Annex B: Horizon scanning reference lists and topic scope

The below reference lists describe all publications identified by the Executive relevant to the horizon scanning topic. A high-level summary of the topic scope is included below each topic subheading.

Unless a paper on the topic was discussed by the SCAAC in 2024, literature searches covered the period between 1st January 2024 – 31st December 2024. For topics brought to 2024 meetings, literature searches were limited to the period since the topic was discussed. Where a new topic has been introduced, literature published over the previous ten years has been included.

The Executive notes that the identified literature is not evaluated for validity.

Alternative methods to derive embryonic and embryonic-like stem cells

Scope: This topic is focused on monitoring the methods used to create, refine and maintain human pluripotent stem cells (induced and embryonic) to ensure that the use of viable embryos in research is justified and able to fulfil the criteria of being ‘necessary and desirable’. Publications which describe the establishment of novel human pluripotent stem cell lines, optimisation of methods, or the evaluation of human pluripotent stem cells will be included. Most recently this has included populations of expanded and extended potential stem cells (EPSCs), eight-cell like cells and methods to derive extraembryonic cell lineages. The scope of this topic does not extend to the development of stem-cell based embryo models or in vitro derived gametes (separate topics). Research into differentiation and application of human stem cells are excluded.

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Artificial intelligence (AI), robotics and automation in fertility treatment

Scope: This topic is focused on the integration of artificial intelligence, robotics or automation at any stage during the fertility journey. This includes the use of robotics for automation in the laboratory (eg automated ICSI, gamete/embryo freezing, preparation of culture dishes) or in the clinical treatment of infertility (eg endometriosis, myomectomy, fibroids, polyps), and AI tools/algorithms for basic science, embryo and gamete selection, and for prediction and improvement of outcomes before and after treatment. Time-lapse imaging is excluded from the search as it is considered under the treatment add-on ‘time-lapse imaging and incubation’. Whilst patient support apps are included, AI apps to improve general health and wellbeing, which in turn impact fertility outcomes, are additionally excluded. Literature on regulation, guidelines and ethical considerations is included.

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Artificial wombs for early or whole gestation (ectogenesis)

Scope: This topic is focused on research relevant to the partial or complete gestation of an embryo or fetus ex utero, including the sustained in vitro growth. As culturing of human embryos for research purposes is limited to 14-days or the appearance of the primitive streak under the HFE Act, research typically utilises animal or stem-cell based models to sustain growth or embryos or fetus' ex utero past 14-days. Although late-gestation support (termed artificial placentas and/or artificial wombs) falls outside the scope of the HFE Act, research in this field is monitored within this topic.

Note: With the introduction of 'Reproductive organoids' as a horizon scanning topic and the monitoring of advances in embryo culture systems through topics of 'Scientific developments relevant to the 14-day rule', the Executive have proposed that the topic of 'Artificial wombs for early or whole gestation (ectogenesis)' is removed from the prioritised list of horizon scanning topics and considered as a 'watching brief' topic. For further information, see associated paper (HFEA (03/02/2025) 008).

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Emerging technologies in gamete and embryo testing

Scope: This topic includes research advancements in embryo testing methods, including but not limited to: non-invasive embryo testing (such as testing for aneuploidy and other parameters), advances in whole genome and exome sequencing, morphological grading with biopsy, novel blastocyst scoring systems, analysis of follicular fluid, novel PGT methods (eg mitochondrial copy number, segmental aneuploidy, PGT-P, etc), and emerging and novel oocyte/semen testing and selection methods. Previously male infertility testing (genetic testing through blood and sperm testing for infertility diagnosis) has been considered within scope.

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Germline/Heritable Genome Editing

Scope: This topic is inclusive of developments in techniques used to manipulate the nuclear, mitochondrial, or epigenome for the alteration of DNA expression. If research is being conducted with the intention to refine a technique or delivery method, the publication will be included in literature scan. Research using models to understand physiology is excluded, however an overview of the applications will be given in the next paper. Literature on human and mammalian models is within scope.

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Health outcomes in children born from ART (including the impact of culture media)

Scope: This topic includes research into the short and long-term health outcomes of children conceived through any form of ART (such as fresh or frozen embryo transfer, embryo testing, use of donor gametes, following male-factor infertility). In the short-term this includes trends in obstetric, maternal, perinatal, and neonatal outcomes, such as twin pregnancies, congenital malformations and birth defects. In the long term, this may include cognitive development, cardio-metabolic outcomes, risk of cancer, metabolic and reproductive functions of ART-concieved men, and other health outcomes (asthma, diabetes, imprinting disorders, cerebral palsy, etc). The effect of culture media on outcomes (including animal and human studies) is in scope.

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Impact of long-term cryopreservation of gametes and embryos

Scope: Following amendments to HFE Act (1990), storage of eggs, sperm and/or embryos for use in a patients own treatment or for donation is permitted for up to 55 years. This topic monitors any safety or viability concerns relating to the keeping of gametes or embryos in long-term storage. As the storage extension applies to gametes preserved within tissue, the impact of long-term cryopreservation of ovarian and testicular tissue is also monitored within this topic. Monitoring of the safety of cryopreservation is also relevant to maintaining the authorised processes list. Studies looking at utilisation rates of cryopreserved gametes are additionally included.

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Impact of stress on fertility treatment outcomes

Scope: This topic looks at the impact of stress in people undergoing ART on fertility treatment outcomes. Research that does not examine ART outcomes is excluded. There are two main areas of research: (1) The impact of psychological factors including stress on treatment outcomes and (2) the impact of interventions to manage stress on treatment outcomes. Research on the impact of the stress hormone cortisol on treatment outcomes is included.

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Impact of the microbiome on fertility and fertility treatment outcomes

Scope: Research into the microbiome with relevance to fertility treatment broadly falls into three areas: (1) understanding the normative microbiota composition of the reproductive tract, (2) understanding an association between reproductive tract microbiota and its role in fertility/infertility, (3) developing interventions to improve fertility and fertility treatment outcomes. Lack of standardisation in the methodological processes has limited research applications, however, commercial tests are being developed for distribution on the UK fertility market. In time, microbiome testing and interventions may be considered for an add-ons rating.

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In vitro derived gametes

Scope: This topic encompasses research into methods for achieving in vitro gametogenesis (organoids, 3D systems, scaffolds, etc) in both human and animal models. This includes the use of embryonic stem cells, induced pluripotent stem cells, immature gametes, and studies which attempt to recreate early stages of gametogenesis (ie primordial germ cells and primordial germ cell-like cells, and their induction to germ cells). In vitro maturation is also considered within scope. Opinion articles on the ethical and legal perspectives relevant to this topic are included.

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Mitochondrial donation

Scope: Under the HFE (Mitochondrial Donation) Regulations, maternal spindle transfer (MST) and pronuclear transfer (PNT) can be performed with HFEA approval in the UK. Relevant research describing the application of MST or PNT in the context of mitochondrial donation to inform SCAAC of its application and safety are the focus of this topic, including approaches to refine techniques to minimise mitochondrial heteroplasmy. The development of alternative techniques for preventing the inheritance of mitochondrial disease is also monitored within this topic, including both mitochondrial replacement techniques and *applications* of mitochondrial genome editing techniques. Expansion of mitochondrial donation techniques as a treatment for infertility (not indicated by mitochondrial disease) are additionally included in the scope of this topic, for example autologous cytoplasmic transfer.

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Reproductive organoids

Scope: This topic covers both human and animal research looking at generating ovarian, fallopian tube, endometrial, uterine, cervical and testicular organoids to study infertility and associated treatments. The focus of this topic restricted to organoid methods, but not conventional methods which precede organoids (such as 2D cultures, organotypic cultures, or other 3D cultures). Use of organoids to model cancer are excluded. Assembolids used to study placentation and foetal-maternal interactions are in scope, whereas assembloids combining organoids or cells with blastoids are considered under the topic of SCBEM.

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Scientific considerations relevant to the 14-day rule

Scope: This topic looks at the characterisation of human embryos in early-stage development (up to 14 days). This includes research studying gastrulation, early organogenesis and neural development, advances in embryo culture systems (including optimisation and extended in vitro cultivation of non-human primates), and the use of stem cell-based embryos models. Papers considering the ethical and/or legal aspects of extending embryo culture beyond 14 days are additionally within scope.

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Stem cell-based embryo models

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Testicular tissue transplantation to restore fertility in males

Scope: This topic monitors developments in autologous and xenotransplantation of human testicular tissue (foetal, pre-pubertal and adult) with the intention of restoring fertility potential in males.

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