Scientific and Clinical Advances Advisory Committee (SCAAC) – Minutes

Monday 6th October 2025, 10:00am – 1:50pm

2 Redman Place, London, E20 1JQ & Microsoft Teams

Authority members	Present	Tim Child (Chair) Stephen Troup (Deputy Chair) Christine Watson Geeta Nargund (virtual) Zeynep Gurtin
	Apologies	Frances Flinter
External advisers	Present	Anthony Perry Scott Nelson (virtual) Alison Campbell Peter Rugg-Gunn Veronique Berman (virtual) Ying Cheong Asif Muneer Sarah Martins Da Silva Laura Shallcross
Speakers	Present	Andy Vail (Expert Statistician, University of Manchester) for item 7 (virtual)
Executive	Present	Julia Chain (Chair of Authority) (virtual) Clare Ettinghausen (Director of Strategy and Corporate Affairs) Rachel Cutting (Director of Compliance and Information) (virtual) Dina Halai (Head of Policy, Scientific) Rebecca Taylor (Scientific Policy Manager) Molly Davies (Policy Manager, Scientific) Mina Mincheva (Policy Manager, Scientific) Dharmi Deugi (Scientific Policy Officer; Committee Secretariat)
	Apologies	Peter Thompson (Chief Executive)
Observers	Present	Amy Parsons (Department of Health and Social Care) (virtual) Several HFEA staff observed the meeting as relevant to their role or induction into the organisation.

1. Welcome, apologies, declarations of interest

1.1. The Chair welcomed the Committee and introduced Professor Laura Shallcross, a new External Adviser (EA) who has joined the SCAAC following an open recruitment process. Professor Shallcross brings both clinical and research expertise in big data, machine learning and AI. She is the Director of the Institute of Health Informatics at University College London and the Professor of Public Health & Translational Data Science at the National Institute for Health and Care Research.

1.2. Apologies were received from Frances Flinter.

1.3. The Chair reminded members of the advisory role of the SCAAC, highlighting that members should advise the HFEA on any significant implications for licensing and regulation arising out of scientific and clinical developments in assisted conception, embryo research and related areas.

1.4. Declarations of interest were made by:

- Alison Campbell (Chief Scientific Officer at Care Fertility) – Care Fertility clinics in Spain offer platelet rich plasma treatment (PRP).
- Peter Rugg-Gunn (Group Leader and Head of Public Engagement at The Babraham Institute) – Involved in research related to stem cells and embryo models.

1.5. No further conflicts of interest were declared.

2. Matters arising

2.1. The Executive updated the Committee on the matters arising as laid out in the matters arising paper for this meeting.

2.2. No further comments were made.

3. Chair's business

3.1. The Chair provided key points for each topic from the annual HFEA Horizon Scanning Meeting (HSM) 2025. The Committee was informed that the HSM takes place during the European Society of Human Reproduction and Embryology (ESHRE) conference as it provides an opportunity to bring together a range of experts on the topics that are being discussed.

3.2. The Chair noted that the Executive are now using Ovid Medline rather than PubMed for literature searches to ensure comprehensive coverage and align with methodology applied for identifying studies on treatment add-ons.

3.3. The Executive are now using Microsoft Excel for presenting horizon scanning topic literature searches rather than summarising publications within the meeting papers themselves. Where possible, literature is categorised under relevant subheadings.

3.4. A retraction tool will also be used to identify whether a paper is under investigation or the (lead/corresponding) author(s) of a study have other papers retracted or under investigation. This will be noted in the table of references.

3.5. The Executive is currently reviewing the horizon scanning process and will present further details at the February 2026 SCAAC meeting.

3.6. The Executive are currently recruiting a pool of External Expert Biostatisticians to assist the SCAAC by undertaking evidence reviews on the efficacy of fertility treatment add-ons. The Executive are hoping to recruit three to five experts with experience in systematic review and evidence assessment using the GRADE methodology.

4. Relevant public health developments and research findings

4.1. The Chair informed the Committee that this item provides members with the opportunity to highlight research relevant to the interests and role of the SCAAC, including those relevant to the horizon scanning topics that SCAAC have prioritised, the 'watching brief' topics (see February 2025 horizon scanning paper), and for treatment add-ons ratings.

4.2. The Committee considered the following research paper and made the following comments:

- Evaluating the Role of rIVM and rICSI in Assisted Reproductive Technology: A Systematic Review and Meta-analysis of Outcomes in Low/Failed Maturation and Fertilisation Cases - European Medical Journal

4.2.1. It was published as an abstract review.

4.2.2. The methodology is not adequately described and as a result different interpretations arose. This included that researchers were excluding day one rescue ICSI (rICSI) as well as rescue in vitro maturation (rIVM) and only focusing on day zero rICSI, and that rICSI may have been performed on oocytes that had failed to fertilise.

4.2.3. The data on in vitro maturation (IVM) with higher miscarriage rates for germinal vesicles (GV) to metaphase II (MII) was interesting as although researchers reported GVs entering MII, in clinical practice generally very few GV prophase immature oocytes reach MII.

4.2.4. The methodology for IVM is not currently standardised or optimal and there might be a risk to stripping oocytes of the cumulus cells, which may be required in important processes during maturation.

4.2.5. Using a questionnaire to collect information from various published papers was not a common method of gathering large amounts of data.

4.2.6. rICSI is permitted in the UK and considered on a case-by-case basis, especially in cases where most or all oocytes collected are immature. The HFEA Code of Practice refers to the UK professional guidance for clinics on the 'Use of ICSI in Assisted Reproductive Technology' which was published jointly in 2023 by the Association of Reproductive and Clinical Scientists (ARCS) and the British Fertility Society (BFS).

4.2.7. Given that rICSI has only been performed for a short period of time, research is still early stage, and more data is needed to evaluate success. The terminology related to rICSI is also particularly challenging.

4.2.8. From a funding point of view, the use of rICSI may prevent patients from undergoing further NHS funded cycles of IVF, which will have cost implications on patients.

4.3. **Recommendation:** To remind clinics of the rICSI professional body guidance via a Clinic Focus article.

4.4. The Committee noted the following two publications on mitochondrial donation which summarised progress on the techniques used and outcomes:

- Mitochondrial Donation and Preimplantation Genetic Testing for mtDNA Disease | New England Journal of Medicine
- Mitochondrial Donation in a Reproductive Care Pathway for mtDNA Disease | New England Journal of Medicine

4.5. The Chair noted that the findings of the paper comparing the outcomes of in-vitro fertilization in same-sex female couples using their partner's egg versus their own egg: a systematic review, resulted in additional minor changes to the updated information on the HFEA website to highlight increased obstetric risks in same-sex female couples undergoing reciprocal IVF.

4.6. In relation to the paper on the induction of experimental cell division to generate cells with reduced chromosome ploidy, members made the following comments:

4.6.1. This technique is still a long way from being introduced in clinical practice due to significant technical barriers. One reason for this is the use of skin cells, which although easy to obtain, accumulate a large number of genetic mutations over time and therefore are considered poor starting material. The technique in the paper demonstrated low efficiency; less than 10% of the embryos developed, and genetic and epigenetic abnormalities would also need to be considered.

4.6.2. Other challenges, not addressed in the paper, included not achieving accurate chromosomal segregation into the polar bodies. Most of the oocytes that were created either had an incorrect number of chromosomes or chromosomes from the wrong origin, as no chromosomes segregated at all in just below half of the cases. The chromosomes that did segregate were random.

4.6.3. It was agreed that the paper did not add many further insights on the topic and further research is required. It was noted that reports in the media may have created a sense of false hope and worry amongst the public, especially as a future treatment for infertility.

5. Alternative methods to derive embryonic and embryonic-like stem cells

5.1. The Committee was reminded that research on the topic of alternative methods to derive embryonic and embryonic-like stem cells was last reviewed in June 2024, during which it was concluded that it was vital that work to derive stem cell lineages through embryo research continues.

5.2. The paper presents research findings on establishing and maintaining stem cell populations derived from human embryos, providing details of literature published between 1st May 2024 and 26th August 2025. The topic remains a high priority.

5.3. The Committee made the following comments and recommendations:

5.3.1. It was flagged that terminology in this field is confusing and contradictory. It was pointed out that that 5.2 in Annex A of the paper, is only one of several definitions of totipotent stem cells. Another

definition describes totipotency as a cellular property that can give rise to an entire organism or individual, including the spatiotemporal organisation and differentiation of various cell types. This latter definition is put forward by Maureen Condic who proposes a new term, “plenipotent” to describe stem cells that can give rise to all embryonically derived cells[1].

5.3.2. Members agreed that stem cell definitions need to be clarified, especially when some cell states can become other cell states.

5.3.3. **Recommendation:** The Executive to review the search terms used to identify studies relevant to this topic to include all relevant terminology.

5.3.4. Significant progress was noted in embryo research in recent years with the development of several novel stem cell lineages which model a variety of properties, including various extraembryonic stem cell types, being derived from embryos.

5.3.5. In addition to the development of trophoblast stem cell lines detailed in the paper, researchers have recently reported deriving extraembryonic mesoderm cell lines from human embryos[2]. Together, these cell lines provide an important resource for understanding the lineage specification of extraembryonic tissue, offering a new resource to investigate placental formation in vitro.

5.3.6. By assembling different stem cell types together, the generation and accuracy of stem cell-based embryo models (SCBEM) can also be improved, enhancing their utility for studying human embryogenesis.

5.3.7. The findings of an unpublished study describing the creation of an embryo model with resemblance to a day 28 human embryo were highlighted. The model included a fore, mid and hindbrain, a body-like structure, a neural tube, and beating cardiac chambers. Such research could generate a significant public reaction, and progress should be monitored in case a statement is required from the HFEA.

5.3.8. It was noted that SCBEMs are not currently covered in the HFE Act 1990 (as amended) and therefore not within the HFEAs remit.

5.3.9. Following discussions on the need for embryos as a gold standard to validate SCBEMs, a member questioned whether the Authority has any power to facilitate the donation of surplus embryos from clinics to research projects. The Executive explained that this has been proposed as part of the law reform proposals (proposal 13), and that further collaboration between clinics and research centres should be encouraged.

5.3.10. From a patient perspective, knowing that unused embryos will be contributing to further knowledge and progress in research could be comforting especially for patients whose treatment progress is slow.

5.3.11. In response to a question on the point at which SCBEMs should be considered indistinguishable from a human embryo, the Executive stated that no conclusions were made during discussions on this topic in October 2024. Until there is more information on the risks associated with SCBEMs

[1] Totipotency: What It Is and What It Is Not - PMC

[2] A blastocyst-derived in vitro model of the human chorion | bioRxiv (preprint).

as well as any differences in development from a human embryo, they should be differentiated as models. The Nuffield report on SCBEM does not provide any conclusions.

5.3.12. A member reminded the Committee that the law currently permits human embryo culture only until day 14, but that discussions on extending this limit have proposed extension to day 28. A reason for researchers proposing a 28-day limit is because day 14 to day 28 is considered a black box due to lack of ability to study this period of embryo development. It is also the period during which there is a high rate of early miscarriages. Research on SCBEMs has been able to culture models to developmental stages beyond 14 days, reaching embryologically significant points including neural tube closure and can therefore provide insights into the causes of neural tube defects. Furthermore, the creation of beating cardiac chambers would provide insight into the origins of early cardiac defects. In respect to this, it is important to note that public engagement work found that the appearance of a beating heart during embryo development has a significant emotional impact amongst the public.

5.3.13. It was stressed that SCBEMs provide only partial insights into the human embryo. These models do not straightforwardly allow investigation of placenta formation or interactions between the placenta and the endometrium, as embryo models typically only recapitulate the embryo itself and the extraembryonic tissues form poorly. Better understanding of placenta formation and interaction could help identify the origins of other conditions, such as preeclampsia and can only be fulfilled by other systems.

5.3.14. Members also noted that some laboratories are working on co-culture of embryo models with endometrial cells, and the development of in vitro implantation-on-chip models.

5.3.15. The Executive informed the Committee that the Nuffield Council on Bioethics will be conducting a UK-based public dialogue to understand public attitudes on extension of the 14-day rule for human embryo research.

5.3.16. Following discussions on the title, members suggested updating the title to ensure that it is clear that both embryonic and extraembryonic stem cells can be derived from the human embryo.

5.3.17. **Action:** The Executive to amend the title of this topic to ‘Methods to derive embryonic and extraembryonic stem cells from human embryos’.

6. Testicular tissue transplantation to restore fertility in males

6.1. The Executive noted that the clinical aspects of this topic were reviewed by an invited speaker at the October 2023 SCAAC meeting who spoke on ‘in vitro derived gametes’. During discussions, it was agreed that the topic of testicular tissue transplantation to restore fertility in males should be considered a distinct topic from ‘in vitro derived gametes’. Testicular transplantation to restore fertility in males was then added to the SCAACs horizon scanning prioritisation as a medium priority topic in February 2024.

6.2. The paper summarises research developments that have taken place in the last 10 years from January 2015 to August 2025.

6.3. The Committee made the following comments and recommendations:

6.3.1. In England, Oxford University Hospitals has been performing testicular tissue cryopreservation for an extended time period, in the hope of using it for future fertility restoration. A few other hospitals across England are also offering this procedure in collaboration with the Future Fertility Programme at Oxford. The Edinburgh Fertility Preservation centre at the University of Edinburgh also provides this service. These services are now beginning to see patients who previously had tissue cryopreserved as prepubertal boys return wishing to use the tissue.

6.3.2. The majority of the research is preclinical, utilising animal models, such as mice and primates. Human based studies where tissue has been transplanted into the scrotal wall, have shown that the tissue is still viable with some neovascularisation.

6.3.3. Optimal methods for testicular tissue cryopreservation and thawing are currently unknown. Given limited research in humans, there are also outstanding questions related to techniques for handling tissue and locations for autografting, alongside tissue viability and the influence of epigenetics.

6.3.4. From a safety perspective there is also a lack of data on long term outcomes of hypogonadism due to the absence of standardised protocols, and need for testosterone replacement therapy (TRT). Another critical concern involves the quality of the tissue, especially due to cancer recurrence risk, and therefore considering tissue screening is important.

6.3.5. Another route to restore fertility that can be considered is the creation of in vitro gametes (IVGs) as they have the potential to produce spermatogonia through the addition of growth factors. If developed safely and successfully, this could potentially in time be preferable to the transplantation of testicular tissue. This is because testicular tissue transplantation requires tissue grafting into a natural environment alongside sperm extraction and ICSI, relying on the expectation that the tissue will successfully graft and produce spermatogonia. The Chair acknowledged that the topic of IVGs has been previously discussed and will continue to be monitored as a distinct topic.

6.3.6. The Executive explained that permitted gametes as defined under the HFE Act 1990 (as amended) covers gametes under any stage of maturation, as long as they are sourced from testes or ovaries. There is a joint HFEA and Human Tissue Authority (HTA) statement currently in place to address the regulatory overlap and licensing processes. Regarding consent processes, the majority of parents will initially consent on behalf of their child, following which after a certain age the patient would return to reconsent.

6.3.7. Consulting prepubertal boys and conducting testicular tissue cryopreservation within fertility clinics was thought to be inappropriate due to the need for additional patient screening as well as obtaining tissue under general anaesthesia.

6.3.8. In Scotland, fertility clinics are not involved in testicular tissue cryopreservation programmes as a national pathway has been set up. The pathway enables patients to consult paediatric urologists and oncologists at Edinburgh Fertility Preservation where biopsies are taken and tissue is stored. In London, patients can consult with Great Ormond Street hospital who are collaborating with Oxford University Hospitals to provide testicular tissue cryopreservation services.

6.3.9. A question was raised as to whether existing pathways could be improved by setting up more referral centres around the UK or if shipping tissue to available testicular cryopreservation centres could help avoid any further stress on young oncology patients, such as, travelling long distances.

6.3.10. Caution was expressed about involving fertility clinics in testicular tissue cryopreservation processes as the responsibility should be with the expert oncology services to ensure they have clear pathways. However, clinics should be aware of these services and referral pathways.

6.3.11. It was highlighted that parents of prepubertal boys with cancer are trying to navigate several different challenges, with the most important being the survival of their child. The hope that testicular tissue cryopreservation can be used for future fertility restoration should be managed.

6.3.12. In response to a question about learnings from ovarian tissue cryopreservation pathways, the Executive noted that the Oxford University Hospitals webpage states that testicular tissue cryopreservation is still experimental and restoring fertility is not yet guaranteed.

7. Rating review for treatment add-ons: Platelet-rich plasma (PRP)

7.1. The Chair welcomed expert Statistician, Andy Vail, from the University of Manchester.

7.2. The Committee were reminded that the June 2025 meeting considered an application to rate intraovarian and intrauterine PRP as a treatment add-on. It was noted that, although the Medicines and Healthcare products Regulatory Agency (MHRA) regulates PRP, the HFEA treatment add-on rating is needed to provide unbiased evidence-based information to patients on treatment add-ons for informed decision-making.

7.3. The add-ons review panel identified five population groups and five outcomes for intrauterine PRP, and two population groups and four outcomes for intraovarian PRP. Given the large number of populations and outcomes, the Committee was asked to consider which populations and outcomes will be the most useful to include on the HFEA add-on ratings webpage.

7.4. The following comments and recommendations were made:

7.4.1. The statistician commented that despite a large number of studies, the quality of research was very poor with high variability, limiting the extent to which findings can inform clinical practice. Most studies do not address treatment safety and with those that do tend to report only on the tolerability of the product rather than method of preparation or administration.

7.4.2. Given the lack of high-quality evidence, a grey rating was recommended for all outcomes and populations for both intraovarian and intrauterine PRP. The statistician stressed that this recommendation was based on statistical analysis alone and that members may wish to consider the safety concerns in further detail.

7.4.3. Significant safety concerns were raised in relation to the preparation and methodological aspects of PRP, including:

- the absence of standardised protocols and training processes, especially in relation to conducting PRP under supervision and with a doppler ultrasound;
- risks associated with the administration of a non-sterile product into the ovary or uterine cavity;
- lack of reporting on serious adverse effects for the patient, including bleeding, infection or allergy;
- limited research into the impact of the product on gametes or embryos themselves;

- variability in product preparation (including either in tubes or kits), and differing techniques used to administer PRP (including the use of different needles, vials, volumes and injection location sites); and
- ensuring that the PRP remains in the targeted location (note: there is some evidence to suggest PRP will remain in its targeted location in closed compartments, however this may not be the case in vascular sites).

7.4.4. It was raised that PRP has a lot of potential to generate profit due to low kit and material costs combined with rapid processing methods involving centrifugation, raising additional concerns about inappropriate use of equipment.

7.4.5. It was suggested that due to significant safety concerns, red ratings should be considered with the associated text clarifying the outcomes reported by the reviewed studies in addition to potential risks.

Intraovarian PRP

7.4.6. Three randomised trials were identified including one credible study with a small sample size (60 patients), which found no benefit and reported lower birth rates in the intervention arm[3].

7.4.7. A study by Herlihy et al (2024) was said to be of better quality but found that intraovarian PRP did not improve oocyte yield[4].

7.4.8. In addition to the risks outlined in paragraph 7.4.3., intraovarian PRP can be associated with additional risks, including those associated with anaesthesia as well as administration of the product directly into the ovary. Performing PRP on women with low ovarian reserve may also carry additional risks as their ovaries tend to be smaller than average sized ovaries, which can more easily be located and blood vessels avoided.

7.4.9. The Committee agreed that the 'general population' group should be removed as intraovarian PRP is only targeted at patients with a poor/diminished ovarian reserve and should not be offered to the general population. Furthermore, it was concluded that rating outcomes such as 'oocyte numbers', 'blastocyst numbers' and 'ongoing pregnancy rates' would not be useful from a patient perspective.

7.4.10. It was flagged that another population to potentially consider is premature ovarian insufficiency (POI), though the Executive explained that the delineation between poor/diminished ovarian reserve and POI is not always clearly defined in the studies.

7.5. Recommendation: The committee agreed the following rating for intraovarian PRP:

- RED for live birth rate for patients with poor/diminished ovarian reserve. This is due to the invasive nature of the method of administration, whereby PRP is administered directly into a solid ovary which carries infection risk and requires anaesthesia, which itself brings risks

Intrauterine PRP

[3] Intraovarian platelet-rich plasma injection and IVF outcomes in patients with poor ovarian response: a double-blind randomized controlled trial | Human Reproduction | Oxford Academic

[4] Effect of intraovarian platelet-rich plasma injection on IVF outcomes in women with poor ovarian response: the PROVA randomized controlled trial | Human Reproduction | Oxford Academic

7.5.1. The statistician noted that all 17 randomised trials were of very poor quality, questioning the ethical aspects of the studies. He also informed the Committee that the Cochrane review grouped several of these studies as “awaiting classification” due to doubts over the trustworthiness of the research.

7.5.2. As mentioned in paragraph 7.4.3, members reiterated the absence of standardised protocols highlighting that variations in the way intrauterine PRP is used, for example, administration of the product directly into the uterine cavity or injecting it during a hysteroscopy, can be associated with additional risks.

7.5.3. It was remarked that the targeted patient populations are quite rare with specific issues such as endometrial thickness or recurrent implantation failure. The chair suggested that instead of assigning ratings to all populations and outcomes, accompanying text could explain the assigned rating.

7.5.4. Members agreed that the ‘general population’ group should be removed as this add-on should not be offered to the general population. Following conflicting views between a grey and red rating, it was agreed that intrauterine PRP should be assigned a red rating due to the associated safety concerns.

7.6. **Recommendation:** The committee agreed the following rating for intrauterine PRP:

- RED for live birth rate for endometrial thickness for thin/refractory endometrium.
- RED for live birth rate for recurrent/repeated implantation failure.
- RED for live birth rate for Asherman’s syndrome/intrauterine adhesions.
- RED for live birth rate for recurrent pregnancy loss.

7.7. Members further discussed the importance of protecting vulnerable patient populations and ensuring that patients can make informed decisions, especially with treatments considered experimental.

7.8. A member stated that over the last couple of years, they had seen an increase in clinics offering PRP, with approximately 20% of clinics they had contact with now offering this. Despite this, only a few clinics are advertising PRP on their websites.

7.9. The Executive reassured the Committee that HFEA inspections review patient information related to treatment add-ons that are being offered by the clinic. The inspectorate ensures that the clinic’s patient facing information is accurate and reflects information provided by the HFEA, noting that not providing this information is regarded as non-compliance. Rating PRP as a treatment add-on will ensure that clinics have a duty to signpost patients to the HFEA rating and provide information on its use.

8. Any other business

8.1. The topic of ‘Reproductive organoids’ is a new topic planned for discussion at the next SCAAC meeting in February 2026. The Chair invited members to share any relevant speakers for this topic.

8.2. The annual Committee Effectiveness Review is due to take place towards the end of the year. The Executive will circulate a self-evaluation form to the Committee for members to complete prior to January.

8.3. NICE have published a draft guideline for consultation on Fertility Problems – Assessment and Treatment. The Executive is examining the draft guideline, in particular the evidence review and recommendations on sperm DNA fragmentation, given that it is to be considered for an HFEA treatment add-on rating.

8.4. In relation to the recommendation of coeliac testing in patients with unexplained fertility and recurrent miscarriages in the NICE draft guidance, it was noted that this falls outside of the HFEAs remit.

9. Meeting summary and close

9.1. The dates for the SCAAC meetings in 2026 have been agreed as follows:

- Wednesday 4th February 2026 (hybrid meeting)
- Wednesday 3rd June 2026 (online meeting)
- Wednesday 7th October 2026 (in person meeting)

9.2. The Chair closed the meeting by thanking the Executive for the putting the papers together and thanking Dharmi Deugi for her support as Scientific Policy Officer and Secretariat of the SCAAC during 2025.

10. Chair's signature

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

Chair: Tim Child

Date: Monday 24th November 2025