Interim CaFC and asking clinics to confirm whether they are in favour of the Interim CaFC using those metrics or prefer delaying publication until a full CaFC publication is possible.

2.4. This survey closed on 11 April. 62 clinics (68% of all licensed clinics) responded and a summary of responses is provided under separate cover. The results were as follows:

- 79% of respondents (49 clinics) were in favour of the interim CaFC publication with the proposed metrics.
- 19% of respondents (12 clinics) preferred publication of the full CaFC only.
- 1 clinic was happy either way.

2.5. Some clinics also provided some narrative explaining their responses, reflecting a variety of views.

2.6. Of those clinics that preferred to wait for the full CaFC publication. one stated that "patients would be better informed by accessing the full data set" and another clinic stated that the publication should "all be done in one go and an interim publication is not ideal".

2.7. Two of the clinics who preferred the full CaFC publication made comments as to what they would like to be published in the full CaFC; one said that a full data set is preferable, "with data split by fresh and frozen transfers and also by embryos transferred and by cycles started" and the other commented that the full results should take account of a significant number of different parameters such as live birth rate per cycle started, live birth rate per egg collection and live birth rate per embryo transfer - with separate results within each of those categories for fresh IVF, fresh ICSI, frozen embryo transfer cycles, egg donation cycles, surrogacy cycles and PGT cycles and with age groups also differentiated. These clinics did not set out any reasons why the Interim CaFC should not be published.

2.8. By contrast, comments provided by clinics in support of the Interim publication focused on the pressing need for the HFEA to publish up-to-date information which was in patients' best interests. Representative comments include:

- "Our patients need access to up to date information they can trust and they trust the HFEA. Clinics should not delay this any further. Without up to date data on the HFEA website, patients only have the clinics own websites as a reference point for their chance of success and we know this can be reported in many different ways which can be misleading…I also feel it is important that all clinics are treated fairly. We have invested a significant amount of time and resources in reporting this data and closing missing outcomes."
- " Our team…have considered this carefully and believe that publication of the latest data is in the best interest of patients, so would support the immediate release".
- "I strongly believe it is in the interest of the patients that data is published. I can see no valid reason to wait".

2.9. Some clinics in support of the Interim publication expressed reservations about the underlying metrics but suggested that as the same metrics were being used for all clinics, it was fair and a useful comparator for patients:

- "I am very happy with the interim proposal, I see nothing but good in sharing data with the public and as long as the data equally represents each clinic I see no harm".
- "[Y]ou should push ahead with publishing the interim data. The current data is so old, it is not [sic] longer helpful for patients making a decision. Whilst I have some misgivings about what is included/excluded in the headline figures, the fact that the same metric is being used for all clinics makes it fair, and enables patients to compare clinics".

2.10. One clinic expressed concerns about combining PGT-A cycles with those that did not have PGT-A and also thought the age categories should be further differentiated. However, overall they noted that "[f]rom the patient's perspective it is better to have some data published than none. How helpful a headline figure is, is debatable, but it is a step in the right direction for the HFEA".

3. Discussion on Interim CaFC Publication

3.1. It is clear that there is strong and majority support for pushing ahead with an Interim CaFC publication. This accords with the HFEA executive's view that it is necessary and appropriate to publish up-to-date data on CaFC as quickly as possible pursuant to its statutory duty under s.8(1)(c) of the Human Fertilisation and Embryology Act 2008.

3.2. In light of some of the narrative feedback received and concerns raised by the proposed claimant to the potential Judicial Review, we have considered alternative headline rates that could be used for the Interim Publication or whether the HFEA should maintain the existing headline rate of births per embryo transferred for women having fresh, stimulated IVF using their own eggs only (in addition to the multiple births headline rate, which will remain in the interim CaFC).

3.3. We recommend that the AGC maintain the HFEA's preliminary decision to include the composite rate as a headline rate. The explanation for this is set out in the January Paper. As a result of the proposed claimant's concerns, we have already agreed to also publish fresh, own egg rates (see 2.2 above) and to include a caveat for clinics who do more than an average number of donor treatments (see 1.3 above). As set out above, the survey on interim CaFC

shows that the HFEA's preliminary decision to publish both headline rates (in addition to the multiple births headline rate) is supported by a majority of the clinics.

3.4. We have considered whether PGT-A should be excluded from the headline metrics, especially as some clinics practice batching PGT-A. For this purpose, we looked at whether and to what extent PGT-A affects success rates. When removing data about embryos that have had PGT-A from overall success rates for clinics with high PGT-A rates, there was a reduction in the success rate. In general, if the PGT-A rate was 10% or under, that would impact on success rates by up to about 2%. In some cases (where clinics had higher PGT-A rates) it affected success rates by about 3% and the most significant impact was 6% (this was for a small clinic whose PGT-A rate is 54%).

3.5. It is possible that including PGT-A in the composite rate could have the effect of promoting the use of PGT-A, contrary to HFEA policy. However, the implications of removing PGT-A data from the composite rate should also be recognised. These include:

- Clinics are expecting PGT-A data to be included (as the proposed rate amalgamates outcomes from all IVF treatments).
- There is little rationale for removing one variable (PGT-A) from the composite rate when so many variables have the potential to affect success rates (eg donor/own eggs).
- Whilst the HFEA does not encourage PGT-A for most patients, removing PGT-A rates altogether undermines patient autonomy. It could be considered better to give a fully informed picture (through further information) than to take that choice away from patients altogether.
- A single, composite rate is ultimately most helpful to consumers and in line with how other regulators present data.

3.6. Our recommendation is therefore to keep the composite rate as calculated, to include PGT-A data and donor egg data (etc), but to support patients in being able to interpret this data by adding a general caveat in the introductory text for all clinics. This will explain 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 are above the national average, we propose to add a note advising patients that this can make it more difficult to compare that clinic's rate against the UK average and other clinics.

AGC is asked to approve our 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 to help inform patients as outlined in 3.6.

4. Full CaFC Publication

4.1. Learning from the interim 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 will be more efficient to undertake one full CaFC - likely to be published

in Autumn 2025. This is because in order properly to calculate births per egg collection we need 3 years of data – 2022, 2023 and 2024 - and if we verify 2023 and 2024 separately, we would effectively be verifying 2023 data twice, first against pregnancies and then against live births.

4.2. The AGC should note that we will be conducting a form of consultation to consider the appropriate metrics for the full CaFC in 2025. In addition, once CaFC is properly re-established, we will undertake a wider piece of work, in line with our business plan, to establish the future of CaFC, which will include consideration of the appropriate metrics for the contemporary fertility sector.

AGC is asked to approve our recommendation to have one full CaFC publication for both 2023 and 2024, rather than the previous plan for two separate publications.