

Scientific and Clinical Advances Advisory Committee (SCAAC) - minutes

3rd February 2016

Etc. Venues Bonhill House, 1-3 Bonhill Street, London EC2A 4BX

Committee members		Yacoub Khalaf (Chair) Kate Brian Andy Greenfield Anne Lampe	
Members of executive		Anna Rajakumar (lead) Anna Quinn (secretary) Peter Thompson Juliet Tizzard Hannah Verdin	Joanne Anton Jessica Watkin Douglas Gray Trisram Dawahoo Nadia Huq
External advisors	Present	Daniel Brison Raj Mathur Gudrun Moore Jane Blower	Robin Lovell-Badge Melanie Davies Sheena Lewis
	Apologies	Joyce Harper	
Observers		Kim Hayes Mojisola Ajeneye	

1. Welcome, apologies and declarations of interest

- 1.1. The Chair welcomed committee members to the meeting and welcomed Anna Rajakumar, Scientific Policy Manager at the HFEA, back from maternity leave. Kim Hayes was welcomed as an observer and Mojisola Ajeneye was welcomed as an MHRA representative.
- 1.2. The Chair noted that Joanne Anton will be taking over as Head of Regulatory Policy whilst Hannah Verdin is on maternity leave.
- 1.3. The Chair conveyed apologies on behalf of Joyce Harper.

- 1.4.** In relation to the meeting agenda, interests were declared by Daniel Brison who has research interests in long term health outcomes of IVF children, culture media and embryo glue; and by Sheena Lewis who is involved in a spin-off company that carries out DNA testing for fertility problems.
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2. Matters Arising

- 2.1.** Minutes of the meeting held on 21 October 2015 were agreed remotely prior to the meeting.
 - 2.2.** The Scientific Policy Manager provided an update to the committee on the recent embryo testing paper that was presented to the Authority. The Authority agreed with option two of the Authority paper, to allow testing of more than one genetic condition or chromosomal abnormality at a time, making sure that patients consent to receive (or not receive) any additional genetic information generated.
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3. Chair's Business

- 3.1.** The Chair noted that committee meetings usually take place on a Wednesday and asked members whether they would find another day more convenient for the June 2016 meeting. Members agreed that Mondays could be a suitable day for future meetings.
- 3.2.** The Chair invited Mojisola Ajeneye (Senior Medical Device Specialist from the Medicines and Healthcare Products Regulatory Agency (MHRA)) to discuss with the committee, concerns that were raised on the topic of culture media at the October 2015 meeting.
- 3.3.** Moji noted that IVF culture media need to be scrutinised by a notified body before they can be CE marked and highlighted that concerns have been raised about the addition of supplements such as proteins and human blood derivatives which may or may not be CE marked. It was noted that this issue is being considered at a European level.
- 3.4.** One committee member indicated that a paper is being written that summarises any potential link between culture media and IVF outcomes and agreed to circulate a copy of the paper to the HFEA and the MHRA.
- 3.5.** The committee asked for greater clarity in the regulatory system, including how the MHRA uses expert advisors. It was also noted that manufacturers should be required to disclose culture media components. Moji informed the committee that the MHRA is looking at providing guidance to clinics on CE marking including the role of the notified body, avoiding off-label use and culture media containing human blood derivatives. The guidance will also explain how to inform the MHRA of safety concerns relating to culture media. One member indicated that as well as working with the Association of Clinic Embryologists (ACE) on this guidance, the MHRA should also involve the British Fertility Society (BFS).
- 3.6.** Manufacturers have a duty to carry out post market surveillance of their products. The committee highlighted the importance of including child health outcomes in post market surveillance of culture media but discussed that would be difficult as clinics do not have to report the type of culture media they use to the HFEA.

- 3.7.** The committee pointed out that the MHRA could approach the Royal College of Pathologists when recruiting experts on culture media.
- 3.8.** The executive agreed to ensure that the HFEA Inspection team are equipped to ask clinics about supplements added to culture media.
- 3.9.** The committee discussed a Cochrane review that shows hyaluronate, 'embryo glue', added to culture media is effective and whether this review was robust. The committee suggested that if they were to consider embryo glue in more detail at a future meeting, it may be useful to send this Cochrane review to an expert in systematic review methodology for comment on the quality of evidence.
- 3.10.** The committee discussed the potential issues relating to CE marking when carrying out a new technique such as mitochondrial donation, as this would include off-label use of reagents. One member also pointed out that many products used during fertility treatment are CE marked for other purposes, such as tissue culture, and not for IVF use.

Action

- 3.11.** The Scientific Policy Manager will work with the MHRA follow up on guidance relating to CE marking and the expert panel compiled by the MHRA. MHRA representatives will be invited to observe any relevant meetings in the future.
 - 3.12.** The Scientific Policy Manager will circulate a proposed date for the June 2016 meeting to the committee (13th June is the proposed date).
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4. Information for Quality update

- 4.1.** The Digital Communications Manager for the HFEA presented an update to the committee on the Information for Quality (IfQ) project which covered the aims of the project and the timeline for delivery. This was followed by a presentation by the HFEA Communications Manager who spoke to the committee about the current website content.
- 4.2.** The Communications Manager asked the committee to discuss whether information about new or unproven treatment 'add-ons' should be included on the HFEA website, and if so, how the committee feels about treatments being categorised according to the strength of evidence supporting their clinical efficacy.
- 4.3.** The committee highlighted the importance of co-ordinating with partner societies and organisations when producing patient information for the website to avoid duplication. It was also suggested that the HFEA could adopt some material from the BFS website as they have recently produced patient information in some areas. Discussions with BFS and INUK are underway.
- 4.4.** Some members noted the risk of having information on the website as it could appear that the HFEA have approved or validated techniques. There were also concerns that information on the website would need to be updated on a regular basis. However, the committee also agreed that patients are likely to go elsewhere for information that is not available on the HFEA website so, on balance, it is important to present authoritative information, making it clear which techniques have a comparatively strong or weak evidence base.
- 4.5.** The committee discussed which techniques are more common or established and may be incorporated into other sections of the website. The committee agreed that the remaining

techniques for discussion could be placed onto a page about 'Treatment add-ons'. It was also agreed that information on this page that refers to freeze-all cycles should refer to 'elective freeze-all' to distinguish this from freeze-all cycles carried out for example, during fertility preservation.

- 4.6.** The committee agreed that they would like further information about embryo glue and endometrial scratching in order to provide advice on patient information on these topics.
- 4.7.** Members discussed the proposed traffic light system for categorising treatment 'add-ons'. Some members suggested a five star system to cover techniques that might fall between the 'limited evidence' and 'backed up by clinic trials' groups, however others preferred the three point system as a simpler way of presenting information to the public. The committee also discussed the symbols and colours that could be used for the categories and agreed to comment on any suggested designs to be circulated by the executive. The committee agreed that language should be restricted to clinical effectiveness.
- 4.8.** The committee agreed that categorising treatment 'add-ons' has the potential to be a useful tool for patients. Members also agreed that it is important to be clear that the categories act as a signpost that will be followed up with a discussion between the patient and their clinician about whether a treatment add-on would be a suitable option.

Actions

- 4.9.** The Executive will circulate some proposed symbols and wording to accompany the categories of treatment 'add-ons' for committee members to comment on.
- 4.10.** The Executive will provide further information about embryo glue and endometrial scratch either in the form of a literature review or an invited speaker to a future meeting.

5. Prioritisation of issues identified through the horizon scanning process

Horizon scanning spreadsheet

- 5.1.** The Scientific Policy Manager presented the horizon scanning spreadsheet to the committee and asked if any members had any additional papers which they felt should be included. One member pointed out that it would have been useful for the spreadsheet to contain links to the papers, as well as the references, so that members could access full texts of papers if required.
- 5.2.** One member pointed out that there have been some studies relevant to the 14 day limit for culturing embryos. The Department of Health representative noted that this limit is enshrined in law, which allows culture of embryos up to 14 days or the appearance of the primitive streak, whichever occurs first.
- 5.3.** In the 'health outcomes' tab, a study by Baker et al was highlighted as high priority due to the large sample size; however the committee agreed that this study would not trigger further work by the Executive. It was noted that not much evidence was included on the male genome and male contributions to child health. The Executive and the committee agreed that this could be included in the standing item on health outcomes in children conceived by assisted reproductive techniques.
- 5.4.** The committee agreed that it would be useful to consider endometrial receptivity assay as a treatment 'add-on' and to invite a speaker to present on this topic.

Genome editing

- 5.5.** The Scientific Policy Manager presented a briefing to the committee on genome editing, including an update on policy work taking place in this area. It was noted that the committee's remit on this topic is on scientific development and basic research, rather than on any legal or ethical issues. The committee discussed the importance of stressing that genome editing techniques, whilst permitted in research, cannot legally be used in treatment. Members also agreed that it would be useful for committee members to receive information about how to deal with the media.
- 5.6.** The committee were informed that the Nuffield Council on Bioethics is looking into what a future public consultation on genome editing would look like and invited the HFEA to be involved in this.
- 5.7.** The committee agreed that there will not be a specific piece of work carried out on genome editing, but research in this area will continue to be monitored with the committee being updated at a meeting later in the year. It was also suggested that an expert on gene editing could be invited to present to the committee later in the year.

In vitro derived gametes

- 5.8.** The Scientific Policy Manager presented a briefing to the committee on the topic of in vitro derived gametes, highlighting some key research that was published last year. The committee suggested some speakers that may be able to present to the committee on this topic.

Use of ICSI

- 5.9.** The Scientific Policy Officer presented a briefing on the use of ICSI, indicating that in 2014 the committee decided to review this topic upon publication of new professional body guidelines. One member informed the committee that professional body guidance is still be drafted by the BFS and confirmed that the topic should remain a high priority issue. The committee discussed potential issues regarding communication of risk to patients as ICSI is now very commonly used in clinical practice. It was suggested that Michael Davies could be invited to speak to the committee to update members on his work in this area.

Non-invasive methods of assessing embryo viability

- 5.10.** The Scientific Policy Manager presented a briefing on non-invasive methods of assessing embryo viability. The committee was updated on key literature in this area and asked if they would like a more in depth literature review on this topic and if they would like to invite a speaker to present at a future meeting. The committee discussed the blastocentesis technique as a less invasive method of assessing embryo viability and agreed that it would be useful to monitor research in this area. One member pointed out that currently there is little evidence to support the use of non-invasive methods in clinical practice; however, there remains strong interest in this area, including research into micro-RNAs. The committee agreed that it would be useful to invite a speaker to present on this topic at a future meeting.

Action

- 5.11.** The Scientific Policy Manager will confirm with members, which papers they felt should be re-categorised in the horizon scanning spreadsheet, develop a committee work plan based on these recommendations and explore options for speakers to invite to present at meetings later in the year.

- 5.12.** The Scientific Policy Manager may alter the committee work plan, as far as possible, if further issues arise over the course of the year which may be relevant to SCAAC discussions.
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6. Committee Work Plan

- 6.1.** Members discussed the remit of the committee providing information on scientific advances in the field of fertility and providing advice for decision making. It was also noted that SCAAC has a role in informing patient information that will be presented on the HFEA website and that this will be reflected in the standing orders for the committee when these are reviewed later in the year.
- 6.2.** The committee discussed the potential benefits of inviting an expert in evidence assessment to meetings to help comment on the quality of studies being discussed. It was agreed that this role can be fulfilled by experts who can be invited to present to the committee as and when required. The Executive noted that the need for expertise in this area can be considered when recruiting new members to the committee.
- 6.3.** The Executive proposed a focussed meeting on embryo testing in 2016 with the remaining standing items being presented to the committee in June and October. Members of the committee agreed that they would like dates for the next meetings to be confirmed as soon as possible so that everyone is able to attend.
- 6.4.** The committee agreed that an in depth literature review on the use of ICSI can be postponed until the professional body guidelines have been published. Members also discussed potential speakers on the topic of simplified IVF and in vitro maturation.

Action

- 6.5.** The Scientific Policy Manager and Scientific Policy Officer will circulate possible dates in 2016 for the remaining SCAAC meetings.
- 6.6.** The Scientific Policy Manager will also ensure that the Standing Orders reflect the remit of the Committee, particularly with reference to their role in advising the Executive on patient information.
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7. Any other business

- 7.1.** The Executive informed the committee that due to the HFEA office move, future meetings will be held at another venue to be confirmed either within the NICE offices or etc. venues near to Marble Arch.
- 7.2.** Members were invited to attend the HFEA annual conference on 24th March.
- 7.3.** The committee was informed that despite recent press the HFEA has not received a formal novel process application for use of the Augment technique in clinical practice.
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8. Next meeting:

- 8.1.** Date and location to be confirmed.

8.2.

Signature



Name Yacoub Khalaf

Committee chair

Date 06/04/16
