

# Certification Module in Quality Management of a Fertility Service



## Introduction

This training programme aims to prepare individuals for the challenges faced in managing a fertility service whether large or small. The scope of duties of the professional working within a fertility unit has widened considerably with the rapid development of assisted reproduction and the changing environment in which it is practised. This programme also assists those aspiring to the position of Person Responsible in establishing a level of knowledge appropriate to this role.

## Who might benefit from this course?

- A scientist, registered with the Health Professions Council, and relevant working experience in the field of assisted conception
- A nurse registered with the NMC and relevant working experience in the field of assisted conception
- A clinician registered with the General Medical Council and with the certificate of completion of training in obstetrics and gynaecology in the UK or equivalent certification from the EEC and relevant working experience in an assisted conception service
- Managers who have responsibility for managing fertility services

## Training programme components

This module is designed to assist those aspiring to the position of PR in establishing a level of knowledge appropriate to this role. The following are essential components of the training course, and all of them have to be completed:

- Trainees should be a member of, and register with the British Fertility Society prior to commencement of training
- A named trainer must sign an educational contract confirming that he / she is able and willing to provide the training contained in the course
- The trainer must be a PR (**licensed by the Human Fertilisation and Embryology Authority**). The trainer will agree to supervise the trainee throughout the course. Some elements of the training will be conducted either as self directed learning or under the supervision of professionals other than the trainer
- It is the responsibility of the trainer to ensure that all elements of the training are satisfactorily completed and that other supervisors are sufficiently competent, willing and able to teach the trainee
- The trainee must spend at least two sessions (1 working day) per week in a licensed assisted conception unit
- The trainee will, during the course of this training, complete and submit together with the log of theoretical knowledge, a project of completed audit / risk management or adverse event analysis
- The trainee must attend the BFS study day “**Effective Fertility Services**” within 12 months of the application for certification of training
- Training will be deemed to be complete when all the components have been undertaken to the satisfaction of the trainer. It is anticipated that training would be completed within 18 months (or equivalent) from the date of registration
- Trainees must submit payment of £120 upon application for this training module

## The logbook (guide to learning)

This logbook defines the skills required for the prospective PR. Completion of the logbook will allow the trainer and trainee to monitor progress and identify deficiencies over the course of training. It is important to note that the logbook is a record of **learning and achievement**. The trainer and trainee will review the progress of training at monthly intervals. Competency is difficult to assess as the areas of knowledge are theoretical and not practical skills therefore the trainer is acknowledging recognition of acquired knowledge rather than competence. Progress will be documented through the trainer signing off the appropriate sections of the logbook when knowledge has been acquired.

## Application for training centre recognition and trainer's contract

To be eligible as a training centre the following criteria must be met:

- The centre should have a current HFEA license
- The centre is approved by the British Fertility Society Training Subcommittee – for application form click [here](#)  
[Link to centre application](#)

The trainee should identify a **Trainer** before registering for training. The purpose of the trainer is to:

- Provide mentorship to the trainee in the role of PR
- To provide advice to the trainee on access to learning resources
- To ensure all elements of the training are completed and to provide verification of this
- To ensure that named supervisors undertaking delegated training are appropriate for the purpose
- To review the trainee's audit / risk management project
- To provide a letter of support to the British Fertility Society Training Subcommittee on the trainee upon completion of the training

Trainers must:

- Be a member of the British Fertility Society
- Agree to supervise the trainee throughout the course
- Sign an educational contract confirming that he / she is able and willing to provide the training contained in the course

Trainers may be working in a centre different to that of the trainee. It is envisaged that the trainee will meet formally with the trainer on a monthly basis during the course of the training.

[Link to trainer application](#)

## Audit / risk management project

The trainee will be expected to complete a project within their work place during the course of their training. This project should be in an area relevant to the course. Examples include:

- Audit project which may be clinical, laboratory based or internal control

- Risk management project such as undertaking a risk assessment and implementation of control measures
- Health and Safety – which may for example be a study of health and safety risks and compliance with preventative measures
- A detailed root cause analysis of a series of adverse events

This project should describe in detail the rationale, methodology, results, outcome and recommendations. The trainer should assess the completed project and submit a copy with the logbook.

**It is imperative that all participants appreciate that progress has to meet standards that satisfy the trainer and the current national, regulatory and professional standards. At the end of the training course, the trainer has to certify that the skills / knowledge attained by the trainee are to his / her satisfaction.**

## Syllabus

This module should provide the trainee with an **understanding** of:

- The roles and responsibilities of the PR
- The legal status of the PR
- Core knowledge required of the PR
- A general understanding of the clinical and laboratory processes involved in the investigation and treatment of the infertile couple
- The principles of storage of embryos and gametes
- Human resources including recruitment, appraisal and disciplinary processes
- Complaints handling and management
- Health and Safety policies and its organization and practice in the workplace
- Data collection, handling and reporting
- Record keeping
- Consent
- Information
- Risk management in the infertility setting (both clinical and laboratory)
- Preparing for inspection by the Human Fertilisation and Human Authority
- Quality systems and management

## References

All references provided are in “**E**” format (which can be found at the end of these notes) and provide a comprehensive resource to support this syllabus. Two key resources referenced in the Guide to Learning section are essential reading:

HFEA Code of Practice 7th Edition

<http://cop.hfea.gov.uk/cop>

NICE Infertility Guideline produced by the National Collaborating Centre for Women’s Health, RCOG, 2004 (full guideline large 1.2MB file)

[http://www.rcog.org.uk/resources/Public/pdf/Fertility\\_full.pdf](http://www.rcog.org.uk/resources/Public/pdf/Fertility_full.pdf)

## Guide to learning

The trainee should sign and date when they consider that the knowledge targets of the guide have been achieved (clear boxes).

When each section is completed the shaded box should be signed and dated by the trainer.

### Appraisal, Assessment and Certification

1. For the trainee the following process should be followed:
  - a. **Appraisal** should be carried out at regular intervals (at least every month) by the **registered trainer**. The trainee meets with the trainer to discuss progress of their training relevant to acquisition of the necessary elements of knowledge as laid out in the syllabus. If there are problems in relation to targets for completion of training then remedial action should be instituted. Appropriate records should be kept of these meetings, which both the trainer and trainee should sign.
  - b. When training is complete the trainee is required to submit the following to the BFS for scrutiny:
    - the Audit / Risk Management project
    - the BFS QMFS study day certificate of attendance
    - the records of appraisal
    - the notification of completion of training form
    - the completed guide to learning
2. **A Certificate of Completion of Training** will be issued, according to the above criteria, signed by the Chair of the BFS Training Subcommittee.

## 1. Roles and responsibilities of the PR

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The trainee should understand the roles and responsibilities as set out in the Human Fertilisation and Embryology Act (1990) and be able to:

Discuss the Human Fertilisation and Embryology Act (1990), its origins and the main themes

Date:

Detail the responsibilities of the PR as it is specified in the 1990 Act and subsequent revisions

Date:

Be able to discuss the legal implications of the role of PR

Date:

Discuss the purpose, themes and legal status of the HFEA Code of Practice

Date:

**Section completed**

Date:

## 2. The principles and practice of infertility treatment

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The trainee should understand the clinical and laboratory processes involved in the investigation and treatment of the infertile couple to include and be able to:

Understand and be aware of the requirements in the initial assessment of the infertile couple

Date:

Understand and be able to discuss male factor, disorders of ovulation, tubal factors, endometriosis and unexplained infertility

Date:

Discuss the possible treatments of infertility including ovulation induction, intrauterine insemination, IVF and ICSI and the use of donor gametes

Date:

Discuss patient selection for IVF, controlled ovarian stimulation, oocyte retrieval and role of ultrasound skills, embryo transfer and outcome of treatments

Date:

Discuss gamete and embryo donation in relation to patient selection, counselling, donor selection, screening, surrogacy and legal aspects

Date:

Discuss how current legislation relates to these processes

Date:

Discuss the principles of evidence based medicine and demonstrate ability to critically appraise the literature

Date:
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**Section completed**

Date:
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### 3. The principles of storage of embryos and gametes including

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The trainee should understand the principles of gamete and embryo storage and the clinical and laboratory processes involved in these processes and be able to:

Discuss the cryobiology of gametes and embryos and the determinants of a successful cryopreservation programme

Date:
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Discuss the processes involved in the use of stored tissue including consent, labeling, witnessing, identification and treatment

Date:
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Discuss the potential risks involved in storage of tissue such as tank failure, human error and the potential for transmission of viral particles

Date:
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Discuss the health and safety issues of storing and handling liquid nitrogen. The trainee should have a working knowledge of characteristics of Liquid N2

Date:
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Discuss the risk management of gamete and embryo storage including the prevention of viral contamination, alarm systems and prevention of loss of material

Date:
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**Section completed**

Date:
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### 4. Human resources

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The trainee should have an understanding of good practice in Human Resources and the law as it applies to this area and should be able to:

Discuss in very broad terms the principles of employment law

Date:
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Understand the current concepts of Employment legislation

Date:
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Understand the principles of good recruitment practice

Date:

Understand enquiries that are made to establish whether a prospective employee has a criminal record including application to the CRB

Date:

Understand the appropriate levels of staff and their skill mix necessary to manage the planned workload and the basis for succession planning in key service areas

Date:

Discuss the principles and practice of employee appraisal and performance review

Date:

Understand the concept of CPD (Continuous Professional Development) and how this should be implemented and monitored

Date:

Discuss the disciplinary process including incidents that may invoke this, the investigatory process, employee rights in this respect and the duties of employers

Date:

Understand the principles of employment practice as they relate to the use of temporary staff to support service during unplanned staff absence

Date:

**Section complete**

Date:

## 5. Complaints management

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The trainee should have a comprehensive understanding of complaint management and should be able to:

Understand the principles of good practice in complaints management. Discuss how a patient can complain about the services they receive and what the responsibilities of the service provider are

Date:

Discuss the complaints regulations and policy in your unit

Date:

**Section completed**

Date:

## 6. Health and Safety in the workplace to include

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The trainee should have a comprehensive understanding of Health and Safety in the workplace including the related legislation and be able to:

Discuss in broad terms legislation as it relates to Health and Safety at work. This should include an understanding of the responsibilities of the employer for ensuring that the workplace is safe for the employees

Date:

Discuss how the Risk Management strategy might incorporate policies for the management of Health and Safety in the workplace

Date:

Discuss in broad terms the principles of the Control of Substances Hazardous to Health (COSHH) regulations

Date:

Discuss in detail the safe handling of liquid nitrogen

Date:

Discuss in detail the prevention of transmission of human virus infection from biological material

Date:

Be aware and discuss the annual statutory staff training requirements

Date:

**Section completed**

Date:

## 7. Data collection, handling, storage and presentation of outcomes

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The trainee should have a comprehensive understanding of the requirements for data collection and reporting including the legislation that relates to data and be able to:

Discuss the principles of the Data Protection Act and how these would be addressed in an Assisted Conception Service

Date:

Discuss the requirements for data collection and the purposes for which this data is used

Date:

Discuss the principles of appropriate presentation of outcome data of an assisted conception service

Date:

Discuss the development and implementation of a security policy for the handling and storage of data and the obligations under the HFEA for access to data about licensed treatments

Date:

Discuss the principles of electronic data interchange

Date:
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Discuss the principles of probity in advertising of services and the production of promotional material

Date:
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**Section completed**

Date:
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## **8. Record keeping**

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The trainee should have a comprehensive understanding of good practice in medical and laboratory record keeping and be able to:

Discuss the current General Medical Council / Nursing and Midwifery Council / Department of Health guidance on record keeping

Date:
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Discuss the requirements in the HFEA Code of Practice on record keeping

Date:
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Discuss the principles and practice of patient confidentiality

Date:
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Discuss the principles of patient access to information and the Freedom of Information Act

Date:
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Discuss the principles of security in relation to the storage of medical records

Date:
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**Section completed**

Date:
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## **9. Consent**

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The trainee should have a comprehensive understanding of good practice in obtaining and documenting consent to medical treatment and be able to:

Discuss the principles of informed consent and legislation that relate to this

Date:
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Discuss current Department of Health guidance on

Date:
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obtaining and documenting consent

Discuss the consent required for treatments licensed under the terms of the Human Fertilisation and Embryology Act (1990)

Date:
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**Section Completed**

Date:
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## 10. Patient information and promotional material

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The trainee should have a comprehensive understanding of good practice in the production of patient information and be able to:

Discuss good practice in the production of patient information

Date:
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Discuss what information an assisted conception service is expected to provide

Date:
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Discuss the standards governing standards of advertising in clinical practice

Date:
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**Section completed**

## 11. Risk management, audit, adverse event reporting and clinical governance in the infertility setting

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The trainee should have a comprehensive understanding of risk management and clinical governance in the infertility / assisted conception setting. This should include both clinical and laboratory risk and should be able to:

Discuss the principles of how to reduce risk

Date:
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Discuss how clinical governance in the assisted conception service interacts with the corporate or institutional governance structures

Date:
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Discuss the audit cycle and illustrate this with examples in the assisted conception setting

Date:
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Discuss the principles of internal audit in the context of a quality management system

Date:
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Discuss the principles of risk assessment / management including how to establish a risk register

Date:
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Discuss adverse event reporting and the principles of managing a serious adverse event including the requirements of reporting AE's to the HFEA

Date:
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Discuss the principles and components of clinical governance

Date:
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**Section completed**

Date:
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## 12. Preparing for inspection

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The trainee should have a comprehensive understanding of what an inspection visit entails and should be able to:

Understand the purpose of the inspection

Date:
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Understand the format of the inspection visit and the construction of the inspection team

Date:
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Understand the current information required by the HFEA and the Health Care Commission (HCC) ahead of an inspection

Date:
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Discuss how to prepare the team for an inspection and how best to conduct an inspection

Date:
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Discuss the key areas of activity that the inspection team will focus on

Date:
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Discuss how to handle an unannounced HFEA inspection

Date:
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**Section completed**

Date:
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### 13. Quality management systems

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The trainee should have a comprehensive understanding of quality management systems and should be able to:

Discuss the principles of quality management

Date:

Discuss the components required in a quality management system

Date:

Discuss the principles of the implementation of a quality management system

Date:

Discuss the role of the Quality Manager

Date:

Estates management; equipment maintenance and security

Date:

Third party agreements

Date:

**Section completed**

Date:

### 14. Managing resources

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The trainee should have a comprehensive understanding of how to manage resources should be able to:

Discuss how patient treatment is funded

Date:

Discuss the steps involved in setting up a business case

Date:

Demonstrate and understanding of financial governance and budgets

Date:

**Section completed**

Date:

# Record of Appraisal

Date	Trainee signature	Trainer signature
<b>Learning targets achieved</b>		
<b>Targets for next month</b>		
Date	Trainee signature	Trainer signature

<b>Learning targets achieved</b>		
<b>Targets for next month</b>		

<b>Date</b>	<b>Trainee signature</b>	<b>Trainer signature</b>
<b>Learning targets achieved</b>		
<b>Targets for next month</b>		

<b>Date</b>	<b>Trainee signature</b>	<b>Trainer signature</b>
<b>Learning targets achieved</b>		
<b>Targets for next month</b>		



Please return completed forms to:  
British Fertility Society Secretariat

Euro House, 22 Apex Court, Woodlands  
Bradley Stoke, Bristol, BS32 4JT, UK  
Tel: +44 (0) 1454 642217  
Fax: +44 (0) 1454 642222  
Email: bfs@bioscientifica.com  
Website: www.fertility.org.uk

# British Fertility Society

## Application to undertake a certification module Quality Management of a Fertility Service

Name .....

Email Address .....

Day-time Phone Number .....

Current Post .....

Qualifications .....

Date of Application .....

Name of approved Training Centre .....

Name of Trainer(s) .....

**Entry Criteria:** *(Please tick the box/s provided)*

Registered Nurse	<input type="checkbox"/>
Medical Practitioner	<input type="checkbox"/>
Scientist	<input type="checkbox"/>
Health Service Manager	<input type="checkbox"/>

<b>Course payment:</b>	Credit Card	<input type="checkbox"/>
	Card no: _____	
	Expiry Date: _____	
	Security No: _____	
	<i>(Last three digits on back of card)</i>	
	Cheque	<input type="checkbox"/>
	<i>(Please make payable to BFS)</i>	

BFS Number .....

Signed .....

Dated .....



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Tel: +44 (0) 1454 642217  
Fax: +44 (0) 1454 642222  
Email: bfs@bioscientifica.com  
Website: www.fertility.org.uk

**Letter of Support from the Trainer for the Applicant**

Name of Trainee .....

Name of Trainer .....

Name of Training Centre .....

**Name of certification module**

Quality Management of a Fertility Service <span style="float: right;"><input type="checkbox"/></span>
Please be aware that there is a £120 charge per course.

**I confirm: (please tick each box)**

That the facilities are available for training in Quality Management of a Fertility Service	
That the trainee has been allocated time for training ( <i>suggested 8 hrs per week over a six month period</i> )	
That I will carry out regular monthly appraisals.	
That I will supervise the trainee.	

**I have read and agreed to follow the [‘Expectations of the Trainer’](#) document**

Signed..... Date.....



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Fax: +44 (0) 1454 642222  
Email: [bfs@bioscientifica.com](mailto:bfs@bioscientifica.com)  
Website: [www.fertility.org.uk](http://www.fertility.org.uk)

## Application for becoming a Trainer

I wish to apply to be a trainer for the following module:

Quality Management of a Fertility Service	<input type="checkbox"/>
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Name of trainer	
Centre	
Post	
Description of relevant duties and responsibilities	
Contact details	E-mail: Daytime phone number:
BFS membership number	If not known, please contact us at the above address

I have read and agreed to follow the ['Expectations of the Trainer'](#) document

Attached is a copy of the HFEA licence

Signed .....

Dated .....



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Email: bfs@bioscientifica.com  
Website: www.fertility.org.uk

## Notification of Completion of Certification Module

(To be completed by trainer)

I certify that

.....

has completed the certification module in Quality Management of a Fertility Service to my satisfaction.  
I confirm that I have had regular assessment sessions with the trainee  
and each of the required skills in the logbook has been attained.

Date of commencement of practical training: \_\_ \_\_/\_\_ \_\_/\_\_ \_\_

Date satisfactorily completed theoretical course: \_\_ \_\_/\_\_ \_\_/\_\_ \_\_

Trainee name: .....

Trainee signature: .....

Date: .....

Trainer(s) in charge of training:

1. **Trainer name:** .....

**Date:** .....

**Trainer signature:** .....

**Department address:** .....

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.....  
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## **E Reference** (as at July 2008)

### **1. Roles and responsibilities of the Person Responsible**

HFEA Code of Practice 7<sup>th</sup> Edition

<http://cop.hfea.gov.uk/cop/>

Human Fertilisation and Embryology Act

[http://www.opsi.gov.uk/acts/acts1990/Ukpga\\_19900037\\_en\\_1.htm](http://www.opsi.gov.uk/acts/acts1990/Ukpga_19900037_en_1.htm)

### **2. The principles and practice of infertility treatment**

NICE Infertility Guideline produced by the National Collaborating Centre for Women's Health, RCOG, 2004 (full guideline large 1.2MB file)

[http://www.rcog.org.uk/resources/Public/pdf/Fertility\\_full.pdf](http://www.rcog.org.uk/resources/Public/pdf/Fertility_full.pdf)

Summary of NICE Guideline, 2004

[http://www.rcog.org.uk/resources/Public/pdf/Fertility\\_summary.pdf](http://www.rcog.org.uk/resources/Public/pdf/Fertility_summary.pdf)

HFEA Code of Practice 7<sup>th</sup> Edition

<http://cop.hfea.gov.uk/cop/>

IBFS/RCOG Management of the Infertile couple and Assisted Conception courses.

[http://www.rcog.org.uk/resources/public/pdf/RCOG\\_Infertile\\_couple.pdf](http://www.rcog.org.uk/resources/public/pdf/RCOG_Infertile_couple.pdf)

[http://www.rcog.org.uk/resources/public/pdf/RCOG\\_Assisted\\_Reproduction.pdf](http://www.rcog.org.uk/resources/public/pdf/RCOG_Assisted_Reproduction.pdf)

### **3. The principles of storage of embryos and gametes including**

HFEA Code of Practice 7<sup>th</sup> Edition

<http://cop.hfea.gov.uk/cop/>

Human Tissue Authority, Code of Practice

[http://www.hta.gov.uk/guidance/codes\\_of\\_practice.cfm](http://www.hta.gov.uk/guidance/codes_of_practice.cfm)

### **4. Human Resources**

Employment Act summary

<http://www.berr.gov.uk/employment/employment-legislation/employment-act-2002/index.html>

Employment Act 2002

[http://www.opsi.gov.uk/acts/acts2002/pdf/ukpga\\_20020022\\_en.pdf](http://www.opsi.gov.uk/acts/acts2002/pdf/ukpga_20020022_en.pdf)

Maintaining high professional standards in the NHS

<http://www.dh.gov.uk/assetRoot/04/10/33/44/04103344.pdf>

Nursing and Midwifery Council Code of Professional Conduct

<http://www.nmc-uk.org/aFramedisplay.aspx?documentID=201>

Code of conduct for NHS Managers

<http://www.dh.gov.uk/assetRoot/04/08/59/04/04085904.pdf>

Knowledge and skills framework

<http://www.dh.gov.uk/assetRoot/04/09/08/61/04090861.pdf>

Appraisal of senior medical staff - guidance

<http://www.dh.gov.uk/assetRoot/04/01/46/07/04014607.pdf>

Criminal Records Bureau

<http://www.crb.gov.uk/>

Criminal Records Bureau Check

[http://www.crb.gov.uk/PDF/CRB\\_DIP017-Applicants-Guide-to-the-CRB's-Disclosure-Service\\_Eng.pdf](http://www.crb.gov.uk/PDF/CRB_DIP017-Applicants-Guide-to-the-CRB's-Disclosure-Service_Eng.pdf)

### **5. Complaints management**

NHS Complaints Policy

<http://www.dh.gov.uk/PolicyAndGuidance/OrganisationPolicy/ComplaintsPolicy/fs/en>

Handling complaints in the NHS – a toolkit for optimum local resolution

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/Browsable/DH\\_4108465](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/Browsable/DH_4108465)

NHS Complaints Regulation

<http://www.opsi.gov.uk/si/si2004/20041768.htm>

NHS Complaints Regulation Amendment (2006)

<http://www.opsi.gov.uk/si/si2006/20062084.htm>

Independent Complaints Advocacy Service

[http://www.dh.gov.uk/PolicyAndGuidance/OrganisationPolicy/ComplaintsPolicy/NHSComplaintsProcedure/NHSComplaintsProcedureArticle/fs/en?CONTENT\\_ID=4127482&chk=/Upod%2B](http://www.dh.gov.uk/PolicyAndGuidance/OrganisationPolicy/ComplaintsPolicy/NHSComplaintsProcedure/NHSComplaintsProcedureArticle/fs/en?CONTENT_ID=4127482&chk=/Upod%2B)

Healthcare Commission Home Page

<http://www.healthcarecommission.org.uk>

Independent complaints and advocacy service

[http://www.dh.gov.uk/PolicyAndGuidance/OrganisationPolicy/ComplaintsPolicy/NHSComplaintsProcedure/NHSComplaintsProcedureArticle/fs/en?CONTENT\\_ID=4127482&chk=/Upod%2B](http://www.dh.gov.uk/PolicyAndGuidance/OrganisationPolicy/ComplaintsPolicy/NHSComplaintsProcedure/NHSComplaintsProcedureArticle/fs/en?CONTENT_ID=4127482&chk=/Upod%2B)

How to make a complaint about the NHS – patient information

<http://www.dh.gov.uk/assetRoot/04/02/00/39/04020039.pdf>

## 6. Health and Safety in the workplace to include

Health and Safety Law – what you should know

<http://www.hse.gov.uk/pubns/law.pdf>

Health and Safety Executive Home page

<http://www.hse.gov.uk/>

Free publications on health and safety

<http://www.hsebooks.com/Books/category.asp?catalog%5Fname=HSEBooks&category%5Fname=Home%3A%3AFree+Leaflets&Page=1>

A Brief guide to the Control of Substances Hazardous to Health regulations (2002)

<http://www.coshh-essentials.org.uk/assets/live/indg136.pdf>

Management of health and safety at work regulations

<http://www.opsi.gov.uk/si/si1999/19993242.htm>

## 7. Data collection, handling, storage and presentation of outcomes

Data Protection Act

[http://www.opsi.gov.uk/acts/acts1998/ukpga\\_19980029\\_en\\_1](http://www.opsi.gov.uk/acts/acts1998/ukpga_19980029_en_1)

NHS Guidance on Data Protection Act

[http://www.dh.gov.uk/PolicyAndGuidance/OrganisationPolicy/RecordsManagement/DataProtectionAct1998Article/fs/en?CONTENT\\_ID=400489&chk=VrXoGe](http://www.dh.gov.uk/PolicyAndGuidance/OrganisationPolicy/RecordsManagement/DataProtectionAct1998Article/fs/en?CONTENT_ID=400489&chk=VrXoGe)

Caldicott Recommendations

<http://www.dh.gov.uk/assetRoot/04/06/84/04/04068404.pdf>

Department of Health Information Policy

<http://www.dh.gov.uk/PolicyAndGuidance/InformationPolicy/fs/en>

Advertising Standards Authority

[http://www.asa.org.uk/NR/rdonlyres/A44808F1-1573-482A-A0E5-D8045943DA57/0/The\\_CAP\\_Code\\_Ed11\\_20061205.pdf](http://www.asa.org.uk/NR/rdonlyres/A44808F1-1573-482A-A0E5-D8045943DA57/0/The_CAP_Code_Ed11_20061205.pdf)

General Medical Council

[http://www.gmc-uk.org/guidance/good\\_medical\\_practice/probity/information\\_about\\_services.asp](http://www.gmc-uk.org/guidance/good_medical_practice/probity/information_about_services.asp)

## 8. Record keeping

Caldicott Report

<http://www.dh.gov.uk/assetRoot/04/06/84/04/04068404.pdf>

<http://www.dh.gov.uk/PolicyAndGuidance/InformationPolicy/PatientConfidentialityAndCaldicottGuardians/fs/en>

Guidance to access to health records

<http://www.dh.gov.uk/assetRoot/04/03/51/94/04035194.pdf>

Freedom of Information Act

[http://www.ico.gov.uk/Home/what\\_we\\_cover/freedom\\_of\\_information.aspx](http://www.ico.gov.uk/Home/what_we_cover/freedom_of_information.aspx)

[http://www.dh.gov.uk/PolicyAndGuidance/FreedomOfInformation/FreedomOfInformationArticle/fs/en?CONTENT\\_ID=4102350&chk=zvZOHL](http://www.dh.gov.uk/PolicyAndGuidance/FreedomOfInformation/FreedomOfInformationArticle/fs/en?CONTENT_ID=4102350&chk=zvZOHL)

<http://www.foi.gov.uk/>

Access to Health Records Act

[http://www.opsi.gov.uk/acts/acts1990/ukpga\\_19900023\\_en\\_1.htm](http://www.opsi.gov.uk/acts/acts1990/ukpga_19900023_en_1.htm)

General Medical Council Guidance

[http://www.gmc-uk.org/guidance/good\\_medical\\_practice/index.asp#Good%20clinical%20care](http://www.gmc-uk.org/guidance/good_medical_practice/index.asp#Good%20clinical%20care)

BMA Guidance

<http://www.bma.org.uk/ap.nsf/Content/accessmedreps> (requires password)

Records Management

<http://www.dh.gov.uk/assetRoot/04/13/31/96/04133196.pdf>

<http://www.dh.gov.uk/assetRoot/04/13/31/97/04133197.pdf>

Nursing and Midwifery Council – guidance on record keeping

<http://www.nmc-uk.org/aFrameDisplay.aspx?DocumentID=4008>

## 9. Consent

DoH Reference guide for consent for examination and treatment

<http://www.dh.gov.uk/assetRoot/04/01/90/79/04019079.pdf>

DoH Good Practice in Consent Implementation Guide

<http://www.dh.gov.uk/assetRoot/04/01/90/61/04019061.pdf>

Guide for patients

<http://www.dh.gov.uk/assetRoot/04/06/69/93/04066993.pdf>

Model consent form (NHS)

<http://www.dh.gov.uk/assetRoot/04/07/46/55/04074655.rtf>

Key points on English Consent Law

[http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/documents/digitalasset/dh\\_075159.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_075159.pdf)

General Medical Council

[http://www.gmc-uk.org/guidance/good\\_medical\\_practice/relationships\\_with\\_patients/consent.asp](http://www.gmc-uk.org/guidance/good_medical_practice/relationships_with_patients/consent.asp)

<http://www.gmc-uk.org/guidance/current/library/consent.asp>

Nursing and Midwifery Council

<http://www.nmc-uk.org/aFrameDisplay.aspx?DocumentID=3983>

## 10. Patient Information and promotional material

Patient information advisory group annual report 2005 summary

<http://www.dh.gov.uk/assetRoot/04/13/08/39/04130839.pdf>

Good practice example of patient information sheet – produced by the DoH

<http://www.dh.gov.uk/assetRoot/04/12/12/55/04121255.rtf>

DoH Toolkit for producing patient information

<http://www.dh.gov.uk/assetRoot/04/06/84/62/04068462.pdf>

Advertising Standards Authority

<http://www.asa.org.uk/>

[http://www.asa.org.uk/NR/rdonlyres/A44808F1-1573-482A-A0E5-D8045943DA57/0/The\\_CAP\\_Code\\_Ed11\\_20061205.pdf](http://www.asa.org.uk/NR/rdonlyres/A44808F1-1573-482A-A0E5-D8045943DA57/0/The_CAP_Code_Ed11_20061205.pdf)

General Medical Council – Good Medical Practice Guide

[http://www.gmc-uk.org/guidance/good\\_medical\\_practice/GMC\\_GMP.pdf](http://www.gmc-uk.org/guidance/good_medical_practice/GMC_GMP.pdf)

[http://www.gmc-uk.org/guidance/good\\_medical\\_practice/probity/information\\_about\\_services.asp](http://www.gmc-uk.org/guidance/good_medical_practice/probity/information_about_services.asp)

HFEA Code of Practice 7<sup>th</sup> Edition

<http://cop.hfea.gov.uk/cop/>

## 11. Risk management, audit, adverse event reporting and clinical governance in the infertility setting

A first class service: quality in the new NHS

[http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT\\_ID=4006902&chk=i2Tt7C](http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4006902&chk=i2Tt7C)

Clinical Governance in the new NHS

<http://www.dh.gov.uk/assetRoot/04/01/20/43/04012043.pdf>

An organisation with a memory

<http://www.dh.gov.uk/assetRoot/04/06/50/86/04065086.pdf>

Creating a patient led NHS – delivery of the NHS improvement plan

<http://www.dh.gov.uk/assetRoot/04/10/65/07/04106507.pdf>

Clinical Governance Reporting Processes

<http://www.dh.gov.uk/assetRoot/04/05/95/03/04059503.pdf>

Toft Report into serious adverse event in assisted conception

<http://www.dh.gov.uk/assetRoot/04/08/43/58/04084358.pdf>

National Patient Safety Agency

<http://www.npsa.nhs.uk/>

A practical handbook for clinical audit

[http://www.cgsupport.nhs.uk/downloads/Practical\\_Clinical\\_Audit\\_Handbook\\_v1\\_1.pdf](http://www.cgsupport.nhs.uk/downloads/Practical_Clinical_Audit_Handbook_v1_1.pdf)

Clinical Governance Defined – original article

<http://www.bmj.com/cgi/content/full/317/7150/61>

NHS Clinical Governance Support Unit

<http://www.cgsupport.nhs.uk/default.asp>

## 12. Preparing for inspection

HFEA Code of Practice 7<sup>th</sup> Edition

<http://cop.hfea.gov.uk/cop/>

HFEA Preparing for Inspection

[http://www.hfea.gov.uk/cps/rde/xbcr/SID-3F57D79B-2C6E2F0F/hfea/Are\\_you\\_ready\\_for\\_Inspection\\_-\\_Standard\\_Document\\_DK.DOC](http://www.hfea.gov.uk/cps/rde/xbcr/SID-3F57D79B-2C6E2F0F/hfea/Are_you_ready_for_Inspection_-_Standard_Document_DK.DOC)

HFEA Pre inspection questionnaire

HFEA Inspection Reports

<http://www.hfea.gov.uk/en/344.html>

Healthcare Commission

<http://www.healthcarecommission.org.uk/homepage.cfm>

[http://www.healthcarecommission.org.uk/db/documents/Submission\\_and\\_use\\_of\\_performance\\_indicators.pdf](http://www.healthcarecommission.org.uk/db/documents/Submission_and_use_of_performance_indicators.pdf)

[http://www.healthcarecommission.org.uk/db/documents/5\\_Self\\_assessment\\_In\\_vitro\\_fertilisation.doc](http://www.healthcarecommission.org.uk/db/documents/5_Self_assessment_In_vitro_fertilisation.doc)

[http://www.healthcarecommission.org.uk/db/documents/9\\_Self\\_assessment\\_Private\\_doctors\\_and\\_independent\\_medical\\_agencies.doc](http://www.healthcarecommission.org.uk/db/documents/9_Self_assessment_Private_doctors_and_independent_medical_agencies.doc)

## 13. Quality management systems

Quality Management Principles

<http://www.iso.org/iso/en/iso9000-14000/understand/qmp.html>

ISO 9000 Series Standards – the basics

[http://www.iso.org/iso/iso\\_catalogue/management\\_standards/iso\\_9000\\_iso\\_14000/iso\\_9000\\_essentials.htm](http://www.iso.org/iso/iso_catalogue/management_standards/iso_9000_iso_14000/iso_9000_essentials.htm)

EU Tissue Directive

<http://www.hfea.gov.uk/en/493.html>

EU first technical directive

[http://www.hfea.gov.uk/docs/First\\_Technical\\_Directive.pdf](http://www.hfea.gov.uk/docs/First_Technical_Directive.pdf)

## **14. Resource mangement**

NHS Payment by results

<http://www.dh.gov.uk/en/Managingyourorganisation/Financeandplanning/NHSFinancialReforms/index.htm>

NHS Financial governance

<http://www.dh.gov.uk/en/Managingyourorganisation/Leadershipandmanagement/Governance/index.htm>