## Scientific and Clinical Advances Advisory Committee (SCAAC) – minutes

**14 October 2019**

**St Martin’s Hall, St Martin in the Fields, Trafalgar Square, London, WC2N 4JH**

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<th>Authority members</th>
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<td>Gudrun Moore (Deputy Chair)</td>
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| Apologies          |         | Richard Scott    |                  |

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<th>Invited speaker</th>
<th>Present</th>
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<th>Madelon Van Wely</th>
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| Observers             | Present | Dafni Moschidou (DHSC) |                  |
|                       |         | James Duffy (University of Oxford) |                  |
1. **Welcome, apologies, declarations of interest**

   1.1. The Chair welcomed the Committee members to the meeting.

   1.2. Apologies had been received from Clare Ettinghausen (Director of Strategy and Corporate Affairs) and Richard Scott. The Chair acknowledged that Gudrun Moore would be leaving the meeting part way through.

   1.3. Declarations of interest were received from Daniel Brison, Joyce Harper, Yacoub Khalaf, Anne Lampe, Sheena Lewis, Raj Mathur and Kevin McEleny.

2. **Matters arising**

   2.1. Minutes of the meeting held in June 2019 were agreed remotely prior to the meeting.

   2.2. The Scientific Policy Manager updated the committee on matters arising. An outstanding action from the June 2017 meeting was for the Chair to review the ICSI literature review which is to be submitted for publication to a journal. This item has been removed from matters arising and will continued to be worked on with relevant members of SCAAC outside of the meeting.

   2.3. A second matter, to update the authorised process list on the HFEA website so that the novel processes are clearly distinguished from the core list, has been completed.

3. **Chair’s business**

   3.1. The Committee will be contacted for the annual self-evaluation of committee effectiveness which is undertaken by all HFEA committees.

   3.2. The Chair informed members of the Research Engagement day hosted by the HFEA that will take place on Monday 18 May 2020. The one-day event is designed to engage researchers across the field of fertility research from licensed embryo researchers to data researcher, ethical, legal and social researchers.

4. **Update from Authority Discussions**

   4.1. The Chief Executive gave the Committee a summary of the discussion on treatment add-ons that took place at the September 2019 Authority meeting\(^1\). The Authority reflected on the progress made to date with the sector and agreed next steps for the treatment add-ons work.

   4.2. Although policy decision regarding treatment add-ons rests with the Authority, their decisions are guided by the expertise of the SCAAC. The Chief Executive expressed his gratitude to the Committee for their continued expert advice and guidance.

   4.3. The Chief Executive explained that the policy for treatment add-ons has been divided into two main elements. The first is to focus on the demand for treatment add-ons by providing patients with an independent expert reference point against which to assess many of the claims made by others. The second is to focus on the supply of treatment add-ons and work

\(^1\) [https://www.hfea.gov.uk/about-us/our-people/authority-meetings/](https://www.hlea.gov.uk/about-us/our-people/authority-meetings/)
with practitioners in the sector around the way in which add-ons are offered in clinics and to bring about a culture change in the sector towards more responsible innovation.

4.4. The Authority agreed that the criteria for a treatment to be considered as an add-on will be (1) additional treatments (to the core treatment eg IVF or IUI) that are being commonly offered in fertility clinics; and (2) where evidence on efficacy or safety for the use of the treatment in a clinical setting is lacking or absent. The Authority took the decision that, in future, HFEA will also provide information on commonly available holistic therapies (eg massage and acupuncture), as highlighted in the Pilot national fertility patient survey 20182.

4.5. The HFEA currently provides information on 11 treatment add-ons3.

4.6. The Chief Executive discussed with the Committee the aims of the treatment add-ons work that were detailed to the Authority. This included:

- Raising awareness of treatment add-ons and the issues therein.
- To encourage responsible supply of treatment add-ons.
- To prevent patients from being misled (in terms of potentially exploiting unfounded expectation) by ensuring, through inspections and our own published information, that patients are provided with information that is clear and reliable.
- To ensure informed consent is obtained.
- To enhance patient safety by investigating how outcomes and follow ups can be best assessed.
- To encourage research, either through randomised control trials or observational studies, to assess whether any current or future add-ons increase success rates.
- To require clinics to provide itemised costed treatment plans to ensure that the costs of treatments add-ons are not lost in package prices.
- Plans to reconvene the consensus working group that, in January 2019, agreed the consensus statement4 on treatment add-ons.

4.7. The Chief Executive and the HFEA Chair asked the Committee to give their comments on the HFEA’s treatment add-ons work and the traffic light system. They were asked to focus their attention on how to make the traffic light system more user friendly and fit for purpose. They were also asked whether they felt any of the aims specified were dependant on each other and whether there was a natural list of priorities. The Committee were then asked to consider what else should be included in the treatment add-ons work.

4.8. The Committee discussed the scope of treatment add-ons including the addition of tests (rather than treatments) and holistic therapies (such as massage, acupuncture and nutritional therapy) to the list of treatment add-ons that the HFEA provides traffic light ratings for. It was agreed that there is a need to find a balance between providing

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3 https://www.hfea.gov.uk/treatments/explore-all-treatments/treatment-add-ons/
information on the whole field of treatment add-ons and information that patients will find useful.

4.9. One Member questioned whether truly informed consent can be given for treatments that lack scientific evidence. Members and the Chief Executive acknowledged that consent is complicated and that patients should be given reasonable balanced information to base their judgement on. The HFEA cannot constantly monitor the taking of consent by clinics but can provide a framework and expectations. One Member suggested providing patients information leaflets to read and have a tick box to confirm they have read them, much like in a research setting.

4.10. The Committee suggested that clinics should also make clear declarations of interests, both financial and other (e.g. committee membership), to patients and on their clinic websites to help patients make an informed decision when choosing treatment add-ons.

4.11. One Member discussed that the responsibility of finding evidence for the effectiveness and safety for treatment add-ons lies with the people providing the treatment, not the HFEA. There is a clinical responsibility to ensure that there is good and reliable evidence from reputable studies for any treatment provided.

4.12. One Member discussed that when patients look at the current traffic light ratings, they are only provided with red and amber ratings. The Member was concerned that bringing in more untested, unproven holistic therapies could potentially increase the number of red ratings, making the HFEA traffic light system more overwhelming and difficult to interpret for patients. Other Members felt that as the HFEA is not a commercial entity, the information provided is unbiased and has to be accurate. One Member suggested that holistic therapies being offered in clinic gives them some validity. The Committee agreed that the traffic light system needs to be more nuanced if these additional treatment add-ons are going to be considered.

4.13. One Member questioned whether patients are aware that if evidence for a red or amber rated treatment add-on is found, it won’t necessarily turn the traffic light rating green, it could prove that the treatment is ineffective or not safe and therefore make the treatment a red rating. The Committee discussed that there is a need for more detail around treatment add-ons on the HFEA website, including links to the available evidence that has informed the traffic light ratings.

4.14. The Committee suggested that there is a need to increase patient engagement, to determine whether patients find the current traffic light rating system helpful. Patients could inform the HFEA about how to improve the traffic light ratings to best suit their needs and help them make an informed decision. One Member suggested working with Fertility Network UK to raise awareness and supply information directly to patients.

4.15. One Member questioned whether there is currently any information on the HFEA website to explain what informed consent is and how it can be achieved. They questioned whether informed consent for treatment add-ons could be taken by an independent person outside of the clinical setting, much like in research. Another Member argued that there is an important relationship between the patient and their doctor during treatment that would be disrupted by an independent person taking the patient’s consent.
4.16. The Committee discussed whether treatment add-ons that are classified as a green traffic light rating (proven to be safe and effective) should be part of standard practice and therefore no longer classified as add-ons. Some Members suggested that green treatment add-ons, such as ICSI for heterosexual couples with male factor infertility and folic acid, should be displayed on the website to give context to the red and amber add-ons. There were concerns that having no green add-ons could encourage patients to choose amber rated add-ons which, in comparison to only red add-ons, seem the safer and more effective option. They questioned whether patients are aware that treatment add-ons can be expensive, potentially ineffective or even reduce success rates or safety.

4.17. One Member suggested that safety and efficacy are not the same when assessing a treatment add-on. Clinics should be asked to justify why they have offered a patient a red rating treatment add-on.

4.18. One Member asked how many patients are visiting the HFEA webpage about treatment add-ons. The Scientific Policy Manager informed the Committee that when the webpage was first launched there was a peak in the number of visitors to the page. Currently, the number of visits has dropped to a ‘normal’ level. The Chief Executive discussed with the Committee that some centres print the HFEA’s traffic light rating information to give to patients, so it is hard to monitor total access to the ratings.

**Action:** The HFEA to determine how often the treatment add-ons webpage is visited.

4.19. One Member expressed concerns over the information that patients are provided to make decision around treatment add-ons, with marketing material sometimes given instead of unbiased advice. The Chief Executive assured that Committee that the HFEA Code of Practice update included guidance that would prevent this and allow inspectors to look into this on inspection.

4.20. Members discussed that although the HFEA has no power to restrict the use of treatment add-ons it does have power to regulate patient information. However, some members felt that if the culture in clinics is to use treatment add-ons the HFEA information may not have a large impact on their use.

4.21. Members discussed that different parts of the UK had different attitude towards treatment add-ons. London has a large number of private fertility clinics in direct competition with each other, this leads to an environment of needing to satisfy patient demand for treatment add-ons in order to retain patients. Other areas of the UK with fewer fertility clinics may not have this problem. There is also a need to empower patients to say no to treatment add-ons and to raise awareness of the success of fertility treatment without add-ons.

4.22. The HFEA chair and the SCAAC chair summarised the discussion in terms of what the SCAAC is able to advise. Their opinions on research can be taken forward to the HFEA Research Engagement day in May. Their comments on how to improve the traffic light system can be discussed with the Authority, including increasing the information provided for patients, including the risk and potential harms of treatment add-ons, increasing the range of treatments included in the traffic light system, working with code of practice to encourage centres to provide helpful information to patients and exploring ways to engage with patients.
4.23. The Chief Executive agreed that the HFEA would take away the SCAACs comments and create a priority list of work.

5. **Review of traffic light ratings for treatment add-ons**

5.1 The Scientific Policy Manager provided an overview on the work that had been done on treatment add-ons to date. In 2017, the patient information and traffic light system were finalised for treatment add-ons that the HFEA felt patients most needed information about. Members made a commitment to review the evidence supporting the use of treatment add-ons at the Committee annually and to monitor major publications on the use of treatment add-ons throughout the year.

5.2 The Scientific Policy Manager explained that treatment add-on traffic light ratings could either be promoted (from red to amber or amber to green) or demoted (from green to amber or amber to red) according to the available published evidence. The current categories of the traffic light ratings were clarified. Red ratings have no evidence to show that it is effective and safe. Amber ratings have a small or conflicting body of evidence, which means further research is still required and the technique cannot be recommended for routine use. Green ratings would require evidence from more than one high quality randomised control trial (RCT).

5.3 The Scientific Policy Manager asked the Committee to consider the quality of the evidence for each treatment add-on, based on the findings of Professor Andy Vail that were circulated to the Committee in advance. The members should then recommend whether the traffic light ratings of each treatment add-on should stay the same, be promoted or be demoted.

**Artificial Egg Activation Calcium Ionophore**

5.4 Artificial egg activation currently has an amber traffic light rating. Prof. Vail provided an overview of his findings and recommended for Artificial Egg Activation to remain as an amber rating (indicating a small or conflicting body of evidence, which means further research is still required and the technique cannot be recommended for routine use). The literature review included two studies. The first study was not an RCT and did not show a benefit to using Artificial Egg Activation over a control group in a non-clinical setting. The second study was an RCT and showed some encouraging results but had methodological limitations restricting its reliability and leaving room for doubt.

5.5 A member questioned whether any CE marked products could be usable in a UK clinic for this treatment add-on. The Committee agreed that as this is a chemical treatment, so CE marked products were not applicable.

5.6 Members agreed to keep the traffic light rating as amber.

**Assisted Hatching**

5.7 Assisted hatching currently has a red traffic light rating. Prof. Vail provided an overview of his findings and recommended for Assisted Hatching to remain as a red rating (no evidence to show that it is effective and safe). The literature review included two studies. One study looked at use with fresh embryos, this was a low-quality study with a high risk of bias and was not relevant to UK setting as it focused on double and triple embryo transfer. A second
study using frozen embryos suggested assisted hatching has some harm to live birth rate. Prof Vail suggested that, as both studies resulted in similar conclusions, it would be appropriate to have a single traffic light rating for assisted hatching using fresh and frozen embryos.

5.8 A member highlighted that the HFEA website should include more detailed information about the evidence base for each of the traffic light ratings and include information where studies have shown that the treatment add-on could reduce success rates. Prof. Vail explained that there was not enough evidence to conclude that Assisted Hatching was harmful but there is some evidence that it might be. Another member suggested that where evidence is inconclusive the HFEA should include discussion of both the potential harm and benefit. A member suggested that there should be separate sentences in the patient information addressing the efficacy and the safety of the treatment add-on.

5.9 Prof. Vail questioned the Committee about the difference between vitrification and standard freezing and whether vitrification could cause Assisted Hatching to be harmful. Members discussed whether there was a potential mechanism by which Assisted Hatching after vitrification could cause harm compared to after standard freezing. The Committee concluded that this is unlikely to be the case.

5.10 Members agreed to keep the traffic light rating as red.

Embryo Glue

5.11 Embryo glue currently has an amber traffic light rating. Prof. Vail provided an overview of his findings and recommended for Embryo Glue to remain as an amber rating (indicating a small or conflicting body of evidence, which means further research is still required and the technique cannot be recommended for routine use). The literature review included an abstract for a study which is unclear whether it represents an RCT or a report of routine clinical data. Prof. Vail attempted to reach out to the authors for further information but was unsuccessful. The outcomes of this study do not alter Prof. Vail’s conclusions based on previous studies reviewed for Embryo Glue.

5.12 Members discussed whether it was within the scope of the Committee to perform a Cochrane review on Embryo Glue. A Member highlighted the possibility that including smaller biased studies in the review of treatment add-ons could undermine the results of larger high-quality studies. Prof. Vail and other Members agreed with this conclusion.

5.13 Members agreed to keep the traffic light rating as amber.

Endometrial Scratching

5.14 Endometrial scratching currently has an amber traffic light rating. Prof. Vail provided an overview of his findings and recommended for Endometrial Scratching to remain as an amber rating (indicating a small or conflicting body of evidence, which means further research is still required and the technique cannot be recommended for routine use). Nine studies were included in the literature review with differences in timings of the scratch within the cycle, methods or co-interventions used and the populations studied. Two of these papers were high quality studies in IVF patients and showed no benefit for using Endometrial Scratching.
5.15 One Member highlighted that the timings of the scratch during the cycle in the studies were unclear. They also questioned whether the studies were applicable to UK practice because they did not specifically look at the use of Endometrial Scratching in recurrent implantation failure. The member requested a meta-analysis of patients with recurrent implantation failure and with the scratch conducted in the correct time in the cycle. Prof. Vail explained that his review suggested no clear pattern between endometrial scratching taking place at different times in the cycle and that it had not benefit for recurrent implantation failure but acknowledged a further in-depth analysis of the data would be needed to back up these initial findings.

5.16 A Member suggested producing a summary for clinicians about the update to traffic light ratings.

5.17 Members discussed separating IUI and IVF ratings for endometrial scratching. Prof. Vail’s review suggested that endometrial scratching was more effective for patients undergoing IUI treatment than IVF/ICSI cycles. He suggested that if there is a plausible mechanism for why there would be different effect in IUI and IVF/ICSI patients then different traffic light ratings could be given. If there is no mechanism then an amber rating could be given to both pending further research. Members suggested that there is a potential for different mechanisms because of the different treatment pathways for IUI and IVF/ICSI. There were no studies within UK practice on the use of endometrial scratching for IUI treatment. The Committee concluded that it would wait for further publication of UK based studies.

5.18 Members agreed to keep the traffic light rating as amber.

**Elective Freeze All Cycles**

5.19 Elective Freeze all cycles currently have an amber traffic light rating. Prof. Vail provided an overview of his findings and recommended for Elective Freeze All Cycles to remain as an amber rating (indicating a small or conflicting body of evidence, which means further research is still required and the technique cannot be recommended for routine use). The literature review included one study. The study had a high risk of bias so despite encouraging results the conclusions were not trust worthy.

5.20 A Member highlighted that Elective Freeze All Cycles are known to be effective for the prevention of Ovarian Hyperstimulation Syndrome (OHSS) and should be rated as green under the traffic light system for this. However, Elective Freeze All Cycles used to increase live birth rate is an amber. The committee felt this highlighted the complexity of treatment add-ons and the need for distinction of the effectiveness and safety in different patient groups.

5.21 Members agreed to keep the traffic light rating as amber.

**Intracytoplasmic Morphological Sperm Injection (IMSI)**

5.22 IMSI currently has a red traffic light rating. Prof. Vail did not carry out a literature review for this treatment add-on because there were no new relevant published studies.

5.23 Members agreed to keep the traffic light rating as red.

**Pre-implantation Genetic Screening (PGS) – day three embryos**
5.24 PGS (day 3) currently has a red traffic light rating. Prof. Vail provided an overview of his findings and recommended for PGS for day three embryos to remain as a red rating (no evidence to show that it is effective and safe). The literature review included one study. The study did show a benefit to live birth rate using fresh embryos but when looking at the cumulative effect of both fresh embryos and vitrified embryos there was no benefit to live birth rate.

5.25 Members agreed to keep the traffic light rating as red.

Pre-implantation Genetic Screening (PGS) – day five embryos

5.26 PGS (day 5) currently has an amber traffic light rating. Prof. Vail provided an overview of his findings and recommended for PGS for day five embryos to be demoted from an amber to a red rating (no evidence to show that it is effective and safe). The literature review included two studies. Both studies showed no benefit to live birth rate. Including three previous RCTs reviewed in 2017 the evidence now suggests that PGS, day five embryo biopsy, should be given a red traffic light rating. There is a lack of evidence of benefit and some evidence of harm.

Recommendation

5.27 The Committee agreed to change the traffic light rating for PGS day 5 embryos from amber to red.

Physiological Intracytoplasmic Sperm Injection (PICSI)

5.28 PICSI currently has a red traffic light rating. Prof. Vail provided an overview of his findings and recommended for PICSI to remain as a red rating (no evidence to show that it is effective and safe). The literature review included one study. Although the study showed a reduction in miscarriage rates of those in the treatment group there was no overall benefit to live birth rate.

5.29 A Member, who is a co-author on the paper, felt that a reduction in miscarriage rate was a clinically significant outcome and is too important to patients to dismiss and classify the add-on as red. Other members, including other co-authors on the same paper, felt that as the primary objective of the traffic light system is to inform patients of the likelihood of increasing their chance of a live birth, the traffic light rating should remain red for PICSI to show that it is not an effective treatment for increasing live birth rate. Other members did agree that the information about the treatment add-on provided by the HFEA should discuss the benefit of reducing miscarriage rate, but this should be described in a way to avoid confusing patients around how there can be a reduction in miscarriages but no overall benefit to live birth rate.

5.30 Members agreed to keep the traffic light rating as red.

Reproductive Immunology Tests and Treatment

5.31 Reproductive Immunology currently has a traffic light rating of red. The review of the traffic light rating for Reproductive Immunology did not take place at this meeting due to lack of time to review the available research. A review of this treatment add-on will take place at the SCAAC meeting in February 2020.

Time lapse Imaging
5.32 Time-lapse imaging currently has a traffic light rating of amber. The review of the traffic light rating for Time-lapse imaging did not take place at this meeting due to lack of time to review the available research. A review of this treatment add-on will take place at a future SCAAC meeting.

5.33 The Committee discussed the difficulties of conducting an RCT for this treatment add-on.

6. The evidence base for clinical application of fertility treatments

6.1. The chair welcomed the guest speakers, Dr. Madelon van Wely and Prof. Vail, and, with the Scientific Policy Manager, introduced the background for the discussion of the evidence base for fertility treatments. When reviewing the effectiveness of treatments, well-designed RCTs are thought to provide the most reliable source of evidence and therefore are considered to be the ‘gold standard’. However, for many reasons including funding and the difficulty of sufficiently large sample sizes, it is unlikely that treatment add-ons will have a well-designed RCT for the foreseeable future. With a potential lack of evidence to support safety and efficacy of treatment add-ons, treatments will not be able to go beyond the ‘experimental’ category.

6.2. The HFEA needs to consider if it should continue with an approach which uses RCTs as the key determinate of any assessment or if it should try to accommodate other types of evidence (notably retrospective studies of large data) into that assessment.

6.3. The Chair and the Scientific Policy Manager asked the Committee, Dr. van Wely and Prof. Vail whether the reduction of RCTs being conducted for treatment add-ons means that the HFEA should include large data studies in the review process for the effectiveness and safety of treatment add-ons.

6.4. Dr van Wely suggested that the data collected by clinics can be biased and often has no control group. She accepted that large data can be useful and add value to RCTs by identifying population sub-groups that could benefit from treatment add-ons, but further high-quality research would be needed to confirm findings. Prof. Vail agreed that with intelligent use large data can compliment RCTs but cannot replace them. He explained that selection bias, the most important bias in clinical research, cannot be removed from observational data. The only way to minimise selection bias is by randomising participants. Prof. Vail informed that analysis of large data is relatively easier and cheaper for long term follow up of patients compared to follow-up within RCTs. Dr. van Wely agreed with Prof. Vail’s points and suggested that large data is also useful for safety outcomes, but the data needs to be of high-quality. A number of high quality linkage studies have already been published using the HFEA data, either alone or by linking to other datasets. These studies have gone on to inform academic and public debate into assisted reproduction and factors affecting outcomes.

6.5. The Committee discussed whether clinics could have a better understanding of evaluating published studies and identifying what the limitations of data produced within clinics can be. Clinics may feel that the treatment add-ons work for their patients but do not wish to publish outcome data they collect, or are unable to publish because the the collection of data was not designed appropriately or the statistical expertise to analyse them is not available.
However, there is an increasing patient culture of reading public access papers so it could be beneficially for clinics to publish their findings.

6.6. The Chair commented that there are arguments for and against large data in place of RCTs but there is always a potential for bias, even unintentionally. Selection bias would mean that studies do not stand up against the same rigor as RCTs, especially if the study involves treatments that are invasive, expensive or have a potential for harm.

6.7. The Committee agreed that large data could not replace RCTs. The Chair invited the committee to discuss their opinions as to how large data from clinical databases could be beneficial.

6.8. One Member commented that the attitude to data in society has changed. Patients are putting more weight on their personal and anecdotal experience as opposed to pure clinical data and RCTs. They suggested that it is important to engage with patients, but researchers should not lower their standards because RCTs are hard to conduct. The scientific community needs to hold themselves to the standard of RCTs because large data studies cannot exclude bias.

6.9. The Chair highlighted that large databases, such as the HFEA register, do not contain all of the information required to identify confounding factors to tell you if an intervention is effective. The Committee questioned Dr van Wely about how large databases, such as the HFEA register, could be used and how they could inform RCTs. Dr. van Wely discussed that large databases are often of poor quality, with selection bias and cancelled treatment cycles are not accounted for.

6.10. The Committee discussed that in the past, clinics did not have the time and resources to submit more than the minimum amount of data required to the HFEA register. However, most clinics now have their own large databases and record more data than the HFEA require. The new HFEA register should make it simple for clinics to submit additional information that they may hold on their personal databases. However, if large databases, such as the HFEA register, are to be used for research, centres need to assure their data is of a certain standard. The data needs to have a quality control, it needs to be peer reviewed and published. Prof. Vail suggested that other areas of medicine feed into a national audit programme and it is extremely useful in answering questions about co-morbidities and rehabilitation.

Action

6.11. The HFEA will review the Stroke national database to see what resources are required to maintain this kind of database.

6.12. Prof. Vail raised concerns over General Data Protection Regulation (GDPR). The Chief Executive confirmed that the HFEA register can identify patients across different treatment cycles and clinics by recording NHS number.

6.13. The Committee discussed whether, in mass data collection, you would need a justification for each data point that was collected and therefore limit the depth of analysis possible or whether the aim is to collect as much data as possible to then identify the cofounding factors that might need to be considered. The Committee discussed that artificial intelligence algorithms are not hypothesis-driven and are a ‘fishing trip’ for information.
There were concerns over whether this ‘data mining’ was GDPR compliant. Comparisons were made to other large data research projects, such as the 100,000 Genomes Project, where patient data is held behind a protective fire wall ‘safe haven’. One member explained that is fairly inexpensive to set up and had been done twice before with the HFEA register data.

6.14. The SCAAC Chair also suggested that if the HFEA highlighted issues in their agenda about further research being needed it would make any grant application more favourable to the Medical Research Council and the Health Research Authority.

6.15. The Committee discussed whether it was possible to make embryos and gametes more available for research by created a central HFEA bank. This would require the possibility of generic patient consent for banking and use of embryos and gametes in future research projects, rather than the current model of seeking project-specific research consent. The project specific consent also makes it difficult to obtain embryos from abroad because donors would have needed to consent to the specific research projects. The Chief Executive advised the Committee that due to the legal status of embryos, previous legal advice had suggested that generic consent for research does not work within the context of the HFE Act. However, the HFEA will review its previous legal advice regarding generic consent to research in relation to research embryo banking.

7. Any other business

7.1. One member raised the topic of preimplantation genetic diagnosis and genome editing as a potential future topic for the committee to discuss. They questioned whether these two technologies are mutually exclusive or can work together.

7.2. One member brought a paper on embryo aneuploidy rates in mild and conventional IVF to the attention of the Committee. The member explained that results are reassuring and relevant for the committee. The Committee suggested ‘mild’ or ‘minimal IVF’ to be considered as a possible future treatment add-on.

7.3. The chair summarised the meeting and thanked the Committee and the guest speakers, Prof. Vail and Dr. van Wely, for a productive discussion.

8. Chair’s signature

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

Signature

Chair: Yacoub Khair
Date: 8/1/2020