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Application for the
Association of Clinical Scientists (ACS)
Certificate of Attainment

Andrea Natalie Other
Assisted Conception Unit (ACU)
xxxxx Hospital
xxxxx

Modality: Clinical Embryology

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**COMPETENCES REQUIRED FOR APPLICANTS
TO ATTAIN STATE REGISTRATION AS CLINICAL SCIENTISTS**

MODALITY:	EMBRYOLOGY	SUBMODALITY: (if applicable)		APPLICANT'S NAME:	A N O T H E R
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APPENDIX 1

This set of documents must be completed and returned in your portfolio.
Please complete the three header sections above on each page.
Refer to the Specific Competences document for guidance in completing this document.
Use typescript or black ink and block capitals for all sections.

EXPERIENCE: The candidate should be able to demonstrate that he/she has worked in an environment that has enabled the individual to receive training and gain experience relevant to the competences set out below.

1-SCIENTIFIC

HPC Standards of Proficiency Codes for Clinical Scientist	AREA OF COMPETENCE	INDICATE SECTION(S) IN PORTFOLIO WHERE COMPETENCE IS DEMONSTRATED
3a.1p	<ul style="list-style-type: none"> understanding the science that underpins the specialty (modality) and the broader aspects of medicine and clinical practice 	Paragraph: 4-9,11-13 Appendix: 3-5
3a.1g	<ul style="list-style-type: none"> demonstrating a strong base of knowledge appropriate to the specialty and to the investigations and therapeutic options available 	Paragraph: 7,9,12,17, 20, 21 Appendix: 3-5
2b.1g 2b.1p	<ul style="list-style-type: none"> experience of searching for knowledge, critical appraisal of information and integration into the knowledge base 	Paragraph: 11,12,13 Appendix: 2-4
2b.1g	<ul style="list-style-type: none"> ability to apply knowledge to problems associated with the routine provision, and development, of the service 	Paragraph: 17, 20, 21, 25, 32 Appendix: 6-7
2a.1p	<ul style="list-style-type: none"> ability to identify the clinical decision which the test/intervention will inform 	Paragraph: 7, 9, 17-21, 24 Appendix: 4, 5
2c.1p	<ul style="list-style-type: none"> ability to make judgements on the effectiveness of procedures 	Paragraph: 7-9, 17, 20, 21 Appendix: 4-6
3a.2g	<ul style="list-style-type: none"> application of the knowledge base to the specialty (modality) and to the range of procedures/investigations available 	Paragraph: 7-9, 12, 17, 20 Appendix: 3-6

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2-CLINICAL

HPC Standards of Proficiency Codes for Clinical Scientist	AREA OF COMPETENCE	INDICATE SECTION(S) IN PORTFOLIO WHERE COMPETENCE IS DEMONSTRATED
2b.1p	<ul style="list-style-type: none"> ability to provide interpretation of data and a diagnostic (therapeutic) opinion, including any further action to be taken by the individual directly responsible for the care of the patient 	Paragraph: 7, 9, 17, 20, 21, 24 Appendix: 4, 5
3a.1p	<ul style="list-style-type: none"> understanding of the wider clinical situation relevant to the patients presenting to his/her specialty 	Paragraph: 10, 18-21 Appendix: 4, 5
2b.3p	<ul style="list-style-type: none"> ability to develop/devise an investigation strategy taking into account the complete clinical picture 	Paragraph: 17 Appendix: 4, 5
3a.2p	<ul style="list-style-type: none"> understanding of the clinical applications of his/her specialty and the consequences of decisions made upon his/her actions/advice 	Paragraph: 9, 17, 20, 21 Appendix: 4, 5
3a.2p	<ul style="list-style-type: none"> awareness of the evidence base that underpins the use of the procedures employed by the service 	Paragraph: 10, 13, 32, 39 Appendix: 4, 5, 8, 13

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3-TECHNICAL

HPC Standards of Proficiency Codes for Clinical Scientist	AREA OF COMPETENCE	INDICATE SECTION(S) IN PORTFOLIO WHERE COMPETENCE IS DEMONSTRATED
3a.2p	<ul style="list-style-type: none"> understanding of the principles associated with a range of techniques employed in the modality 	Paragraph: 4-10, 16-24 Appendix: 4, 5
3a.2p	<ul style="list-style-type: none"> knowledge of the standards of practice expected from these techniques 	Paragraph: 4-10, 23, 38 Appendix: 4, 12, 13
2b.4p	<ul style="list-style-type: none"> experience of performing these techniques 	Paragraph: 4-10, 16-23 Appendix: 4,5
2b.4p	<ul style="list-style-type: none"> the ability to solve problems that might arise during the routine application of these techniques (troubleshooting) 	Paragraph: 17, 20, 21, 25 Appendix: 5, 7
2c.2g	<ul style="list-style-type: none"> understanding of the principles of quality control and quality assurance 	Paragraph: 25, 26, 28, 30, 31 Appendix: 5, 7
2c.1p	<ul style="list-style-type: none"> experience of the use of quality control and quality assurance techniques including restorative action when performance deteriorates 	Paragraph: 25, 26, 28, 30 Appendix: 7

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4-RESEARCH AND DEVELOPMENT

HPC Standards of Proficiency Codes for Clinical Scientist	AREA OF COMPETENCE	INDICATE SECTION(S) IN PORTFOLIO WHERE COMPETENCE IS DEMONSTRATED
2b.1p	<ul style="list-style-type: none"> ability to read and critically appraise the literature 	Paragraph: 3, 8, 11-13, 34, 36, 43-49 Appendix: 2-4, 6, 9
2b.1p	<ul style="list-style-type: none"> ability to develop the aims and objectives associated with a project 	Paragraph: 3, 8, 34, 43-49 Appendix: 2, 6, 9
2b.1p	<ul style="list-style-type: none"> ability to develop an experimental protocol to meet the aims and objectives in a way that provides reliable and robust data (i.e. free of bias) 	Paragraph: 35, 43-49 Appendix: 9
2b.1p	<ul style="list-style-type: none"> ability to perform the required experimental work ability to produce and present the results (including statistical analysis) 	Paragraph: 8, 42-49 Appendix: 6, 9
2b.1p	<ul style="list-style-type: none"> ability to critically appraise results in the light of existing knowledge and the hypothesis developed and to formulate further research questions 	Paragraph: 34, 42-49 Appendix: 9
2b.1p	<ul style="list-style-type: none"> ability to present data and provide a critical appraisal to an audience of peers – both spoken and written 	Paragraph: 8, 25, 26, 42, 49 Appendix: 6, 7, 9

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5-COMMUNICATION

HPC Standards of Proficiency Codes for Clinical Scientist	AREA OF COMPETENCE	INDICATE SECTION(S) IN PORTFOLIO WHERE COMPETENCE IS DEMONSTRATED
-	<ul style="list-style-type: none"> ability to assess a situation and act accordingly when representing the specialty 	Paragraph: 20, 21, 24, 27 Appendix: 5
1b.2p	<ul style="list-style-type: none"> ability to respond to enquiries regarding the service provided when dealing with clinical colleagues 	Paragraph: 17-21, 26 Appendix: 5, 7
1b.4g	<ul style="list-style-type: none"> ability to communicate with patients, carers and relatives, the public and other healthcare professionals as appropriate 	Paragraph: 17-21, 27, 32, 34, 37, 41 Appendix: 5, 8, 14
1b.5p	<ul style="list-style-type: none"> ability to communicate the outcome of problem solving and research and development activities 	Paragraph: 26, 42-49 Appendix: 7, 9
2b.1p 1b.5p	<ul style="list-style-type: none"> evidence of presentation of scientific material at meetings and in the literature 	Paragraph: 8, 26, 42 Appendix: 6, 7, 9

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6-PROBLEM SOLVING

HPC Standards of Proficiency Codes for Clinical Scientist	AREA OF COMPETENCE	INDICATE SECTION(S) IN PORTFOLIO WHERE COMPETENCE IS DEMONSTRATED
2a.2g 2c.1g	<ul style="list-style-type: none"> to assess a situation 	Paragraph: 20, 21, 25 Appendix: 5, 7
2b.1g	<ul style="list-style-type: none"> determine the nature and severity of the problem 	Paragraph: 20, 21, 25 Appendix: 5, 7
2b.1g	<ul style="list-style-type: none"> call upon the required knowledge and experience to deal with the problem 	Paragraph: 20, 21, 25 Appendix: 5, 7
2b.1g	<ul style="list-style-type: none"> initiate resolution of the problem 	Paragraph: 20, 21, 25 Appendix: 5, 7
-	<ul style="list-style-type: none"> demonstrate personal initiative 	Paragraph: 20, 21, 25, 30 Appendix: 5, 7

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7-MANAGEMENT

HPC Standards of Proficiency Codes for Clinical Scientist	AREA OF COMPETENCE	INDICATE SECTION(S) IN PORTFOLIO WHERE COMPETENCE IS DEMONSTRATED
1a1.g	<ul style="list-style-type: none"> Understanding of the legal and ethical boundaries of the modality, and the ethical aspects of scientific research. 	Paragraph: 10, 21, 47 Appendix: 4, 9
1b.1g, 1a.5g	<ul style="list-style-type: none"> Ability to recognise the limits of personal practice and when to seek advice. 	Paragraph: 20, 23 Appendix: 11
1a.6g	<ul style="list-style-type: none"> Ability to manage personal workload and prioritize tasks appropriately. 	Paragraph: 48 Appendix: 9, 10
2c.2g 1a.3g	<ul style="list-style-type: none"> Understanding of the principles of clinical governance including clinical audit, accreditation requirements relevant to the modality. The importance of confidentiality, informed consent and data security 	Paragraph: 10, 25, 26, 31, 40, 50, 53 Appendix: 7, 12
1b.3g	<ul style="list-style-type: none"> Ability to contribute effectively to work undertaken as part of a multi-disciplinary team 	Paragraph: 24, 27, 31 Appendix: 5
	<ul style="list-style-type: none"> Ability to supervise others as appropriate to area of practice. Understanding of the role of appraisal in staff management and development. 	Paragraph: 33, 34 Appendix:
1a.7g 1a.8g	<ul style="list-style-type: none"> Understanding of the need for career-long self-directed learning and the importance of continuing professional development. 	Paragraph: 36, 40, 50, 52, 53 Appendix: 13
3a.3g	<ul style="list-style-type: none"> Understanding of the need for, and ability to establish and maintain, a safe practice environment. 	Paragraph: 38 Appendix: 13
	<ul style="list-style-type: none"> Understanding of the structure and organization of the department and how it fits into the local clinical setting, General understanding of the way the modality is structured and practised in other locations within the UK. Basic understanding of the importance of financial accountability, budgetary control and resource management. 	Paragraph: 21, 31, 33, 40 Appendix: 13

Note:

The above are the generic competences that must be met by all Clinical Scientists. These competences have also been mapped onto specific subjects. Copies of these can be obtained from the ACS Administrative Office and the website.

1 Summary

Paragraph

1

I graduated from xxxxx University in xxxx with a First Class Bachelor of Science Degree (with Honours) in xxxxx xxxxx. This degree allowed me to develop my fascination with human embryology and fetal development and encouraged my interest in infertility and *In Vitro Fertilisation* (IVF). In xxxxx xxxx I was selected for a Grade A Trainee Embryologist position that began later in xxxx xxxx following graduation. My trainee position was located in the Assisted Conception Unit (ACU), xxxxx Hospital, xxxxx, and was based on a two year contract to allow completion of the ACE Postgraduate Diploma in Clinical Embryology. After completing the diploma in xxxx xxxx, I was given the opportunity to undertake a PhD within the xxxxx Department of xxxxx University. The PhD was on a part-time basis, allowing me to continue to work clinically and to continue with pre-registration training. After completing my research in xxxx xxxx, I was employed as a permanent, full-time Grade B Pre-Registration Embryologist at xxxx Hospital, my present position.

3 Portfolio

3.1 Pre-Grade A Training

3.1.1 BSc (Hons) Degree

Paragraph

2

I studied xxxxx xxxxx at xxxxx University between xxxxx xxxx and xxxx xxxxx. The xxxxx xxxxxx degree course allowed me to gain a broad understanding of mammalian embryology, problems in reproduction, and infertility techniques. The first honours year covered molecular biology techniques, statistics, and mammalian reproduction and embryology. The mammalian reproduction and embryology lectures and laboratory sessions gave an insight into the first two weeks of life and subsequent development of the body systems, and allowed me to develop microscope and dissection skills. The second (final) honours year covered four modules including: Cells into Organs, Viruses and Disease, Genes and Development, and Problems in Mammalian Reproduction. The Cells into Organs, and Genes and Development modules allowed many aspects of embryology and fetal development, both anatomical and genetic, to be learned. The final module, Problems in Mammalian Reproduction gave an introduction into infertility and IVF, problems with implantation and developmental defects, and prenatal diagnostic techniques.

Please refer to Appendix 1 for BSc (Hons) xxxxx Degree Certificate.

3.1.2 BSc (Hons) Thesis

Paragraph

3

In the final year of my BSc (Hons) degree I carried out my undergraduate research project with Drs xxxxx and xxxxx. I studied “The role of E-cadherin in gonadal differentiation.” This project involved the dissection of mouse embryos of 13.5 days post-coitum (dpc) from the uterine horn. The urogenital complexes were subsequently removed and separated from the adjacent mesonephros. The paired gonads were sexed and then separated for culture. One gonad, used as control, was chemically and mechanically dissociated and subsequently cultured for three days to allow re-association. The second gonad was dissociated in the same way, but subsequently cultured with anti-E-cadherin antibody. The re-associated control and experimental gonads were fixed, sectioned and stained for analysis. The tissue sections were analysed to assess whether the differentiating mouse gonad requires the presence of

2b.1p

functional E-cadherin to re-form cell-cell adhesions and to continue normal differentiation. This work gave me experience in micro-dissection, microscopy (light and electron) and sterile culture techniques, and allowed me to develop skills in data collection and analysis and data presentation both in written and verbal form.

Please refer to Appendix 2 for BSc (Hons) Thesis Abstract.

3.2 Grade A Training (ACE Postgraduate Diploma in Clinical Embryology)

Paragraph

4

I began my career in Clinical Embryology in xxxx xxxx, when I started the position of Grade A Trainee Embryologist, within the ACU at xxxxx Hospital, xxxxx. The position was under the direct supervision of the Senior Clinical Embryologist (SCE) and overseen by xxxxx xxxxx (Person Responsible to the HFEA). The two year training period involved the completion of the ACE Postgraduate Diploma in Clinical Embryology. The diploma consisted of:

3a.1p, 3a.2p,

2b.4p

- a) a practical aspect, involving the gaining of clinical/practical experience under direct supervision, to ensure core practical skills are learned. The core skills are then recorded in a validated logbook.
- b) a theoretical aspect, which involved completion of three written assignments (see Appendix 3) and,
- c) a written formal examination and VIVA.

3.2.1 Laboratory experience with completion of logbook

Paragraph

5

During the two year training programme I gained practical experience in all aspects of clinical embryology while under direct supervision from the SCE. All experience gained was documented in a validated logbook. The core practical skills learned included:

3a.1p, 3a.2p,

2b.4p

- **Tissue Culture:** aseptic techniques, water purification and glassware preparation, media preparation, culture conditions, equipment handling and maintenance, and quality control.

- **Semen Analysis and Preparation:** semen collection, semen analysis, sperm function assessments, sperm preparation techniques, semen cryopreservation and thaw, epididymal and testicular sperm retrieval and preparation, and retrograde ejaculation.
- **Oocyte Retrieval:** collection techniques, oocyte grading, and IVF insemination.
- **Fertilisation, Embryo Culture, Embryo Transfer, and Cryopreservation:** embryo culture techniques, fertilisation checks, embryo grading, embryo transfer, and embryo cryopreservation.
- **HFEA Regulations, Documentation, Communication, Code of Conduct, Analysis of Results and Trouble-Shooting:** HFEA Code of Practice, Laboratory Practice, Communication, Code of Conduct, Analysis of Results and Trouble-Shooting.

A sixth, literature-based module ‘Basic Aspects of Human Reproductive Function’ was also completed. Details of this module are detailed in section 2.2.2.

Module 1: Tissue Culture

Paragraph
6

This module provided the basic skills required for work in any laboratory based clinical science. It was designed to teach the trainee embryologist fundamental laboratory skills for the day-to-day running of a successful clinical embryology laboratory. These skills are required before a trainee can progress to more clinically orientated laboratory procedures.

3a.1p, 3a.2p,
2b.4p

Major practical skills learned included:

- sterilising techniques for laboratory equipment with prevention of hazardous contamination and elimination of any contamination problems. This involved a tutorial with the microbiology department and the use of contact agar plates for evidence for cleaning/decontamination techniques. The results of these tests raised awareness amongst other laboratory staff of potential ‘dirty areas’ within the laboratory. This subsequently resulted in several changes to laboratory practice, with cleaning carried out more frequently and more attention paid to those ‘dirty areas’, and work within hoods altered to allow more efficient airflow.

- Use and maintenance of water purification systems. This involved a visit and tutorial with the Renal Dialysis Unit technicians. The tutorial provided me with information regarding the use, maintenance, cleaning and sanitation of water purification systems. Although these skills are not routinely used within an embryology laboratory, this knowledge has assisted me with the use of water purification in other research laboratories.
- Aseptic techniques were expanded with the preparation of culture media. Luria Base (LB) broth and Earle's media were prepared and subsequently cultured for 48 hours. The presence of any bacterial growth was tested through the bacteriology department, and a negative result provided evidence of competence in aseptic technique and media preparation.
- My ability to use and understand a variety of culture systems within the embryology laboratory was confirmed with the day-to-day use of 4-well dishes, the petridish microdrop system and culture in test tubes, in clinical practice under the supervision of the senior clinical embryologist.
- Competence in the handling and maintenance of equipment was gained during unit closures, during which time the embryology laboratory shuts down and thorough disinfection/cleaning of all laboratory equipment occurs. The bi-annual shut-down of the ACU also allows incubators to be serviced by external contractors, and allows thorough cleaning, de-contamination cycles, and equilibration to occur.
- Quality Control procedures are in place to ensure that traceability of all consumables can occur and the introduction of any new consumables means that toxicity testing must be carried out. I have carried out numerous Sperm Survival Tests, overseen by the supervising senior embryologist, to test the toxicity of culture oil and non-sterile gloves.

Module 2: Semen Analysis and Preparation

When I became competent in basic laboratory skills (Module 1) this second module was designed to cover the principals in semen analysis and preparation of semen samples for treatment. It was vital that the completion of this module, and the following two modules, was done in unison with the sixth, literature-based module 'Basic Aspects of Human Reproductive Function'. This allowed the practical skills to be learned, competences to be gained, and the basic science underpinning the clinical work to be understood.

3a.1p, 3a.1g,

2a.1p, 2c.1p,

3a.2g, 2b.1p,

3a.2p, 2b.4p

Major practical skills learned included:

- The collection of semen samples for use in IVF/ICSI treatment allowed me to gain confidence in interacting with patients, and allowed me to understand the importance of sample traceability. I was required to gain competence in ensuring all identity checks were in place before samples were collected and then used for treatment purposes. It was vital that I understood the risks involved in patient sample cross-over, and therefore the importance of clear and precise sample labelling. The risks involved in handling biological specimens also needed to be understood and safeguarded against.

- Basic semen analysis skills were taught within the laboratory, whilst working alongside trained members of staff and overseen by the supervising clinical embryologist. Competence could only be gained with the performance of multiple volume measurements, density counts and motility counts, done concurrently with a trained member of staff and results compared. Only when results were within 10% accuracy could competency be verified and recorded. This allowed me to recognise possible sources of error and eliminate these for future analyses. All semen analyses were done in conjunction with the WHO manual (WHO Laboratory Manual for the Examination of Human Semen and Sperm-Cervical Mucus).

Sperm viability tests including Eosin-Y staining and the HOS test were carried out despite not being routinely performed in the laboratory. This gave me the opportunity to investigate several sperm viability tests, learn protocols and adapt them to our particular laboratory practise.

- The methodologies for sperm preparation for both semen analysis and IVF/ICSI treatment were taught within the laboratory by the supervising clinical embryologist. Several methods for sperm preparation were taught including swim-up, density gradients and mini density gradients. This allowed me to understand the way one sperm preparation technique, routinely used within the clinical setting, can be adapted to allow for variety of parameters within different semen samples. Competence could only be gained when comparisons were made between different sperm preparation techniques, with the use of sperm function testing, and a basic understanding of the methodologies communicated to the supervising clinical embryologist. When carrying out sperm preparation for treatment purposes, I was able to identify times of potential error/sample cross-over, allowing me to understand the importance of witnessing procedures, and clear and precise labelling of all samples.
- Semen cryopreservation and thaw. The principles of cryopreservation were taught within the laboratory. Semen cryopreservation was carried out for oncology patients and male partners with problems producing semen samples, or those male partners not available at the time of infertility treatment. Dealing with pre-chemotherapy patients gave me the opportunity to observe another side/function of assisted conception. It allowed me to understand the necessity for preserving fertility in those not ready to start a family, but that require gamete storage for their future use. Competency at freezing and thawing of semen samples, and in the preparation of cryoprotectant solutions was demonstrated and verified.
- Epididymal and testicular sperm retrieval and preparation, and retrograde ejaculation collection and preparation: Competency in each of these techniques was gained by working alongside trained members of staff, and reading available literature. This allowed me to learn those techniques routinely carried out within our theatre and laboratory, but also to understand the physiology underpinning the need for epididymal or testicular sperm retrieval, and the causes of retrograde ejaculation. With a thorough understanding of sperm preparation techniques, I was able to adapt our preparation methods to ensure optimal numbers and quality of sperm was recovered for treatment purposes.

Gaining competence in semen analysis and semen preparation for treatment, has allowed me to interpret semen analysis results and advise other members of staff in the appropriate treatment plan for the patient. This includes the substitution of IVF with ICSI techniques, or vice versa, and the termination of IUI treatments and organisation of review appointments for those patients with poor prognosis. This has given me a critical understanding of the need for diagnostic testing in infertility treatments, and competence in communicating the appropriate treatment plan with colleagues.

Module 3: Oocyte Retrieval

Paragraph
8

The third module was designed to cover the core practical skills required for oocyte collection, oocyte grading and IVF insemination. This module was completed after I had gained competency in basic laboratory skills (Module 1) but ran concurrently with the sixth literature-based module. This ensured that the practical skills were gained with an understanding of the physiology of the female reproductive cycle, including the ovarian cycles, resumption of meiosis, ovulation, timing of oocyte retrieval and ovarian stimulation.

3a.1p, 2c.1p,
3a.2g, 3a.2p,
2b.4p, 2b.1p,
1b.5p

Major practical skills learned included:

- Competency in the practical skills involved in oocyte retrievals, oocyte grading and IVF inseminations was gained under the direct supervision of the senior clinical embryologist and documented in a validated logbook. These skills included understanding the importance of sample traceability before and after oocyte retrieval; preparation of tools and equipment used for oocyte retrieval; oocyte collection methods; identification of immature, mature and atretic cumulus cells; and the identification of cysts and endometriomas; and IVF insemination procedures.
- This module also allowed me to develop a broader understanding of the practicalities of IVF procedures, with respect to differing culture systems, the importance of temperature, pH and osmolarity maintenance in all culture systems, and different oocyte retrieval methods.

- A more critical understanding of the female menstrual cycle, superovulation, and assisted conception was gained through the completion of the literature-based Module 6.
- Gaining competence in insemination procedures and becoming more aware of various methodologies in IVF insemination allowed me to carry out a retrospective audit of our IVF insemination procedures and a comparison of results. The data comparing ‘short’ and ‘long’ insemination techniques was presented to nursing, scientific and medical staff during a clinical governance meeting within the unit. The abstract is included in Appendix 6.

Module 4: Fertilisation, Embryo Culture, Embryo Transfer and Cryopreservation

Paragraph
9

The fourth and final practical module was completed in unison with the literature-based module 6. This ensured that all practical skills including, fertilisation checks, embryo culture, embryo grading, embryo transfer, and embryo cryopreservation, were learned in parallel with an understanding of the scientific basis for the methods used in a clinical embryology laboratory.

3a.1p, 3a.1g,
2a.1p, 2c.1p,
3a.2g, 2b.1p,
3a.2p, 2b.4p

Major practical skills learned included:

- Competency in manipulation of inseminated oocytes to assess the fertilisation status was developed under the direct supervision of the senior clinical embryologist. This involved gaining competency in the preparation of micro-tools for dissection, and an awareness of the physiology of ovarian morphology, oocyte maturity and fertilisation.
- Developing skills in embryo culture, embryo grading and embryo transfer allowed me to gain an understanding of the optimal culture conditions for embryo culture, and to achieve a critical understanding of the importance of evaluating embryo development for use as a tool to develop an individual treatment plan. I developed sufficient expertise to interpret the information gained from embryo culture/embryo grading and use this information (with any patient history available) to determine the optimal day for embryo transfer.

- Competency in embryo cryopreservation and embryo thaw also allowed me to achieve a sufficient level of knowledge and skill to manage a patient's treatment with respect to the optimal day for cryopreservation, the number of embryos to freeze per treatment cycle/thaw, and the optimal day for thaw and transfer. These skills provided me with the ability to communicate treatment plans to my clinical colleagues and the patients involved.
- Completion of this module provided me with experience in both failed fertilisation and failed thaws and the ability to identify ways to rectify any problems and make any changes to treatment plans. This also involved communicating the bad news to both the patient and the relevant members of staff involved in the treatment cycle.

Module 5: HFEA Regulations, Documentation, Communication, Code of Conduct, Analysis of Results and Trouble-shooting

Paragraph
10

The fifth module was designed to ensure that I gained a critical understanding of the HFEA and the statutory framework governing assisted conception techniques, including the Code of Practice, COSHH and safe working practice.

3a.1p, 3a.2p,
2b.4p, 1a.1g,
2c.2g, 1a.3g

Major skills learned included:

- A complete knowledge of the HFEA Code of practice and the guidelines regulating the clinical embryology laboratory, including safety procedures when handling liquid nitrogen and general safe working practice. An understanding of the importance of patient confidentiality and data security was also gained.
- In order to highlight any unexpected outcomes from routine IVF, I set up an IVF database to accumulate all IVF data on a weekly basis. This allowed me to perform regular performance audits and compare IVF outcomes with laboratory consumables on a week-by-week basis. Any adverse/unexpected situations were then raised with the SCE.

Module 6: Basic Aspects of Human Reproductive Function

Paragraph
11

The sixth, literature-based module was completed in parallel with the previous, practical-based modules to accomplish a deeper and more complete understanding of

3a.1p, 2b.1g,
2b.1p

the scientific methods employed in clinical embryology. This module is explained in more detail in sections 2.2.2 and 2.2.3.

3.2.2 Written reports/assignments

Paragraph
12

During my Grade A training, the completion of the practical training was done in parallel with a sixth, literature-based module entitled 'Basic Aspects of Human Reproductive Function' (see above). This module was concerned with the theory underpinning the practical elements of clinical embryology, and competence was assessed by means of a formal written examination and the submission of three written assignments. The latter consisted of extended essays, detailed below, and the former is detailed in section 2.2.3.

3a.1p, 3a.1g,
2b.1g, 2b.1p,
3a.2g

Appendix 3 contains an abstract of these reports.

Assignment 1

'Summarise the necessary preliminary tests that should be performed for both the male and female partners prior to commencing treatment. How do these tests help to decide treatment options, and what are the unaccountable risks of treatment?'

The research/literature searching involved in writing this assignment provided me with a broad understanding of the application of the various investigative methods and diagnostic tests involved in the diagnosis of the infertile couple; and the correct interpretation of these tests to ensure the correct clinical decisions are made and the optimal treatment plan is chosen.

Assignment 2

'Outline the culture requirements of human oocytes, zygotes, embryos and blastocysts.'

Reading the relevant literature for this report gave me an insight into the dynamic and complex microenvironment of human gametes and embryos *in vivo* that leads to their specific requirements *in vitro*, and the research that has taken place to improve the culture conditions for human oocytes and embryos. I gained a critical understanding of the limitations of single culture media and the requirement for sequential media in

modern day IVF. I also became aware of the concerns for the long-term effects of extended culture to the blastocyst stage, in sub-optimal culture conditions.

Assignment 3

‘What is your understanding of the word “cloning”? Comment on reproductive and therapeutic cloning techniques, as mentioned in the 7th Annual Report of the HFEA. What potential uses and abuses might be foreseen?’

When completing this assignment I became fascinated by the ethical and moral issues that surrounded embryology and its associated technologies. I gained an awareness of the legal and ethical boundaries that limit research using human gametes and embryos, and the importance of the media and public opinion. I became aware that just because technologies are available and successful in animal subjects does not mean they should be applied to humans. Searching the literature also helped me recognise the importance of critically reviewing published work, and allowed me to develop the ability to interpret data published by various working groups.

3.2.3 ACE Written Examination and VIVA

Paragraph
13

A formal (unseen) written examination was completed in xxxx xxxx. This carried 75% of the overall weighting of the diploma and a 50% pass grade was required. The written examination was followed by a VIVA lasting approximately 90 minutes, which was assessed by an external assessor.

3a.1p, 2b.1g,
2b.1p, 3a.2p,
2b.1p

Both the written exam and VIVA were concerned with the theory behind the practical elements of clinical embryology. Module 6 ‘Basic Aspects of Human Reproductive Function’ gave an outline of the broad syllabus to be included and contained several ‘essential topics’ that would be assessed in the examinations. This allowed me to prepare for the exam with the use of all available literature. The ‘essential topics’ covered in the examinations included:

- The hypothalamo-pituitary-gonadal axis
- The menstrual cycle and superovulation
- The testis and male reproductive function
- Fertilisation and the establishment of pregnancy
- Basic endocrinology

- Infertility – causes and treatment options
- Donor gametes
- History of present day regulations and ethical issues

3.2.4 Meetings, tutorials and training courses

Paragraph
14

During my two year training programme I regularly attended meetings and participated in seminars both locally and nationally (see Appendix 12). I also participated in internal clinical governance meetings and presented data from a retrospective audit of our IVF insemination procedures. An abstract is included in Appendix 6. I also attended a British Infertility Counselling Association (BICA) training day ‘Working with the Emotional Impact of Infertility’ (see Appendix 13). This allowed me to develop and improve my communication skills and abilities to communicate sensitively with patients attending the unit.

3.2.5 ACE Postgraduate Diploma

Paragraph
15

I was awarded the ACE Postgraduate Diploma in Clinical Embryology in xxxx xxxx, and it was presented at the British Fertility Society Annual Meeting, xxxx in xxxx xxxx (see Appendix 4). However, the ACE Executive and Training Committee introduced the Certificate in Clinical Embryology later in xxxx, which also held Department of Health Approval and was required for State Registration. I was therefore awarded the Certificate in Clinical Embryology in xxxx (see Appendix 4).

3.3 Pre-Registration/Grade B Training and Experience

Paragraph
16

After completing the ACE Postgraduate Diploma in Clinical Embryology in xxxx, I was given the opportunity to undertake a PhD within the xxxxx Department of xxxxx University. The PhD was on a part-time basis, allowing me to continue to work clinically and to continue with pre-registration training.

3a.2p, 2b.4p

3.3.1 Day to Day Routine

Paragraph
17

As a pre-registration/Grade B embryologist I perform all aspects of clinical embryology on a day-to-day basis, under in-direct supervision of the SCE.

I carry out all aspects of semen analysis and preparation for treatment purposes, and only refer to the senior embryologist with any adverse/unexpected results. This has

3a.1g, 2b.1g,
2a.1p, 2c.1p,
3a.2g, 2b.1p
2b.3p, 3a.2p,
2b.4p, 1b.2p,
1b.4g

allowed me to gain experience at implementing investigative strategies for patients presenting with azoospermia. I decide on the appropriate processing technique to gain more information of the extent of azoospermia (or cryptozoospermia). For example, processing the 'neat' semen sample, followed by plating out the recovery, and assessing for the presence of motile sperm to determine which treatment options are available to the patient. This involves advising clinical colleagues and patients on the interpretation of semen analyses and of the most suitable treatment plan such as diagnostic surgical sperm retrieval, ICSI, or treatment with donor sperm. Semen Analysis can also involve advising patients on variations and changes to a treatment plan and gaining informed written consent. For example, the need for second semen samples for IVF treatment, conversion from IVF to ICSI and vice versa. I also communicate with couples attending for Intrauterine Insemination (IUI) if semen parameters are suboptimal, and advise them on appropriate treatment options.

Paragraph

18 Semen cryopreservation for treatment purposes, sperm donors and pre-chemotherapy patients is also part of my daily routine in the clinical embryology laboratory. This involves ensuring sufficient consents are in place and screening for blood-borne viruses (BBVs) has been completed. Cryopreservation for treatment purposes involves discussion with the patient regarding the number of samples required for storage. Semen cryopreservation for donation involves constant interaction with the sperm donor to ensure sufficient samples are stored, within a suitable timetable for both the donor and the embryology laboratory. Constant discussion with administration staff to ensure all donor expenses are covered is also important. I also deputise for the SCE responsible for cryopreservation, in ensuring that sperm donors have a final BBV screening appointment six months after completing donation and in the transfer of fully screened semen samples from quarantine into storage available for use.

Paragraph

19 Cryostorage of semen samples for pre-chemotherapy patients involves liaising with the patient to ensure sufficient samples are stored before chemotherapy treatment begins. Pre-chemotherapy patients are often referred to the ACU at a very late stage therefore it is important that I am aware of their chemotherapy treatment timetable to allow the patient to store as many samples as possible without compromising their health. I also aim to synchronise hospital appointments as much as possible to avoid 'taking over' the patients life at such an emotional and worrying time. Dealing with pre-chemotherapy

*2a.1p, 3a.1p,
3a.2p, 2b.4p,
1b.2p, 1b.4g*

patients requires sensitivity and empathy when discussing their future treatments and can often lead to informal counselling sessions with in-depth discussions regarding the impact of treatment on their future.

Paragraph
20

Oocyte Retrievals, IVF inseminations, pronuclear screening, embryo culture, and embryo transfer are also carried out on a daily basis without direct supervision. I routinely advise patients regarding number of oocytes fertilised, which also involves the counselling of those with failed fertilisation. I frequently assess the optimal day (day 2 or day 3) for embryo transfer and discuss with the patients the merits of extended embryo culture. This can often involve changing a treatment plan according to embryological observations and explaining my opinions to both clinical colleagues and the patient themselves. Unfortunately this can also lead to counselling those patients whose embryos have failed to develop.

3a.1g, 2b.1g,
2a.1p, 2c.1p,
3a.2g, 2b.1p,
3a.1p, 3a.2p,
2b.4p, 1b.2p,
1b.4g, 2a.2g,
2c.1g, 1b.1g,
1a.5g

I also have to ensure I can identify those patients whose chances of success are high and would benefit from a single embryo transfer. I then have to discuss these patients with the SCE and appropriate clinician to give my opinion and confirm this is an appropriate treatment plan. I then discuss this at length with the patient, inform them of the risks/benefits of such a decision, and help the patient alter written consent forms accordingly.

Paragraph
21

Embryo cryopreservation and thaw are a routine aspect of my clinical embryology duties. I frequently make decisions based on embryological observations to assess if embryos are suitable for cryopreservation following routine IVF/ICSI treatment. This involves providing advice to the couple regarding the suitability of embryos for cryopreservation, counselling the couple of the chances of embryo survival and pregnancy following cryopreservation, and in-depth discussion of the number of embryos frozen, the number to be thawed at one time, and the possibilities for extended culture post-thaw. This also requires the ability to understand local health board funding with regard to frozen embryo transfers, and advising the patients accordingly. I routinely organise and alter patient treatment plans for frozen embryo transfers, with respect to the schedule for embryo thaw based on the HRT or natural cycle of the female patient. This includes assessing the stage of development of the embryos in storage; advising both the couple and nursing staff if extended culture post-thaw is

3a.1g, 2b.1g,
2a.1p, 2c.1p,
3a.1p, 3a.2p,
2b.4p, 2a.2g,
2c.1g, 1a.1g

appropriate; and setting-up the patient accordingly. With HRT cycles, this involves advising nursing staff of changes in stimulation prior to thaw, and the requirement and timing of a scan for natural cycles. I also routinely discuss the thaw procedure with the couple, advise on chances of embryo survival and pregnancy, discuss the possibilities of thawing more than one vial of embryos if survival is poor, and gain written, informed consent to thaw and transfer. Unfortunately the thaw procedure can sometimes lead to discussion with patients whose embryos have failed to survive.

Paragraph
22

To carry out all the aspects of clinical embryology detailed above, I need to hold a complete awareness of the importance of accurate recordkeeping, sample traceability, and patient confidentiality.

3a.2p, 2b.4p

3.3.2 Further Clinical Training

Paragraph
23

While continuing with my day-to-day clinical embryology duties I am also continually training to increase my capabilities and extend my understanding of clinical embryology. Since completing my PhD research and returning to full-time clinical embryology duties, I have been able to begin ICSI training. I have recently received my ICSI licence, and I am currently collecting data and results for my three month submission to the HFEA (Appendix 10). This has allowed me to broaden my technical skills, and ensured that I now have an appropriate level of experience in all embryology techniques available to the infertile couple.

3a.2p, 2b.4p,
1b.1g, 1a.5g

Paragraph
24

I am currently undertaking training for setting-up patients to begin their IVF or ICSI treatment. This involves assessment of 'Day 8' or 'action' scans to determine the optimal day for Oocyte Retrieval. Discussion with clinical, nursing, and administration staff is crucial to ensure all aspects of each individual patient's treatment are taken into account, and that all relevant staff are aware of any idiosyncrasies for each particular patient. I must be able to take into account any previous treatment cycles the patient has received, and advice clinical, nursing and administration staff of any changes to the treatment I believe to be of benefit. For example, the need for an extra day of stimulation in those patients with high oocyte immaturity in a previous cycle. This is also an opportunity to ensure all BBV screening and relevant consents have been completed.

2a.1p, 3a.2p,
1b.3g

3.3.3 Responsibilities

Paragraph

25

I have been responsible for the management of all IVF data since xxxx. This involves the collation of data from all IVF cycles carried out each week, inputting this data into a specified database, and analysing the data for quality management purposes. I have chosen the prime indicators for assessment of laboratory performance, including fertilisation rates, embryo development, embryo cryopreservation and implantation rates, and use these to detect any problems in the clinical embryology laboratory. I collect the data on a weekly basis to ensure swift recognition of any problems and to be able to rapidly respond to any adverse outcome. This involves close discussion with the SCE, the person responsible and other laboratory staff. Each IVF treatment is given a treatment cycle number, which is closely linked to the use of new culture media and laboratory consumables, therefore allowing me to associate any deterioration of laboratory performance with any changes in external or internal factors. By choosing indicators for laboratory performance I am able to assess our laboratory practise with the development and use of 'Key Performance Indicators'.

2b.1g, 2b.4p,

2c.2g, 2c.1p,

2b.1p, 2a.2g,

2c.1g, 1a.3g

Paragraph

26

In xxxx xxxx I gave a presentation to clinical, nursing, laboratory and administration staff, to explain the importance of key performance indicators and to demonstrate ways in which the laboratory collates and audits data. This was to try and offer an insight into the benefits of performing data audit, and to make suggestions in ways to carry out data collection and data analysis, specific to each discipline.

2c.2g, 2c.1p,

2b.1p, 1b.2p,

1b.5p, 1a.3g

An abstract from this presentation is included in Appendix 7.

Paragraph

27

I am currently representing the clinical embryology staff in a 'Donor Recruitment Team.' This has involved designing posters to advertise in the local area for both sperm and oocyte donors, contacting local doctors surgeries, health centres, nurseries etc for permission to display our posters and information leaflets. I also managed a stand at xxxx University 'Fresher's Fayre' to try and recruit students for sperm donation. This has given me the opportunity to communicate with members of the public regarding gamete donation and given me a better understanding of the public opinion. This I have used to try and overcome public misconceptions to infertility treatments with gamete donation to try to increase the availability of donors.

1b.4g, 1b.3g

Paragraph

28

Within the clinical embryology laboratory I am responsible for the maintenance of heated laboratory equipment, supervising daily and monthly temperature monitoring.

2c.2g, 2c.1p

On a monthly basis, I also ensure that culture incubators are kept adequately humidified and free of contamination.

Paragraph

29 I currently deputise for the senior clinical embryologist in all aspects of cryopreservation, including the annual audit of all sperm and embryos in liquid nitrogen storage, the verification of BBV screening results and subsequently the transfer of quarantined samples into liquid phase storage ready for use, and the availability of donor sperm for treatment.

Paragraph

30 I am also responsible for the development of an internal quality management system, with regard to pronuclear screening and embryo grading. This is still in development and will involve the assessment of embryos thawed for perish for training and quality management purposes. I am currently deputising for the senior clinical embryologist in maintaining our involvement in the NEQAS external quality management system.

2c.2g, 2c.1p

3.3.4 Service Development

Paragraph

31 Between xxxx and xxxx xxxx I was closely involved in the production of 'Standard Operating Procedures' (SOPs) for quality management purposes. I became the author of approximately 15 embryology SOPs, and I am now a trained auditor of clinical practice for continued quality management. My involvement in setting up the quality management system helped the unit receive ISO 9001 (2000) certification in xxxx xxxx.

2c.2g, 1a.3g,

1b.3g

Paragraph

32 I attended an Association of Biomedical Andrologists (ABA) semen analysis course in xxxx xxxx to identify ways in which our unit could improve our semen analysis techniques and hopefully improve and develop the service we provide. I passed the ABA semen analysis with distinction (see Appendix 8). The ABA semen analysis course provided me with the ability to precisely assess semen parameters for diagnostic and treatment purposes. It also allowed me to return to clinical work with improved techniques, and to communicate to other embryology staff changes that needed to be put into place to improve our service. The suggested changes were put into place immediately in the clinical embryology laboratory.

2b.1g, 3a.2p,

1b.4g

I also developed health questionnaires that are now used by all staff to question male patients of their health status prior to providing a sample. I have designed an information leaflet that is sent to all patients with appointments for semen analysis, to

ensure the patients are fully informed with regard to where and when to produce their sample, and the importance of the analysis in deciding the optimal treatment plan.

3.3.5 Additional Competences

Paragraph

33

I am currently assisting the senior clinical embryologist in the training of a trainee embryologist. This involves answering any questions or queries that the trainee may have and offering advice when needed, and explaining any changes to standard embryology practice that may occur. This has allowed me to share my experiences from my time in a Grade A training position.

Paragraph

34

I have recently assisted the Person Responsible with supervising a medical student with his 'Special Study Module' (SSM) looking at failed fertilisation in IVF patients who subsequently undergo ICSI treatment. This involved sharing data taken from the IVF database, advising the student where to locate the relevant information, which clinical indicators to compare, and how to audit the collated data. The information gained from the SSM project contradicts previous literature and it is hoped that an article will be published from this work. Supervising this project has allowed me to develop my management skills in assessing and appraising scientific reports and in identifying limitations of research findings.

1b.4g, 2b.1p

Paragraph

35

I am currently trying to introduce new media for semen cryopreservation into the clinical embryology laboratory. This has involved presenting a brief description of the new media, reasons for making the change, and a protocol for carrying out a trial against the current media, to the senior clinical embryologist, Person Responsible, and the Quality Manager. I have liaised with the manufacturer to answer any queries raised by the team and have carried out a blind trial to compare the two media. This has allowed me to develop an understanding of quality control procedures and given me the opportunity to design a simple clinical trial to develop and improve our routine laboratory techniques.

2b.1p

Paragraph

36

I have recently become registered with the ACE on-line CPD scheme, which will allow me to continually develop my skills and increase my knowledge in the clinical embryology field. I regularly attend Journal Clubs organised by the ACU staff, which keeps me up-to-date with current literature.

1a.7g, 1a.8g,
2b.1p

Paragraph
37

My daily duties within the clinical embryology laboratory also involve frequent consultations with patients attending the unit or who have telephoned the unit. Many patients have questions regarding the embryology and/or andrology side of infertility treatment, or may have concerns regarding infertility treatment and just require reassurance.

3a.2p, 3a.3g,
1b.4g

Paragraph
38

I regularly attend lectures on fire safety, CPR, manual handling, general health and safety, and data protection. Certificates of recent lectures attended are included in Appendix 11.

3a.2p, 3a.3g

3.3.6 Meetings, tutorials and training courses

Paragraph
39

I regularly attend annual society meetings such as BFS and ACE (see Appendix 12 for certificates of attendance). Attending these annual meetings allows me to keep up-to-date with current research and practice in other units around the world. Following every meeting attended I write a summary of the most interesting topics and distribute this for all my colleagues to read. This gives me time to digest all that I have learned from each meeting and to subsequently discuss these findings with my laboratory colleagues. Any areas of interest are discussed in a small group, and any topic that may apply to our current practise can be addressed. This ensures that our clinical practice continually evolves with the advances in infertility technologies around the world.

3a.2p

In xxxx xxxx I completed the ABA semen analysis in xxxx. See 2.3.4 for more details.

Paragraph
40

In xxxxx xxxx I attended the 'ACE Membership update – looking to the future' meeting at the Royal College of Pathologists, London (see Appendix 12). This one-day meeting was intended to provide me with an insight into how the Association of Clinical Embryologists is evolving and explained the benefits of becoming members of the Royal College of Pathologists. The meeting gave me an understanding of the needs of the embryology profession and as clinical scientists we must be recognised for our skills and competencies alongside our clinical colleagues. Attending this meeting also gave me the opportunity to become familiar with the accreditation schemes required for progression in the field of clinical embryology.

2c.2g, 1a.3g,
1a.7g

Paragraph

41 Also in xxxxx xxxx I attended a course on the ‘Emotional impact of infertility’ (see Appendix 13). This one-day training course gave me further insight into the emotional side of dealing with infertility from a patient’s perspective. I returned to clinical embryology with a broader awareness of how patients feel when going through infertility treatment, and developed appropriate skills in communicating with our patients with empathy and sensitivity.

1b.4g

Paragraph

42 In xxxx xxxx I will be attending the xxxx Meeting of xxxx in xxxxx. I will be orally presenting some of the work carried out during my PhD, entitled ‘*Expression of the glucose-6-phosphatase system in human embryonic and early fetal development*’ (see Appendix 9 for abstract). Despite regular presentations to other scientific staff during my PhD (see 2.3.7 for more details), this will be my first formal oral presentation at a society conference. I hope that this will give me the confidence to continue to present my data at future meetings, and help me to develop my communication skills to become a clear and effective speaker.

2b.1p, 1b.5p

3.3.7 PhD and Research

Paragraph

43 In xxxx xxxx I began a part-time PhD within the xxxxx Department of xxxxx University. I have two PhD supervisors the first is Professor xxxx, a Medical Biochemist whose area of interest is the biogenesis, regulation and genetic deficiencies in the glucose-6-phosphatase enzyme system. My second supervisor is Professor xxxx, a Consultant Paediatrician, whose area of expertise is developmental disorders in infants and the development of therapeutic strategies for their prevention.

2b.1p, 1b.5p

Paragraph

44 In collaboration with my two supervisors the aim of my research was to investigate the expression of the glucose-6-phosphatase system during human embryonic and fetal development. It is essential for the transition from intra-uterine to extra-uterine life, that the human infant is able to ‘switch on’ a functioning glucose-6-phosphatase system as development progresses towards term. Disorders in the glucose-6-phosphatase system have been implicated in diabetes mellitus, intra-uterine growth restriction infants and in sudden infant death syndrome. Before my research started, little was known of where or when expression of the glucose-6-phosphatase enzyme system occurs during human embryonic and fetal development.

2b.1p, 1b.5p

Paragraph
45

Using immunohistochemistry and RT-PCR, various tissue systems were investigated to observe the distribution and expression of the enzyme system and its associated proteins, during life *in utero*. When sequencing of genomic PCR products suggested the presence of mutations in the glucose-6-phosphatase gene, transient transfections were carried out to assess if the mutations were functional.

2b.1p, 1b.5p

Paragraph
46

Completion of my PhD has provided me with many valuable skills and has increased my understanding of the scientific basis of the methodologies we employ in clinical embryology. However, the scientific techniques I have learned are only a small part of what I have achieved through this experience.

2b.1p, 1b.5p

Paragraph
47

I have learned to appreciate many of the ethical, moral and legal constraints that surround research with human tissues. Working with embryonic and fetal tissues in my research has also reinforced my understanding of confidentiality issues, the legal requirement for precise and detailed record keeping, and the ethical issues involved in storing human tissues for research.

2b.1p, 1b.5p,
1a1.g

Paragraph
48

Carrying out my research on a part-time basis has provided me with excellent time-management skills, and a critical understanding for the need for deadlines. Upon learning new techniques in a research laboratory you quickly become the 'resident expert' in this technique and are promptly responsible for teaching others the skills you have acquired. This has made me proficient in teaching others, and allowed me to quickly develop the ability to write clear protocols that others can follow.

2b.1p, 1b.5p,
1a.6g

Paragraph
49

Throughout my five years of research I regularly presented my work to other students, post-doctoral research fellows, staff from within the department and staff from other disciplines. This enabled me to gain confidence in speaking in front of a scientific audience with a range of knowledge and skills. It also encouraged me to routinely review the work I had already carried out, summarise my findings in a clear and precise manner, and focus on new research targets. A list of titles from these presentations are included in Appendix 10.

2b.1p, 1b.5p

3.3.8 The Future

Paragraph

50

Upon attaining the ACS Certificate of Attainment I aim to immediately apply for HPC Registration. When fully state registered I will become deputy to the SCE, allowing me to supervise work in the clinical embryology laboratory in their absence.

2c.2g, 1a.3g,

1a.7g, 1a.8g

Paragraph

51

State registration will also allow me to become involved in the on-call rota system that is currently in place on a one in four week rotation. This rota ensures that a clinical embryologist is available 24 hours a day to respond to a call-out from the clinical embryology laboratory within 30 minutes of call-out. A request for call-out is issued if any alarm sounds from culture incubators and liquid nitrogen (low level oxygen) alarms.

Paragraph

52

When I have completed writing up my PhD thesis, the unit's aim is to develop a research programme within the clinical embryology laboratory, and I initially hope to establish small, embryology-based research projects for the embryology team to become involved with.

1a.7g, 1a.8g

Paragraph

53

When I have achieved HPC Registration, I aim to continue with my professional development and begin proceedings to become a member of the Royal College of Pathologists.

2c.2g, 1a.3g,

1a.7g, 1a.8g

Appendix 1
(Supporting Evidence)

Bachelor of Science (Hons) Degree
Certificate

'The role of E-cadherin in gonadal differentiation.'

Cadherins are associated with cell recognition and selective adhesion during embryonic development. Despite this, little is known of the molecules involved in the process of gonadal differentiation. The functional role of E-cadherin in gonadal differentiation of the 13.5 dpc mouse embryo has been investigated using the dissociation/re-association method. The principal aim was to determine whether a dissociated, differentiating mouse gonad requires the presence of functional E-cadherin to reform cell-cell adhesions and continue normal differentiation.

Both control and antibody-treated ovarian and testicular cells were able to re-associate in culture. However, the reformed tissue in both control and experimental tissues appeared unorganised, with an almost indifferent phenotype. In the re-associated testes, the absence of E-cadherin did not produce any differences in tissue structure when compared to the control testes. In the reconstituted antibody-treated ovaries however, germ cell-germ cell contacts were interrupted by intercellular spaces, which were not present in the control ovarian tissue. This study suggests that 13.5 dpc mouse gonads are unable to differentiate when isolated from the mesonephros, under both control and experimental conditions. The mesonephros is still needed as a source of supportive somatic cells for the developing gonad. Secondly, E-cadherin has no vital function at 13.5 dpc in the differentiating mouse testis. In contrast to this, the differentiating ovary requires functional E-cadherin to maintain germ cell-germ cell contacts. Cadherins not only mediate cell-cell adhesion, but are also a means of communication between cells. Therefore it is possible that E-cadherin may mediate germ cell-germ cell communication in the differentiating ovary.

Appendix 3: Grade A Training Written Reports (Abstracts)

Assignment 1

‘Summarise the necessary preliminary tests that should be performed for both the male and female partners prior to commencing treatment. How do these tests help to decide treatment options, and what are the unaccountable risks of treatment?’

Assisted reproductive techniques (ART) have become well-accepted methods of treatment for the infertile couple since the birth of Louise Brown in 1978. A wide range of techniques now exist, making it possible to choose a treatment which is most likely to benefit the individual couple. There are also many investigative methods and diagnostic tests available to aid the clinician in diagnosis, and in identifying the most appropriate treatment method. However some of these tests are often excluded from the preliminary investigations (or delayed) due to their invasive nature, and each treatment carries its own risks and benefits. It is therefore important that a specific pathway for investigation of the infertile couple is followed. This will ensure the clinician diagnoses correctly and subsequently chooses the optimal treatment, with the minimum risk to the patient. The most informative preliminary tests including semen analysis, endocrine profiling and utero-tubo-peritoneal investigations are the most likely to aid diagnosis. These tests, in turn, will assist the clinical embryologist in making an informed decision in the clinical embryology laboratory with regard to a specific patient’s treatment plan.

This report focuses on the preliminary tests routinely performed and their contribution to the diagnosis of infertility and the subsequent management within the clinical embryology setting. It also looks at the treatment options available and the putative risks of each treatment pathway.

Assignment 2

'Outline the culture requirements of human oocytes, zygotes, embryos and blastocysts.'

Historically, the composition of the majority of human embryo culture media has been based on simplistic salt solutions supplemented with metabolites at concentrations that sustain mouse embryo development. However, the demand for improved success rates while simultaneously reducing the risk of multiple gestation has pushed many IVF units to aim towards extended embryo culture, and single blastocyst transfer. This, coupled with a wider awareness of the risks of extended culture in sub-optimal culture conditions, has led to a resurgence of interest in the development of sequential media. Modern day human gamete and embryo culture media must reflect the dynamic and complex microenvironment that human gametes and embryos encounter *in vivo*, and must support the immature oocyte through to the developing blastocyst.

The physiology of the human oocyte and preimplantation embryo is both unique and dynamic, and embryologists can no longer compromise human development with the use of a single, substandard culture medium. It is clear that the human oocyte, zygote, early cleavage embryo and blastocyst have different nutritional and metabolic requirements throughout development. Briefly, the human zygote and early cleavage embryo require a lactate and pyruvate rich environment that is virtually glucose-free. Glycolysis can be inhibited further with the inclusion of EDTA and supplementation with non-essential amino acids is also beneficial. As development progresses through compaction to the blastocyst stage, a culture media with increased levels of glucose is required, without EDTA and with a full complement of all 20 amino acids.

Further work is still required to investigate the potential benefits of further supplementing culture media with growth factors and vitamins, as the available sequential culture media are still far from optimal, and may only become so with a complete understanding of the specific requirements of the human embryo.

Assignment 3

‘What is your understanding of the word “cloning”? Comment on reproductive and therapeutic cloning techniques, as mentioned in the 7th Annual Report of the HFEA. What potential uses and abuses might be foreseen?’

In February 1997 the media erupted with news of the first cloned vertebrate from an adult somatic cell. Dolly the sheep was the result of work at the Roslin Institute, Edinburgh, to improve methods for the genetic modification of livestock, and her birth was hailed as a remarkable scientific breakthrough as it was previously thought that the adult cell nucleus is irreversibly programmed, and incapable of reprogramming to produce new offspring. Since Dolly’s birth, concerns have been raised concerning the implications of this technology and the potential risks/benefits of applying this work to the cloning of human beings.

Many misconceptions exist concerning cloning and the ways in which cloning techniques are applied to animals and could possibly be applied to humans. These misconceptions can arise from a lack of understanding of cloning and its associated techniques, or from strong religious and ethical beliefs regarding the potential risks or benefits that a human application may confer. Considerable media hype may be the cause of many of these untruths and may have irreversibly swayed public understanding and opinion regarding the topic of cloning.

This essay gives an explanation of the term *cloning* including an overview of the different concepts that are routinely described using this term. Various cloning techniques are described, with explanations of the methods used in *therapeutic* and *reproductive cloning*. The opposing views of government, religious leaders, scientists and the HFEA are mentioned in this report, however the potential uses and abuses of human therapeutic and reproductive cloning is essentially a matter of personal opinion, which importantly, may be swayed by an association of an individual with a particular working group. For example, a consequence of human cloning which a scientist believes is beneficial to the human race, a member of the

Catholic Church may see as a slippery slope towards a 'Brave New World'.
The aim of this essay is to provide a comprehensive view of the potential
uses and abuses that have been raised so far.

Appendix 4: Postgraduate Diploma and Certificate from ACE

I was awarded the ACE postgraduate Diploma in Clinical Embryology in xxxx xxxx (copy of Diploma attached). However, the ACE Executive and training Committee made changes to the ACE training scheme and introduced the Certificate in Clinical Embryology later in xxxx, which also held Department of Health Approval and was required for State Registration. It was the opinion of the ACE Executive that the 'old style' Diploma was at least equivalent to the Certificate in content. I was therefore awarded the Certificate in Clinical Embryology in xxxx. A copy of both the ACE Executive explanatory letter and Certificate are attached overpage.

Appendix 5

Letter confirming Grade A Supervision and Grade B (Pre- Registration) Training

Appendix 6: Insemination Data Analysis Presentation Abstract

‘Does duration of gamete co-incubation effect IVF outcome?’ A retrospective study

During a standard IVF cycle the insemination procedure is performed over a 16-18 hour period. This means that the oocytes and spermatozoa are co-incubated ‘overnight’ to let fertilisation to occur, and subsequently allow visualisation of the pronuclei to assess fertilisation status the following morning. This prolonged co-incubation is the standard methodology employed at xxxxx Hospital ACU and most other units, until recently.

There is now evidence to suggest that fertilisation actually occurs very rapidly, as the spermatozoa enters the cumulus cortex within 15 minutes of insemination, traverse through the cumulus within 3 hours, and appear within the oocyte cortex by 4 hours post-insemination (Gianaroli et al., 1996). Research has also shown that a reduced insemination protocol of 1-4 hours does not reduce fertilisation rates or significantly effect embryo quality (Plachot et al., 1986), and may actually increase implantation rates (Gianaroli et al 1996).

It has since been suggested that overexposure of oocytes to spermatozoa can actually be detrimental to future embryo development, due to the production of reactive oxygen species (ROS) via spermatozoa metabolism. This, in turn, can lead to zona thickening or hardening (Dirnfeld 2003). This research has lead to the introduction of ‘short’ insemination techniques where the oocytes and spermatozoa are co-incubated for 2-4 hours only. The oocytes are then removed, excess cumulus cells removed, and oocytes transferred to culture overnight. This protocol was adopted at Ninewells ACU for a selected group of patients. Selection criteria:

- Initial sperm parameters of $>15 \times 10^6$ /ml, motility of Grade A, A/B
- >5 oocytes retrieved
- History of good fertilisation.

As a retrospective study, patients who were selected for the 'short' insemination protocol were compared to patients who matched these criteria, but received IVF treatment before the 'short' insemination protocol was put into place, and therefore received 'standard' or 'long' insemination IVF. The parameters investigated included:

- % fertilisation
- embryo quality/development
- pregnancy rate
- implantation rate

This study found no differences between the two groups with fertilisation, embryo development, pregnancy rates or implantation rates. However, a higher number of embryos were found to be of better quality, and therefore more embryos were cryopreserved in the 'long' insemination control group when compared to the 'short' insemination study group. This difference was not significant. No results were collated from subsequent frozen embryo transfers.

References

Dirnfeld et al., (2003) A prospective randomised controlled study of the effect of short co-incubation of gametes during insemination on zona pellucida thickness. *Gynecol Endocrinol* 17, 39-403

Gianaroli et al., (1996) Reducing the time of sperm-oocyte interaction in human in vitro fertilisation improves the implantation rate. *Hum Reprod* 11, 166-171

Plachot et al., (1986) Timing of in vitro fertilisation of cumulus-free, and cumulus-enclosed human oocytes. *Hum Reprod* 4, 237-242

Appendix 7 IVF Data Audit *Presentation Abstract*

'Performance Indicators for IVF: A Lab Perspective'

Performance indicators in the clinical laboratory allow clinical scientists to assess and analyse clinical results on a regular basis to ensure that any problems or issues are recognised and addressed swiftly and appropriately. In a standard clinical IVF laboratory the most useful performance indicators are easily recognised. Oocyte immaturity, fertilisation rate, abnormal fertilisation, embryo development, and pregnancy and implantation rates are all useful parameters to determine the quality of the work being performed. In the xxxxx Hospital Assisted Conception Unit (ACU) IVF data is collected on a weekly basis to ensure a rapid response to any adverse outcome. All IVF data is entered onto a designated database, which also includes details such as patient age, cycle number, and indicated cause of infertility. The accumulated IVF data is then analysed and assessed against 'target' results, devised from the previous 12 months data. Each week's accumulated IVF data is plotted to determine if targets have been reached, or fall within the standard deviation. Some anomalies can be produced due to a small number of cycles occurring in one week, and can be rectified by the use of a 'three week moving average' data trend. Any improvements or problems observed in the performance indicators are discussed between the clinical embryologist team, with alterations in laboratory practice also taken into account. Changes in laboratory practice can include batch changes in consumables, altered laboratory environment, or changes in culture conditions. Factors outwith the laboratory must also be taken into account, such as stimulation changes, or the average age of the patients receiving treatment.

Performance indicators must be continually assessed to ensure that future changes in clinical IVF practice such as the introduction of air quality control systems or CE marked consumables, have the desired effect of improving the success of assisted reproduction.

Appendix 8

ABA Semen Analysis Course certificate

Appendix 9 PhD Abstract

The human fetus maintains blood-glucose levels by the constant supply of glucose from the mother, through the placenta. However it is vital that the human fetus develops the ability to regulate their glucose levels by activating glycogenolysis and gluconeogenesis. Glucose-6-phosphatase (G6Pase) is a key enzyme involved in the terminal step of glucose production via both glycogenolysis and gluconeogenesis. It is known that G6Pase is predominantly expressed in adult liver and kidney, playing a major role in homeostatic regulation of blood-glucose levels. Key components of the G6Pase enzyme system have previously been identified in various human embryonic and fetal tissues, indicating that the G6Pase system may also play a significant role in glucose regulation during human embryonic and fetal development. The presence of a functional G6Pase system during human development may be vital for localised glucose production and regulation at a time of high metabolic demand, and therefore may be essential for continued embryonic and fetal development. In order to increase our understanding of the expression and distribution of the G6Pase system during human embryonic and early fetal development, this study uses immunohistochemistry and molecular biology techniques to identify key components of the G6Pase system in human embryonic and fetal tissues.

Human embryonic and fetal tissues were obtained following elective termination of pregnancies. Stage of development was carefully estimated according to established morphological criteria. Tissues were fixed in 10% buffered formalin and processed routinely to paraffin wax, or snap frozen and stored at -80°C until use. The peroxidase anti-peroxidase technique of immunohistochemistry was used to confirm the presence and distribution of key components of the G6Pase system in human embryonic and fetal tissues, using monospecific antibodies raised against G6Pase and its associated proteins. Genomic RNA was extracted, reverse transcribed and used in RT-PCR reactions to confirm expression of the G6Pase system.

Appendix 10 PhD Presentations
List of oral and poster presentations

Presentation 1: ‘Human Embryonic Development’ xxxx xxxx

Oral presentation to other PhD students, post-docs and staff of the xxxxx Department, including my PhD supervisors.

Presentation 2: ‘Glucose-6-phosphatase in human embryonic and fetal red blood cells’ xxxx xxxx

Oral presentation to other PhD students, post-docs and staff of the xxxxx Department, including my PhD supervisors.

Presentation 3: ‘Human development and the glucose-6-phosphatase enzyme system’ xxxx xxxx

Oral presentation to other PhD students, post-docs and staff of the School of xxxxx, University of xxxxx. This presentation was a brief outline of my first year of PhD work.

Presentation 4: ‘Immunohistochemical localisation of human adult hepatic proteins in human embryonic and fetal red blood cells’ xxxx xxxx

Oral presentation to other PhD students, post-docs and staff of the xxxxx Department, including my PhD supervisors.

Presentation 5: ‘Co-localisation of GLUT2 and iodothyronine deiodinases type I and type III in human embryonic and fetal red blood cells’ xxxx xxxx

Oral presentation to other PhD students, post-docs and staff of the xxxxx Department, including my PhD supervisors.

Presentation 6: ‘Co-localisation of GLUT2, sulfotransferase 1A1, dehydroepiandrosterone sulfotransferases and iodothyronine deiodinases in human fetal liver’ xxxx xxxx

Poster presentation to other PhD students, post-docs and staff of the School of xxxxx, University of xxxxx. This presentation was a brief outline of my second year of PhD work.

Presentation 7: 'Iodothyronine deiodinase type III (D3) in human fetal adrenal' xxxx xxxx

Oral presentation to other PhD students, post-docs and staff of the xxxx Department, including my PhD supervisors.

Appendix 11

Letter confirming ICSI training

Appendix 12

Evidence of Internal Training Courses

Appendix 13

National/International Meetings: *Evidence of Attendance*

Appendix 14

Infertility Counselling Training: *Certificates*