Unit 27: Prepare Documents for the Transport of Gametes and Embryos to and from Other Fertility Clinics

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 the documents and equipment required for the transport of gametes and embryos to and from other fertility clinics.

Transport of gametes and embryos takes place between fertility clinics. These may be HFEA-licensed fertility clinics in the UK, and internationally where import licence applications with the HFEA are required. These transfers occur within the legal framework of the Human Fertilisation and Embryology Act 1990, as amended 2008, and there are detailed requirements to ensure that the transport is within the requirements of the act and that it protects the safety and quality of gametes and embryos.

The task, to prepare documents and equipment for the transport of gametes and embryos, requires the highest standards of laboratory practice and is performed under the direction of suitably qualified and registered staff within the HFEA-licensed fertility clinic.

Underpinning knowledge, including an understanding of the required documentation, patient-consent screening results, the cryopreservation method and conditions for transport are critical to ensure the safety, survival and integrity of gametes and embryos during transit. Control of temperature and labelling of the transport vessel are prerequisites for safe transit. Error or omission can jeopardise the survival of gametes and embryos. Timely preparation of associated documentation and ensuring that effective consent is in place are key activities critical to the transport of gametes and embryos.

Excellent communication between fertility clinics and any courier is essential to ensure that the task is completed as required and within the framework of the act.

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:

- national and local guidelines
- policies
- protocols
- professional guidelines
- Standard Operating Procedures, including:
    - ensuring that all relevant aspects relating to the transport of gametes and embryos between centres are considered and undertaken
    - the responsibilities of the sending centre and the receiving centres
    - ensuring that any discrepancies or omissions in any aspect of the preparation for the transport of gametes or embryos are noted, reported and followed up
    - the requirement for a third-party agreement to be in place with the centre to which the gametes or embryos are being transported to or from, and with any courier of gametes and embryos
- requirements for authorisation of any individual transportation in own clinic
- requirements of the Human Fertilisation and Embryology Authority Code of Practice relating to documentation and transportation.

AC1.3 includes:

- the additional considerations if either gametes or embryos are from donors
- how the aspects of arranging the documentation and the physical transport is scheduled to ensure timely completion of each element of the arrangements for the transport of gametes and embryos.

AC1.6 includes:

- the effect of any omissions or irregularities.

AC2.1 includes:

- Standard Operating Procedures, standard laboratory documentation, individual information and consent forms required for the transport of gametes and embryos to and from other centres
- making a plan for the transfer of gametes and embryos, listing the methods and checks performed to ensure the transport is prepared in advance of clinical need
- checking the arrangements to ensure that effective consent has been given by the individual(s) and/or donors for the use, storage and transport of all gametes or embryos to be transported
- where the consent of more than one individual is required for a single procedure, checking that the consents of each individual are in accordance with the proposed use, storage and transport
- listing the checks performed to ensure that transport is undertaken for the correct individual and includes all items on the right day and at the right time
- communicating effectively between own clinic and:
    - individual(s) wishing to carry out the transport
    - individual(s) wishing for transport to be arranged
    - clinics involved in the transport of the gametes or embryos
- selection of the current documentation for transport into another centre and preparation of the documentation, explaining the need for the following:
    - documenting appropriate consent for transport
    - documenting agreement from the other centre
    - confirming which screening test results and what dates are required
    - confirming screening status of the storage vessel
    - documenting patient consent for storage and/or treatment
    - describing the materials and cryopreservation methods
    - confirming the safety checks on the transport vessel, including temperature monitoring and security
    - checking labelling of the transport vessel
    - provision of consumable batch-tracking information
- selection of the current documentation for transport from another centre and preparation of the documentation, explaining the need for the following:
    - documenting appropriate consent for transport
    - documenting agreement from the other centre
    - confirming which screening test results and what dates are required
    - confirming screening status of the storage vessel

    - documenting patient consent for storage and/or treatment
    - obtaining information about the materials and cryopreservation methods
    - confirming the safety checks on the transport vessel, including temperature monitoring and security on arrival
    - providing information for the labelling of the transport vessel
    - obtaining consumable batch-tracking information
- managing workload, taking into account the progress of the arrangements for transport, the efficient use of resources and the multidisciplinary team.

AC2.2 includes:

- following Standard Operating Procedures to demonstrate competence in:
    - the safe use and safe handling of liquid nitrogen
    - preparing a dry shipper for use, including how to confirm it is suitable for use
    - the correct labelling of the shipper in preparation for transport.

AC2.3 includes:

- following Standard Operating Procedures to demonstrate competence in:
    - the correct procedures for witnessing the movement of gametes and embryos into the dry shipper for transport
    - the correct procedures for witnessing the movement of gametes and embryos out of the dry shipper for cryostorage
    - checking that the unique identifier corresponds to the individual's details
    - where gametes or embryos from more than one individual are transported, check that the unique identifiers for each individual are in accordance with all records and documentation
    - keeping contemporaneous records
- acting if a documentation error or omission is noted.

AC2.4 includes:

- following Standard Operating Procedures to demonstrate:
    - the correct recording of the transport and updating of records
    - ensuring the transport of gametes or embryos is reported to the HFEA
    - acknowledging receipt of gametes or embryos with the other clinic and with the individual
    - the storage or return of the empty dry shipper
- demonstrating effective communication on all aspects of the transport of gametes and embryos
- acting on any event that requires immediate action in accordance with local policies and procedures

- compiling reports on the transport of gametes and embryos for audit or quality-assurance purposes.

AC3.2 to include but is not limited to:

- mismatch of labelling
- mismatch of consent
- concern that the shipper has been tampered with
- concern that the shipper has not maintained at a low temperature
- contingency arrangements in the event of an unforeseen problem arising
- recall procedure for gametes and embryos
- limits of the learner's authority and who to report to.

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 HFEA Code of Practice requirements relating to the documents required before transport of gametes and embryos to and from other fertility clinics	1.1	Summarise current legislation and guidance that must be adhered to before transporting gametes and embryos to and from HFEA-licensed fertility clinics			
		1.2	Evaluate the HFEA decision tree, summarising what centres must consider when transporting gametes in the UK and abroad.			
		1.3	Explain the importance of checking that effective consent has been given by the patient(s) for the use, storage and transport of all gametes or embryos to be transported			
		1.4	Assess the local health and safety information and risk assessment(s) relating to the transport arrangements for gametes and embryos			
		1.5	Discuss the witnessing requirements at each stage of the arrangements and the specific inherent risks that are checked through the witnessing procedure			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
		1.6	Describe the factors that might give rise to risks for the safety and quality of gametes or embryos			
		1.7	Summarise the elements of the local quality-management system relating to the transport arrangements for gametes and embryos			
2	Be able to prepare documents for the transport of gametes and embryos to and from other fertility clinics	2.1	Prepare the necessary documents for the transport of gametes and embryos to and from other fertility clinics			
		2.2	Perform safe preparation and use of the transport vessel			
		2.3	Act as a witness when gametes or embryos are transported			
		2.4	Report and conclude the transport procedure in line with local policies			
3	Understand how to deal with adverse incidents and emergencies	3.1	Explain when and why a discrepancy in delivery time should be reported			
		3.2	Explain the remedial action to be taken when adverse situations, problems or events occur			
		3.3	Explain the context within which an event during the transport of gametes or embryos becomes an incident to be reported to the Human Fertilisation and Embryology Authority			

Learner name: _____ Date: _____

Learner signature: _____ Date: _____

Assessor signature: _____ Date: _____

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