Scientific and Clinical Advances Advisory Committee (SCAAC) – Minutes

Monday 3rd June 2024, 10:20am – 2:00pm

Microsoft Teams

Authority members	Present	Tim Child (Chair) Alex Kafetz Frances Flinter (virtual until 11.45am) Christine Watson (virtual) Zeynep Gurtin (virtual)
External advisers	Present	Jason Kasraie Robin Lovell-Badge Anthony Perry Scott Nelson (virtual) Kevin McEleny (virtual) Richard Anderson (virtual) Ying Cheong Peter Rugg-Gunn Veronique Berman
	Apologies	Alison Campbell
Executive	Present	Julia Chain (Chair of Authority) Clare Ettinghausen (Director of Strategy and Corporate Affairs) Rachel Cutting (Director of Compliance and Information) Joanne Anton (Head of Regulatory Policy) Rebecca Taylor (Scientific Policy Manager) Mina Mincheva (Policy Manager) Molly Davies (Scientific Policy Officer; Committee Secretariat)
Observers	Present	Kath Bainbridge (Department of Health and Social Care) Jane Saxton (HFEA Scientific Inspector) Konstancja Neville (HFEA Scientific Inspector) Dharmi Deugi (HFEA Policy Officer) Anis Dadou (HFEA Research Manager, Civil Service Fast Stream)

1. Welcome, apologies, declarations of interest

1.1. The Chair welcomed the Committee and introduced three new External Advisers to the SCAAC:

- Ying Cheong will be supporting the Committee with expertise in Reproductive Medicine.
- Peter Rugg-Gunn will provide advice on Developmental Genetics and Developmental Models.
- Veronique Berman will offer a perspective on Fertility Patient Support.

1.2. Apologies were received from Alison Campbell.

1.3. No declarations of interest were received in relation to the meeting agenda.

1.4. 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.

2. Matters arising

2.1. The Executive updated the Committee on the matters arising from the meeting:

2.1.1. In the July 2023 meeting, the Committee requested that an application for androgen supplementation as a treatment add-on was brought back for consideration following amendments made to the add-on's application form and decision tree. The application is due to be discussed at this meeting under item 7.

2.1.2. The topic of 'AI, robotics and automation in fertility treatment' was discussed at the February 2024 meeting. The Executive has since initiated a dedicated project on AI, robotics and automation, which involves regulatory mapping and compiling the uses of AI within fertility treatment. The Executive will communicate with the sector and patients as appropriate.

2.1.3. Following discussions on the impact of long-term cryopreservation of gametes and embryos at the February 2024 meeting, the Executive updated the patient-facing website information to note that there is a lack of evidence regarding the impact of long-term storage of the viability of gametes and embryos.

2.1.4. At the February 2024 meeting the Committee agreed that the review of treatment add-ons ratings will be carried out every five years, or when new substantial evidence comes to light. The treatment add-ons webpage has been updated to reflect the agreed review frequency.

2.1.5. With the expansion of the topic on genome editing, the Committee recommended that the Executive considers consulting an expert on epigenetics to comment on techniques of modifying the epigenome of the early embryo. Since this recommendation was made, an External Adviser with expertise in epigenetics, Peter Rugg-Gunn, has joined the SCAAC.

3. Chair's business

3.1. The Chair informed members that Kate Brian's term as an External Adviser to the SCAAC ended in April 2024, between meetings. The Committee recognised Kate's contributions to the SCAAC and thanked Kate for her invaluable work on patient support during her time on the Committee.

3.2. This will be Robin Lovell-Badge's final SCAAC meeting in his capacity as an External Adviser. The Chair acknowledged Robin's expertise in stem cell biology and developmental genetics, thanking him for his valuable contributions to discussions on the 14-day rule and stem-cell based embryo models. Robin has been invited to return to the SCAAC in October 2024 as an expert speaker on these topics.

3.3. The Chair welcomed Rebecca Taylor as the HFEA's new Scientific Policy Manager who will have oversight of the SCAACs workplan and horizon scanning function.

3.4. The Chair notified the Committee that, following the March Authority meeting, the Committee's Standing Orders have been updated to give the SCAAC power to make decisions in relation to authorised processes. As the primary function of the SCAAC remains advisory, the Authority decided that the Committee will continue to be referred to as the Scientific and Clinical Advisory Committee.

3.5. The Chair reminded the Committee that the Executive is currently planning the HFEA's Annual Horizon Scanning Meeting which will be held during the 40th Annual Meeting of the European Society of Human Reproduction and Embryology (ESHRE). Topics planned for discussion at the meeting include:

- Genetic screening of the embryo: polygenic traits and conditions
- The promise of organoids – recreating the reproductive system in vitro
- Future uses of Artificial Intelligence in the IVF lab – what are the possibilities?
- Ovarian rejuvenation – emerging strategies

3.6. The Executive noted that the Horizon Scanning Meeting is held as a closed meeting and attendance of the meeting is by invitation only.

4. Relevant public health developments and research findings

4.1. At the June 2020 meeting, the SCAAC agreed to take on a monitoring role looking at the effects of COVID-19 on fertility, assisted conception and early pregnancy. In June 2022 the Committee agreed to retain this item, using it as an opportunity to discuss relevant public health developments which may impact upon assisted conception and embryo research.

4.2. During the October 2023 meeting, this item was further expanded to include research findings outside the scope of public health developments which are relevant to the interests and role of the SCAAC, including research developments relevant to the add-ons ratings. This could be research that may change a rating for an add-on, or to highlight new add-ons that are being offered in UK clinics with an unevidenced claim that they improve live birth rates.

4.3. Prior to the meeting, the Executive and a member of the SCAAC had highlighted the following papers to the Committee for consideration:

- Does recurrent implantation failure exist? Prevalence and outcomes of five consecutive euploid blastocyst transfers in 123 987 patients | Human Reproduction | Oxford Academic (oup.com)
- Impact of coronavirus disease 2019 vaccination on live birth rates after in vitro fertilization - Fertility and Sterility (fertstert.org)
- High levels of weedkiller found in more than half of sperm samples, heightening fertility risk concerns | Climate News | Sky News
- Screening embryos for polygenic disease risk: a review of epidemiological, clinical, and ethical considerations | Human Reproduction Update | Oxford Academic (oup.com)

4.4. In relation to the paper on preimplantation genetic testing for polygenic disease (PGT-P), the Committee made the following comments and recommendations:

4.4.1. At a population level polygenic risk scores are enhancing understanding of how inherited susceptibility works. However, the technology is not sufficiently advanced for application in embryo testing, with scores giving information relevant to populations rather than individuals. In addition, the tests often claim to predict susceptibility to late onset diseases, such as cancer or diabetes, for which the clinical treatment may progress in future.

4.4.2. Screening embryos using PGT-P is likely to reduce the number of embryos available for transfer, thereby reducing the chances of having a healthy baby overall. This is because embryos that would have been healthy at birth may be excluded due to a perceived increased risk of disease which may never develop.

4.4.3. It was noted that many healthy individuals may have increased risk of certain polygenic diseases, and that behaviour (diet, physical activity, alcohol consumption, smoking status etc.) throughout the course of an individual's life will have a significant effect on the likelihood of a disease developing. In addition, there is little evidence to support that being made aware of a polygenic risk score will have a positive influential effect on the behaviour of that individual. At a population level, encouraging and supporting healthy lifestyles would likely have a more significant effect on disease prevention than selection using polygenic risk scores. Interpretation of polygenic risk scores can therefore be overly deterministic.

4.4.4. Assessing polygenic risk scores in the UK is currently illegal because PGT-P does not meet the criteria defined in the HFE Act. As per the Human Fertilisation and Embryology Act 1990 (as amended) embryo testing licences can only be granted where there is a significant risk of serious disease. At present the HFEA Statutory Approvals Committee licence on the basis of Online Mendelian Inheritance in Man (OMIM) variants in single genes which indicate a significant risk of serious disease. In theory, the *absolute* risk of a polygenic risk score may in future cross the relevant threshold for HFEA licencing, however, at present it is unlikely that any current polygenic risk scores would reach the threshold required to be approved for a licence.

4.4.5. It was then noted that whilst a particular selection of markers may indicate a slight increase in relative risk for an individual, that same set of markers may result in a reduction in risk for another disease. The ability to test for the relative risk of numerous diseases using a single test will depend upon the number of loci tested for. It was further added that knowledge of variable relative

risks for numerous diseases would make it difficult for a couple to select an embryo to be transferred, in the event of having a number of embryos to choose from.

4.4.6. The Committee considered the circumstances in which PGT-P would be authorised by the HFEA. A member noted that whilst polygenic risk scores can indicate an increased *relative* risk to an individual for developing a disease, the *absolute* risk of developing the disease is likely to be small in most cases.

4.4.7. It was noted that this technology has seen a large rise in commercialisation overseas, with companies pursuing private equity funding to expand into the European fertility markets. A member highlighted that patients may therefore travel internationally to seek testing. However, it was also noted that the cost of treatment and testing may be a prohibitive factor, limiting its use to a niche group of consumers. ESHRE has issued a position statement making it clear that testing using PGT-P is clinically inappropriate.

4.4.8. A member noted that it will be important to understand how clinics that are interested in developing and commercialising these technologies, will market them to patients. This will be particularly important when it comes to ensuring patient information on PGT-P and polygenic risk scores addresses the marketing messages used.

4.4.9. It was queried whether it was likely that PGT-P may eventually be introduced as part of a tiered package of genetic testing whereby embryos are tested using preimplantation genetic testing for monogenic disorders (PGT-M), followed by preimplantation genetic testing for aneuploidy (PGT-A), then subsequently tested for relative risk using PGT-P. A member reiterated that both PGT-A and PGT-P testing would reduce a couples chance of having a healthy baby by reducing the total number of embryos available for transfer (4.4.2).

4.4.10. It was noted that there is already a shortage of genetic counsellors available to provide support for patients going through preimplantation genetic testing, which would be amplified should PGT-P be introduced to market. Patients may turn to advice provided by generative AI to support fertility decisions. In addition, it was asked how children born from the selected embryos would be appropriately counselled and supported, having been born with an identified increased susceptibility to known disease(s)?

4.4.11. The Committee agreed that at present the disadvantages of preimplantation testing for polygenic risk scores significantly outweigh the advantages.

4.5. **Recommendation:** The Executive to prepare a robust evidence-based statement on the use of PGT-P, including why PGT-P may be offered, the risks and concerns therein, and explaining that PGT-P is not permitted in the UK.

4.6. In relation to the publication on recurrent implantation failure, the Chair noted that although the study focused on 105 patients not 123,987 as noted in the title, the paper is still of interest. This is as it highlights that for this patient group there is a 92% cumulative live birth rate after three euploid blastocyst transfers, which increases to 98% following further transfer of a fourth or fifth blastocyst. The clinicians discussed the relevance of these findings:

4.6.1. The Chair noted that in the paper the researchers excluded patients with fibroids, recurrent miscarriage or using donor eggs.

4.6.2. It has previously been argued that there is a population of patients with an unidentified uterine factor which has prevented implantation despite repeated transfer of high-quality embryos. This paper adds to the debate on recurrent implantation failure diagnoses and suggests that, with repeated transfer of known good quality embryos, only a very small population of women are unable to get pregnant following numerous opportunities. However, a member cautioned that the data is not new, and that there are methodological flaws in the study including removing patients more likely to have worse outcomes.

4.6.3. A member reasoned that, the fact that they are not seeing the success rates that you would expect, suggests there may be other reasons why implantation does not occur when using euploid blastocysts in this population.

4.6.4. It was noted that mitochondrial replacement therapies are being used to treat patients with poor embryo quality overseas, and these are being mentioned as a technique which may be applied for patients with recurrent failure, although this is not legal in the UK.

4.7. In relation to the paper looking at the impact of the coronavirus disease vaccination on IVF outcomes, the Chair noted that the paper was in keeping with other studies which indicated that vaccination had no impact on IVF outcomes.

4.8. In relation to the publication on high levels of weedkillers being found in seminal fluid, the Chair noted that monitoring of environmental toxins and their impact on fertility is being increasingly investigated. The Executive noted that horizon scanning for studies relevant to the impact of environmental toxins on infertility parameters is not monitored by the SCAAC as an individual topic but that this could be considered.

4.9. A member raised a paper titled 'Intracytoplasmic sperm injection versus conventional in-vitro fertilisation for couples with infertility with non-severe male factor: a multicentre, open-label, randomised controlled trial - The Lancet', noting that use of ICSI in this population did not improve live birth rates compared to conventional IVF, and that routine use of ICSI is not recommended in this population. Another member highlighted that the trial's conclusions were consistent with the 2023 joint professional body guidelines on the use of ICSI in ART.

4.10. **Recommendation:** The Executive to review patient-facing website information to ensure it is clear to patients that there is no evidence-base to support the use of ICSI for non-male factor infertility, which is in line with professional body guidelines.

5. Emerging technologies in embryo and gamete testing

5.1. A summary of the paper highlighting the key developments in the emerging technologies in embryo and gamete testing was presented to the Committee. It was noted that this topic was expanded to include gamete testing in January 2022, with the further addition of metabolomics profiling in February 2024. Established techniques of embryo testing are not included in the paper.

5.2. In addition to the comments made on PGT-P under the item 'Relevant public health developments and research findings', the Committee provided feedback on the recent developments on the topic:

5.2.1. A member noted that the HFEA regulates the purpose of the test, not necessarily the technology used. At present, preimplantation genetic testing for monogenic disorders (PGT-M) and structural rearrangements (PGT-SR) following blastocyst biopsy remains the gold standard. As it currently stands, other methods of testing for monogenic disorders or structural rearrangements do not appear to be as accurate as established techniques. In due course, the sensitivity and specificity of techniques may improve.

5.2.2. The member went onto comment that that there remains a large volume of research attempting to test embryos for aneuploidy, despite preimplantation genetic testing for aneuploidy (PGT-A) not being clinically indicated: rated red as a HFEA treatment add-on and not recommended by ESHRE. Therefore, although new methods which do not require embryo biopsy may be sold as methods of PGT which reduces the risk to the embryo, testing itself will still reduce the chances of having a healthy baby by limiting the number of embryos available for transfer.

5.2.3. It was additionally noted that mosaicism of the embryo may be a normal part of human development and something that spontaneously corrects.

5.2.4. A member commented on a selection of legal cases resulting from the transfer of an aneuploid embryo following the use of techniques which combine PGT-A with PGT-SR, without declaration of the PGT-A result. It was noted that there are also some legal cases against clinics concerning potentially healthy embryos which were discarded following PGT-A, on the grounds that this reduced the patients' chances of IVF success.

5.2.5. In addition, the a member highlighted findings from non-selection studies, showing that non-viable embryos are not being transferred. They commented that, although PGT-A testing may reduce the chances of having a healthy baby for most patients by a small percentage, patients may be prepared to accept this reduction, and any subsequent costs of further treatment to prevent the transfer of non-viable embryos. Therefore, it may be appropriate for clinicians to have more refined conversations about testing with patients. It was noted that non-selection studies have not been performed for all emerging embryo testing techniques.

5.2.6. In response, a member commented that it is necessary for clinicians to be having detailed conversations with patients to make clear that, with aneuploidy screening, there is a risk that patients will exclude embryos that have potential to lead to a healthy live birth. Another member raised concerns that patients are not clearly being informed of these risks, while at the same time these technologies are being aggressively marketed to patients.

5.2.7. The Chair noted that with regards to PGT-A for older women, this add-on is rated grey for both reducing the chances of miscarriage and for improving the chances of having a baby: Pre-implantation genetic testing for aneuploidy (PGT-A) | HFEA.

5.2.8. The Committee discussed the 2014 NHS Clinical Commissioning Policy for Preimplantation Genetic Diagnosis, which is currently under review. PGT-A is currently specifically excluded from the commissioning criteria which applies to England. Funding for PGT cycles by NHS Scotland is commissioned by the National Services Directorate (NSD) who have recently moved to the use of commercial services providing two-tiered PGT-SR and PGT-A results.

5.2.9. In the context of the study by Cimadomo *et al.* (2023), summarised in paragraph 2.7 of the Emerging technologies in embryo and gamete testing paper, a member informed the Committee that a VISA randomised control trial paper submission has just been accepted for Nature

Medicine. This trial looks at the use of the iDAScore® deep-learning model for embryo selection in comparison to standard morphological testing. Results may have relevance to the add-on rating for time-lapse imaging and incubation.

5.2.10. The Chair noted that, although the formal review of add-ons rating has been agreed to be held every five years, any interim high-quality developments which may alter the ratings will be considered at the next relevant SCAAC meeting.

5.2.11. A member highlighted a recent publication which noted that an increase in cell contractility is needed to generate the blastocyst. In the study blastocysts that failed to generate were found to have defects in contractility. Consequently, methods of measuring biomechanics or forces of the embryo have been proposed as a future method of non-invasive screening which may be considered as part of this topic going forwards.

5.2.12. The Committee praised the Executive on the quality of the paper.

6. Artificial wombs for early or whole gestation (ectogenesis)

6.1. The Committee were reminded that the topic of artificial wombs for early or whole gestation (ectogenesis) was introduced to the SCAAC horizon scanning function in January 2022 and is currently considered a low priority topic. This is the first time this topic has been brought to the Committee for discussion.

6.2. The Committee made the following comments and recommendations:

6.2.1. Developments in *ex utero* culture should also be considered as part of the topic of ectogenesis.

6.2.2. Significant efforts have been made by those deriving stem cell-based embryo models (SCBEM) to facilitate growth of both SCBEM and embryos *ex utero* up to and possibly beyond 14-days. However, current research using SCBEM, growing to early post-gastrulation and limb bud formation, has been very inefficient. The quality of such SCBEM at this stage are considered relatively poor, although the technology has seen rapid improvement in recent years.

6.2.3. A member added that a number of committees, including the UK's SCBEM Code of Practice Working Group and the International Society for Stem Cell Research (ISSCR), are currently trying to address issues associated with early ectogenesis. Discussions about how strongly to prohibit early or whole ectogenesis with human embryo models are ongoing. It is generally agreed that such experiments should be prohibited. It was noted that the upper limit on experiments has not yet been established, although it is considered that the oversight committee proposed by the SCBE Code of Practice Working Groups would prevent research which attempted to grow SCBEM's close to the limit of viability.

6.2.4. It was noted that it will become increasingly difficult to define the limit of viability once partial ectogenesis techniques are introduced for late-gestation support. Future developments with such technologies may move the limit of viability of premature babies below the current twenty-two-week limit.

6.2.5. The Chair commented on studies exploring the ethical considerations in relation to complete and early partial ectogenesis, noting that the ethical debates relevant to early and whole ectogenesis vary from that of partial ectogenesis for late-trimester support.

6.2.6. The Executive noted that regulation of medical devices, such as those used for late-gestation support in ectogenesis, would fall within the remit of the Medicines and Healthcare products Regulatory Agency (MHRA). The application of such late ectogestation technologies would fall outside the remit of the HFEA and be considered by other agencies such as the Human Tissue Authority (HTA), Care Quality Commission (CQC), the National institute for Health and Care Excellence (NICE), and the General Medical Council (GMC). The Committee suggested that it might be useful to discuss this topic further at a later date with the relevant agencies to understand any potential regulatory overlap.

6.2.7. The Committee discussed the relevance of this topic to proposals on law reform, specifically those relevant to future proofing the Act to accommodate developments in scientific advances and innovation. Early ectogenesis will be further considered by the SCAAC in relation to the topic of SCBEM in their October 2024 meeting.

6.2.8. The Committee agreed that the priority of this topic at this time remains low and that developments relevant to early ectogenesis should continue to be monitored through the horizon scanning function.

7. Androgen supplementation as a treatment add-on

7.1. The Committee were reminded of their previous recommendations in relation to androgen supplementation as a treatment add-on, as outlined in the related meeting paper. The Committee were asked to advise whether androgen supplementation meets the criteria set out by the treatment add-ons decision tree to be eligible for a HFEA rating. It was noted that the Executive are not asking the Committee to make a recommendation on the rating itself at this meeting.

7.2. In relation to the application, the Committee discussed the following:

7.2.1. The Chair highlighted that androgen supplementation is one example of a pre-treatment drug, however, there are many other examples of pretreatment supplements (including CoQ10, ubiquinol, melatonin, antioxidants etc.) that may be marketed for fertility patient's pre-treatment.

7.2.2. It was noted that, although there is not much evidence available for the use of each of these supplements, research is being conducted. Studies from animal models, including those using non-human primates, suggest that androgen supplementation treatments increase follicular activation, and therefore demonstrate a biological plausibility for their application.

7.2.3. The primary criterion for an add-on is the claim that its use will improve live birth rates for patients, if the treatment is being marketed to improve general health, then it should not be considered as an add-on. The Committee agreed that androgen supplements are being advised to patients with the claim they increase live birth rate.

7.2.4. To define which pre-treatment supplements would be classified as meeting the add-on criteria, a member suggested that compounds should be only rated where they require a prescription from a clinician, fulfilling the criterion that the treatment is being offered in the licensed fertility clinic itself. In the UK, testosterone, melatonin, and dehydroepiandrosterone (DHEA) are prescribable drugs and not legally available on the UK market. As a prescribable drug, DHEA is available only as prasterone (vaginal pessaries) for treatment of vaginal and vulvar atrophy. Both prasterone and testosterone are drugs controlled under the misuse of drugs regulations, marked as Class C

under the Misuse of Drugs Act 1971, and listed in Schedule 4, part II under the Misuse of Drugs Regulations 2001). This means that there is strict regulation around the prescription and possession of drugs in these categories. However, it is known that patients are able to purchase both testosterone and DHEA (as a health supplement) from overseas via online retailers. The Committee agreed that they will consider supplements as add-ons where they are drugs which are only accessible on the UK market when prescribed by a clinician.

7.2.5. The commercial relationship between the clinic and patients with relation to marketing supplements was also discussed as a benchmark.

7.2.6. A member noted that many clinics use specialist pharmacies to despatch drugs to patients. Some of these pharmacies may market many different agents to patients on top of those prescribed by their clinic, so patients may not be able to discern which compounds required a prescription. The British National Formulary (BNF) and the NHS dictionary for medicines and devices (dm + d) can be used to discern what compounds would be considered prescribable drugs.

7.2.7. The Executive highlighted that the Advertising Standards Authority (ASA) may be able to act intervene where products are not being marketed appropriately.

7.3. **Recommendation:** The Committee agreed that, according to the decision tree, androgen supplementation (testosterone) is eligible for a HFEA rating and DHEA is not. The Executive is to commission an expert literature review on evidence of the use of testosterone supplementation as a treatment add-on. This will be brought to a future meeting of the SCAAC for an official rating. The Committee also agreed that they will consider supplements as add-ons where they are drugs which are only accessible on the UK market when prescribed by a clinician.

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

8.1. The Committee were reminded that, in the UK, research involving the derivation of human embryonic stem cells (hESC) from embryos or hESC-like cells from human gametes is licenced under a HFEA research licence. Section 3A(1)(c) of Schedule 2 of the Human Fertilisation and Embryology Act 1990 (as amended) requires embryo research to be “necessary or desirable” for defined purposes. If alternative methods of deriving hESC or hES-like cells become fully developed, it may become less ‘necessary’ for licensed research groups to use viable embryos in all of the research purposes for which they are currently used. Therefore, it is important for the Authority to keep up to date with developments regarding these alternative methods so that the HFEA Licence Committee can bear them in mind when considering research licence applications in line with the Act.

8.2. A summary of the paper highlighting the key developments in methods to derive embryonic and embryonic-like stem cells was presented to the Committee. This included research into expanded and extended potential stem cells, eight-cell like cells, and deriving extraembryonic cell lineages.

8.3. In relation to this topic the Committee made the following comments:

8.3.1. As methods to derive hESC and hESC-like cells are being refined, technologies are introducing fewer errors into stem cell lineages and as such the quality of cell types representing the biological tissue are improving. However, at present, there remains gaps in our ability to derive all

cell types from hESC-like cells, including the ability to derive a hypoblast-like cell type from the embryo. Despite research in this area growing, the absence of this model is a current drawback to the generation of representative stem-cell based embryo models, therefore ongoing work is needed.

8.3.2. A member highlighted an additional study, published in May 2024, which demonstrates how the FGF signalling pathway plays an important role in influencing whether inner cell mass (ICM) cells in the early blastocyst segregate into hypoblast or epiblast cells. This research overturns a prevailing model and defines the short window in blastocyst formation when cells are responsive to FGF. Based on this mechanism authors were able to generate more authentic hypoblast-like cells by converting them from embryonic stem cells, demonstrating first-hand how continued stem cell research is improving tools to derive different cell lineages.

8.3.3. A member commented that there will always be a need to derive stem cell lineages from embryos as, when testing new methods of deriving hESC-like stem cells, embryonic cells will be required to compare quality, functionality, and utility of new cells to the embryonic derived counterpart.

8.3.4. A barrier for research into SCBEM and newly derived cell lineages remains a lack of high-quality research using human embryos, specifically with regards to the second week of development and beyond. As novel lineages may have the potential to develop into cell types which only arise during the second week of development or later, characterisation of these cells is limited by available research and restrictions such as the 14-day rule.

8.3.5. It was noted that new methods to derive stem cell lineages are improving in consistency, however, concerns with epigenetic errors or the introduction of mutations persist. If such errors prevail in initial hESC-like cell lineages, development of subsequent SCBEM or organoids may not be truly representative of human development.

8.3.6. The Committee agreed that it was vital that work continues on embryo-derived stem cell lineages and that the SCAAC will continue to monitor developments through the horizon scanning function.

9. Any other business

9.1. The Chair shared the dates for the 2025 SCAAC meetings.

9.2. The Executive noted that the October 2024 meeting will contain an update from the mitochondrial donation team at the Newcastle Fertility Centre at Life, and the Committee suggested that it may be beneficial to hear an update from both the clinical and laboratory teams. The SCAAC will also discuss the 14-day rule, SCBEM and in vitro derived gametes, relevant to the Modernising the Act proposals, at the October meeting. Any recommendations will be subsequently considered by the Authority in November 2024.

10. Meeting summary and close

10.1. The Chair thanked the Executive for the volume of work put into the papers in preparation for the meeting.

10.2. The next SCAAC meeting will be held in person on Monday 7th October 2024.

10.3. The Chair closed the meeting by once again thanking Robin Lovell-Badge and Kate Brian for their contributions to the SCAAC.

11. Chair's signature

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

Chair: Tim Child

Date: 20th August 2024