

Scientific and Clinical Advances Advisory Committee (SCAAC) – minutes – Mitochondrial Donation update

Tuesday 25th July 2023, 10:30am – 12:30pm

Wandle room, 2nd Floor, 2 Redman Place, London, E20 1JQ & MS Teams

Authority members	Present	Tim Child (Chair) Frances Flinter Jason Kasraie (Deputy Chair) (online) Alex Kafetz Christine Watson
External advisors	Present	Richard Anderson (online) Kate Brian Alison Campbell Robin Lovell-Badge (online) Raj Mathur (online) Scott Nelson (online) Anthony Perry
	Apologies	Frances Ashcroft Zeynep Gurtin Kevin McEleny
Executive	Present	Dina Halai (Head of Regulatory Policy, Scientific) Ashley-Anne Brown (Meeting secretariat and Scientific Policy Officer) Anna Coundley (Policy Manager) Mina Mincheva (Policy Manager) Beth Lockwood (Civil Service Fast Streamer) Julia Chain (HFEA Chair) Peter Thompson (Chief Executive) Clare Ettinghausen (Director of Strategy and Corporate Affairs) Rachel Cutting (Director of Compliance and Information)

Invited speakers	Present	Mary Herbert, Louise Hyslop, Jane Stewart, Rekha Neelakanta Pillai (Newcastle Fertility Centre at Life)
Observers	Present	Shamima Rahman, Julie Steffann, Bert Smeets (SAC external advisers) Amy Parsons, Kath Bainbridge, Steve Pugh (Department of Health and Social Care)

1. Mitochondrial donation – background for the committee

- 1.1. The Chair reminded members that the role of SCAAC is to 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.
- 1.2. The Chair noted that to date only Newcastle Fertility Centre at Life is licensed to offer pronuclear transfer (PNT) in the UK and that SCAAC members Frances Flinter, Tony Perry and Robin Lovell Badge were part of the original committee who reviewed the evidence on mitochondrial donation treatment before the law was passed to allow its use in specific circumstances.
- 1.3. The Chair noted that the last update from Newcastle to SCAAC on the programme was in January 2022 and that the [minutes](#) from that meeting said that “The research presented to SCAAC will be published in a peer reviewed journal in due course.” He stated that to the best of our knowledge there has been no publication since then.
- 1.4. The Chair added that progress may have been slower than originally hoped for, but there is considerable public interest in the outcome and long-term follow-up of any children born from PNT following press coverage in May this year.
- 1.5. The Chair informed the committee that three external advisers who advise the HFEA Statutory Approvals Committee (SAC – who consider each application for mitochondrial donation treatment) will be in attendance and the committee were happy for them to also ask questions of the Newcastle team.
- 1.6. The Chair stated that following the update from Newcastle Fertility Centre at Life team, SCAAC members will be asked to:
 - 1.6.1. Share their views and ask further questions they have for the Newcastle team regarding the update on the programme.
 - 1.6.2. Assess the success/limitations of the mitochondrial donation programme at the Newcastle Fertility Centre at Life.
 - 1.6.3. Consider if they have anything they would like to advise the HFEA relating to implications for licensing or regulation.

2. Mitochondrial donation discussion

- 2.1. The Chair welcomed the guest speakers from the Newcastle Centre at Life: Dr Jane Stewart (Clinical Lead), Dr Rekha Neelakanta Pillai (taking over from Dr Jane Stewart in Autumn 2023), Professor Mary Herbert (Professor of Reproductive Biology, now partly at Monash University in Australia) and Dr Louise Hyslop (Embryologist).
- 2.2. Dr Jane Stewart provided an update on the progress of the mitochondrial donation programme covering embryological and clinical aspects of the service:

- 2.2.1. She explained that the team carefully select patients for the PNT programme, directing patients toward PGT-M where it was more appropriate. She continued with an update on clinical outcomes, laboratory outcomes, dropout of the programme, and reasons for it.
- 2.2.1.1.1. Dr Hyslop then provided with details on the clinical route for PNT treatment programme and the patient/donor pathway. She stated that 32 patients had received approval for PNT since the centre licence was awarded in 2017. Continuing, Dr Stewart gave an overview of the results following fertilisation in terms of blastocyst formation rate and blastocyst quality rates, information on clinical outcomes following embryo transfer (pregnancy/live birth) and the reasons for drop off during treatment course.
- 2.2.1.1.2. Dr Hyslop finished the presentation with overall reflections on the programme to date and limitations.
- 2.3.** The SCAAC members and SAC external advisers asked questions on outcomes and Dr Stewart confirmed that follow-up is ongoing.
- 2.4.** Professor Mary Herbert provided further clinical research data and considered options for future work.
- 2.5.** The SCAAC members and SAC external advisers asked the team from Newcastle Centre at Life further questions on reversion and screening of donors after which SCAAC committee members had a closed discussion about the mitochondrial donation programme.
- 2.6.** The committee agreed that while the programme has not progressed as quickly as hoped, this should not in any way diminish the excellence of the work undertaken at Newcastle and the team should be congratulated for their successes to date. Members noted that given the relatively small numbers of patients accepted onto the programme to date (32 patients), it was not yet possible to draw firm conclusions about the effectiveness of PNT, either in general or for certain categories of patients.
- 2.7.** It was noted that while the HFEA regulatory regime provides some information in the public domain about the mitochondrial donation programme, this is not a substitute for the detailed oversight of scientific and clinical matters that would normally become public through a peer-reviewed publication. While acknowledging there are external circumstances influencing the peer-reviewed publication process of data, the SCAAC members agreed that the information they heard should be made public as soon as possible.

3. Meeting summary and close

- 3.1.** The SCAAC members agreed on the following action points and recommendations to the Authority:
- 3.1.1. Three HFEA Authority members of SCAAC together with a SCAAC adviser will visit Newcastle to hear about the organisation and staffing of the mitochondrial donation programme in more detail.
- 3.1.2. The team at Newcastle Fertility Centre for Life will be invited to the February 2024 SCAAC meeting to give a progress update.

4. Chair's signature

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

Signature

A handwritten signature in black ink that reads "Tim Child". The signature is written in a cursive style with a long horizontal stroke at the beginning.

Chair: Tim Child

Date: 13 October 2023