Unit 26: Prepare Culture Systems for Gametes and Embryos in the HFEA-licensed Reproductive Science Laboratory

Level:	**4**
Unit type:	**Optional (Reproductive Science)**
Credit value:	**5**
Guided learning hours:	**40**

Unit summary

In this unit, you will gain knowledge and understanding of the principles and practice of preparing culture systems for gametes and embryos in the HFEA-licensed reproductive science laboratory within the HFEA-licensed Fertility Clinic. Culture systems are highly specialised to meet the needs of human gametes and embryos, and preparation requires the highest standards of laboratory practice.

Underpinning knowledge includes: an understanding of sterile technique, the control of temperature, pH and osmolarity of solutions, and the metabolic requirements of the gametes and embryos. This knowledge is required to ensure that the correct solutions are selected. Timely preparation of sufficient materials is a key laboratory activity and is critical to the successful running of the clinical service. Omission can jeopardise treatment, while excess preparation can waste resources and lead to future insufficiency. To ensure the task is completed as required by caseload, excellent communication is essential.

The task, to prepare the culture systems for the service, is undertaken using local policies and procedures to verify and document compliance with requirements.

Training will be performed under the supervision of a designated assessor and with the approval of the person responsible within the HFEA-licensed Fertility Clinic. All activities during the training period require direct supervision by a suitably qualified member of the multidisciplinary team.

Any external assessor or trainer must be authorised to access the HFEA-licensed Fertility Clinic.

Evidence must be anonymised to remove patient-identifiable data. Section 30 of the Human Fertilisation and Embryology Act 1990 imposes a legal duty of confidentiality, and a breach of this provision is a criminal offence.

Unit assessment requirements

There are no specific assessment requirements for this unit. Please refer to the assessment strategy in *Annexe B*.

Additional information

AC1.1 includes:

- current national and local guidelines, policies, protocols, Standard Operating Procedures, and professional guidelines relating to the preparation of culture systems for human gametes and embryos
- requirements of the Human Fertilisation and Embryology Authority Code of Practice relating to the preparation of culture systems for human gametes and embryos
- how adherence to Standard Operating Procedures ensures that:
    - all relevant aspects of preparation of the culture systems for human gametes and embryos are considered and undertaken
    - any discrepancies or omissions in any aspect of the preparation of culture systems are noted, reported and followed up
- how sterility is safeguarded during the preparation of culture systems, including but not limited to:
    - sterile working practice
    - identification of potential sources of contamination
    - how to monitor and record the required environmental parameters
    - how to ensure environmental parameters are within set limits
- how the constituents of culture systems and their correct preparation are designed to meet the needs of gametes and the stage-specific needs of embryos, including but not limited to:
    - control of temperature
    - control of pH and buffer systems
    - control of osmolarity
    - provision of nutrients
    - provision of macromolecules
    - supplementation with antibiotics
- the importance of accurate and timely preparation of culture systems, including:
    - time required for pre-equilibration prior to use for culture
    - quantities and types related to planned clinical activities
- the features of a variety of culture systems, the containers and the media and methods of patient identification, including but not limited to:
    - containers

    - media
    - oil
    - incubators
    - labelling for patient identification
- the requirements for traceability specified by the HFEA Code of Practice and the methods used for consumables tracking, appropriate storage, stock rotation, ordering and disposal
- the requirements for recording the critical equipment used and the type and batch of consumables used during preparation of culture systems
- how to minimise the risk of introducing contamination during preparation of culture systems
- the operational principles and requirement for operation of workstations within the laboratory, including the features that safeguard the culture system and the quality and safety of gametes and embryos, and the features that protect the safety of the operator
- the function of all critical laboratory equipment used during setting up culture systems and how to check they are within operational limits
- health and safety information and risk assessment(s) relating to the preparation of culture systems
- procedure-related risks to the operator, gametes, embryos and patients
- the factors that might influence the preparation of culture systems, including the effect of omission or irregularity
- the factors that might give rise to risks for the safety and quality of gametes or embryos
- the elements of the local quality-management system that relate to preparation of culture systems
- the relevance of quality control and quality assurance to the culture of human gametes and embryos.

AC1.2 includes:

- how and when to report with regard to preparation of culture systems, including but not limited to:
    - equipment malfunction
    - shortage of culture media
    - shortage of consumables
    - deficiencies in communication
- the preventative maintenance routines for relevant critical equipment within the laboratory that are required for the preparation of culture systems
- the laboratory key performance indicators that relate to culture conditions and how they may be used to monitor the preparation of culture systems
- the remedial action to take when adverse situations, problems or events occur

- the contingency arrangements in the event of an unforeseen problem arising
- the limits of the learner's authority and who to report to
- the context within which an event connected with the preparation of culture systems may become an incident to be reported to the Medicines and Healthcare Products Regulatory Agency
- the context within which an event connected with the preparation of culture systems may become an incident to be reported to the Human Fertilisation and Embryology Authority.

AC2.1 includes:

- the local Standard Operating Procedures and standard laboratory documentation for the preparation of culture systems
- the methods and checks employed to ensure that the required culture systems are set up in advance of clinical needs, including but not limited to:
    - the planned procedures
    - the correct individuals
    - sufficient items
    - on the right day
    - at the right time
- selection and preparation of laboratory documentation, making clear and accurate entries on documentation as required by local procedures
- selection of appropriate personal protective equipment (PPE)
- confirmation that materials to be used are fit for purpose and are in sufficient quantity
- cleaning the environmental area using correct cleaning materials
- preparation of the laboratory workstation and consumables used during the setting up of culture systems, including selection of the correct materials and knowledge of batch tracking and expiry dates
- performance of checks on all critical equipment to show that set points are correct and explain how any deviations may affect the integrity of the culture system
- importance of temperature and CO_2 equilibration and selection of the correct medium type and batch number according to the planned procedures.

AC2.2 includes:

- following Standard Operating Procedures for the preparation of culture systems
- checking that the unique identifier corresponds to the individual's details where culture elements are required to be pre-labelled
- keeping contemporaneous records in accordance with local policies and procedures
- acting if an error, omission or equipment malfunction is noted

- managing workload, taking into account the prioritisation and urgency of cases, the efficient use of resources and the multidisciplinary team.

AC2.3 includes:

- updating records in accordance with local and national policies and procedures
- using effective communication on all aspects of the preparation of culture systems and reporting completion of setting-up tasks in accordance with local policies and procedures
- acting on any event that requires immediate action in accordance with local policies and procedures
- use of correct local procedure for:
    - documentation of consumables used
    - documentation of batch numbers used
    - documentation of critical equipment used
- disposing of used consumables, clearing the workstation and returning unused consumables to appropriate storage, in accordance with local policies and procedures.

Learning outcomes and assessment criteria

To pass this unit, learners need to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements that the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles underpinning the preparation of culture systems	1.1	Evaluate current national guidelines, policies, protocols, Standard Operating Procedures and professional guidelines related to preparation of culture systems for human gametes and embryos in the HFEA-licensed Fertility Clinic			
		1.2	Explain the context, troubleshooting and when to take advice in relation to the preparation of culture systems			
2	Be able to prepare culture systems for gametes and embryos	2.1	Prepare to set up culture systems in the HFEA-licensed reproductive science laboratory			
		2.2	Demonstrate the ability to set up culture systems in the HFEA-licensed reproductive science laboratory			
		2.3	Communicate with colleagues following completion of setting-up tasks according to local policies and procedures			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
		2.4	Compile reports on the preparation of culture systems for audit or quality-assurance purposes			

Learner name: _____ Date: _____

Learner signature: _____ Date: _____

Assessor signature: _____ Date: _____

Internal verifier signature: _____ Date: _____
(*if sampled*)