

Prioritisation of issues identified through the horizon scanning process

Strategic delivery: Safe, ethical, effective treatment Consistent outcomes and support Improving standards through intelligence

Details:

Meeting Scientific and Clinical Advances Advisory Committee (SCAAC)

Agenda item 4

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Output:

For information or decision? For decision

Recommendation Members are asked to:

- note the issues identified as high priority through the horizon scanning process;
- consider the high priority issues and work recommendations; and
- consider whether advice from additional external advisors would help in achieving the work recommendations.

Resource implications Depends on the number of issues the Committee agrees to be high priority

Implementation date The Committee work plan for 2019/2020

Communication(s) Work priorities (as defined by the Committee) will be communicated to the Head of Planning and Governance

Organisational risk Low Medium High

Annexes Annex 1: Briefing on new issues that have been identified as high priority through the horizon scanning process
Annex 2: Issues identified through the horizon scanning process (see spreadsheet)

1. Background

- 1.1. The Authority established a horizon scanning function in 2004, the purpose of which is to identify issues that could have an impact on the field of assisted reproduction or embryo research. By identifying these issues, the Authority can be aware of potential licence applications and prepare, if necessary, a policy of position or relevant patient information.
- 1.2. Issues are identified from journal articles, conferences and contact with experts such as members of the Authority's Horizon Scanning Panel. The Horizon Scanning Panel is an international panel of experts who meet annually and are contacted via email throughout the year.
- 1.3. The horizon scanning process is an annual cycle that feeds into the business planning of the Executive, the Scientific and Clinical Advances Advisory Committee (SCAAC) and the Authority's consideration of ethical issues and standards.

2. Prioritisation process

- 2.1. A full list of issues identified since February 2018 can be found in Annex 2 to this paper.
- 2.2. To help with the business planning process, it is important for the Executive to be fully aware of which issues members consider to be high priority. New issues which have been identified this year have been categorised as high, medium or low priority using the following criteria:
 - Within the HFEA's remit
 - Timescale for likely introduction (2-3 years)
 - High patient demand/clinical use if it were to be introduced
 - Technically feasible
 - Ethical issues raised or public interest
- 2.3. New issues are high priority if they are within the HFEA's remit and meet at least two other criteria. New issues are medium if they are within the HFEA's remit and meet one other criteria or are outside of HFEA remit but meet at least two other criteria. Whilst low priority issues are those outside of HFEA's remit and unlikely to impact on research or treatment in the near future, published studies in these areas will continue to be collected and considered as part of the horizon scanning process.
- 2.4. High priority is also given to established techniques or issues which fall within the HFEA's remit and require ongoing monitoring or provision of patient information.

3. High priority issues

- 3.1.** The Executive considers the following topics (not listed in any particular order) to be high priority for consideration in 2019/20. Artificial Intelligence is the only new topic added to the high priority list based on horizon scanning findings:
- a) Mitochondrial donation
 - b) Synthetic human entities with embryo like features, “SHEEFs”
 - c) Genome editing
 - d) Embryo culture media
 - e) Health outcomes in children conceived by ART
 - f) Alternative methods to derive embryonic and embryonic-like stem cells
 - g) New technologies in embryo testing (including embryo biopsy and non-invasive methods for PGD)
 - h) Treatment add-ons
 - i) Artificial intelligence (AI)
- 3.2.** A briefing on artificial intelligence, the only new topic added to the high priority list based on horizon scanning findings, can be found at Annex 1. Briefings have not been written for the remaining high priority areas, as these topics are either standing items that are considered by the committee every year, or they have already been considered by the Committee recently.
- 3.3.** Two of the high priority issues for 2018/2019, namely the impact of stress on fertility treatment outcomes and the impact of the microbiome on fertility and fertility treatment outcomes, have been categorised as medium priority for 2019/2020. This has been done according to the prioritisation criteria ie they are outside of the HFEA’s remit but meet at least two other criteria and the HFEA are keen to continue their awareness of these issues.
- 3.4.** Following discussions, the Executive asks the Committee to consider whether any of the priorities should be amended.

Annex 1: Briefings on new issues that have been identified as high priority through the horizon scanning process

1. Artificial intelligence

Background

- 1.1.** Artificial intelligence (AI) is an area of computer science that involves the use of intelligent machines designed to perform a task. AI research within medicine is growing rapidly and is increasingly being used in fertility treatment, from fertility apps to in vitro fertilisation (IVF).
- 1.2.** At the October 2018 SCAAC meeting it was highlighted that artificial intelligence is gaining profile in the media and there is increasing interest in using AI in the provision of fertility treatment and the Committee agreed that this topic should be discussed further.
- 1.3.** In recent years, AI systems based on the time-lapse imaging have been researched and used to more accurately assess embryo morphology. A visual assessment of an embryo's morphology has been the key to measuring embryo quality for IVF. Inter-observer variation in the assessment of embryos has long been recognised. The demands on morphological assessments in embryo selection have become even greater with the uptake of single embryo transfer in the prevention of multiple pregnancy; now, the embryo with the highest implantation potential must be selected for transfer.

Summary of developments

- 1.4.** A 2016 study from Australia concluded that the agreement between embryologists selecting a single day 5 embryo for transfer was "generally good, although not optimal, even among experienced embryologists" (Storr A, et al).
- 1.5.** A study presented at the 33rd Annual Meeting of the European Society of Human Reproduction and Embryology (ESHRE) in July 2017 suggested that algorithms can classify time-lapse images of an embryo's development automatically and so remove the human variable from the morphological assessment. The study reported that increasing objectivity and repeatability in embryo assessment using AI can improve the accuracy of diagnosing embryo viability.
- 1.6.** Research presented at the 34th meeting of the ESHRE in July 2018 showed how AI is much faster and more consistent at classifying embryos using time-lapse versus the variability and heterogeneity linked to the work of the human operator.
- 1.7.** A study published in October 2018 claimed to have successfully applied AI to predict blastocyst quality with high accuracy and suggested this data-driven approach could provide a novel way of assessing embryo quality which is likely to increase the chance of pregnancy.

Impact

- 1.8.** The SCAAC will play a key role in this work by advising the Authority on any developments in the literature and commenting on any follow up data received by the HFEA.

Level of work recommendation

- 1.9.** The Committee will be asked to monitor any further developments in scientific and clinical literature relating to the use of AI in the provision of fertility treatment. To aid discussions on this topic, the Committee is asked if they would like to invite any expert speakers to present at the relevant meeting and take part in discussions with the Committee. The Executive will carry out a more detailed literature review for this relevant meeting. These discussions will help the Executive in their monitoring of AI in the provision of fertility treatment and highlight any possible issues with changes to routine practice.

References

Storr A, et al. Inter-observer and intra-observer agreement between embryologists during selection of a single Day 5 embryo for transfer: a multicenter study. *Hum Reprod* 2016; 32: 307-314

ESHRE Abstract O-162, Tuesday 4 July 2017. Using artificial intelligence to improve blastocyst morphology evaluation

Zaninovic N, Khosravi P, Hajirasouliha I, Malmsten J, Kazemi E, Zhan Q, Toschi M, Elemento O, Rosenwaks Z. (2018). Assessing human blastocyst quality using artificial intelligence (AI) convolutional neural network (CNN). *Fertility and Sterility*. 110. e89.