Certification Module in Quality Management of a Fertility Service

British Fertility Society

Published for the British Fertility Society

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 approved BFS Study Week theoretical course on **PR Effective Fertility Services** within 18 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 6-12 months (or equivalent) from the date of registration
- Trainees must submit payment of £150

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

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.

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

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 PR Effective Fertility Services study day certificate of attendance
    - the records of appraisal
    - the notification of completion of training form
    - the completed guide to learning
    - the online Trainee Feedback form

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

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

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:
Section completed	Date:

3. The principles of storage of embryos and gametes including

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:
Discuss the processes involved in the use of stored tissue including consent, labeling, witnessing, identification and treatment	Date:
Discuss the potential risks involved in storage of tissue such as tank failure, human error and the potential for transmission of viral particles	Date:
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:
Discuss the risk management of gamete and embryo storage including the prevention of viral contamination, alarm systems and prevention of loss of material	Date:
Section completed	Date:

4. Human resources

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:
Understand the current concepts of Employment legislation	Date:

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

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

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

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

8. Record keeping

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:
Discuss the requirements in the HFEA Code of Practice on record keeping	Date:
Discuss the principles and practice of patient confidentiality	Date:
Discuss the principles of patient access to information and the Freedom of Information Act	Date:
Discuss the principles of security in relation to the storage of medical records	Date:
Section completed	Date:

9. Consent

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:
Discuss current Department of Health guidance on	Date:

obtaining and documenting consent

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

10. Patient information and promotional material

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:
Discuss what information an assisted conception service is expected to provide	Date:
Discuss the standards governing standards of advertising in clinical practice	Date:
Section completed	Date:

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

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:
Discuss how clinical governance in the assisted conception service interacts with the corporate or institutional governance structures	Date:
Discuss the audit cycle and illustrate this with examples in the assisted conception setting	Date:
Discuss the principles of internal audit in the context of a quality management system	Date:

Discuss the principles of risk assessment / management including how to establish a risk register	Date:
Discuss adverse event reporting and the principles of managing a serious adverse event including the requirements of reporting AE's to the HFEA	Date:
Discuss the principles and components of clinical governance	Date:
Section completed	Date:

12. Preparing for inspection

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:
Understand the format of the inspection visit and the construction of the inspection team	Date:
Understand the current information required by the HFEA and the Health Care Commission (HCC) ahead of an inspection	Date:
Discuss how to prepare the team for an inspection and how best to conduct an inspection	Date:
Discuss the key areas of activity that the inspection team will focus on	Date:
Discuss how to handle an unannounced HFEA inspection	Date:
Section completed	Date:

13. Quality management systems

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

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
Learning targets achieved		
Targets for next month		
Date	Trainee signature	Trainer signature

Learning targets achieved		
Targets for next month		

Date	Trainee signature	Trainer signature
Learning targets achieved		
Targets for next month		

Date	Trainee signature	Trainer signature
Learning targets achieved		
Targets for next month		

Please complete and return the form preferably by email to:
bfs@profileproductions.co.uk

Or post to: BFS Secretariat C/o Profile Productions Ltd
Boston House, 69-75 Boston Manor Road, Brentford, TW89JJ
t: +44 (0)20 3725 5849

British Fertility Society

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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CHECKLIST FOR SUBMISSION OF BFS QUALITY MANAGEMENT OF A FERTILITY SERVICE DOCUMENTS

The following materials are required to be submitted to the Training Subcommittee for their consideration:

- Certificate of attendance from the most recent BFS PR Effective Fertility Services Study Day
- Audit / Risk Management Project
- Completed Guide to Learning
- Completed Appraisal Record
- Signed Notification of Completion form
- Completed online Trainee Feedback form on Survey Monkey:

  https://www.surveymonkey.co.uk/r/YTQVCT6

Please do not submit your documentation until you have all elements listed above.

E Reference (as at July 2008)

1. Roles and responsibilities of the Person Responsible

HFEA Code of Practice 7th Edition
http://cop.hfea.gov.uk/cop/
Human Fertilisation and Embryology Act
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
Summary of NICE Guideline, 2004
http://www.rcog.org.uk/resources/Public/pdf/Fertility_summary.pdf
HFEA Code of Practice 7th 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_Assisted_Reproduction.pdf

3. The principles of storage of embryos and gametes including

HFEA Code of Practice 7th Edition
http://cop.hfea.gov.uk/cop/
Human Tissue Authority, Code of Practice
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
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

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
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
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
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
NHS Guidance on Data Protection Act
http://www.dh.gov.uk/PolicyAndGuidance/OrganisationPolicy/RecordsManagement/DataProtectionAct1998Article/fs/en?CONTENT_ID=4000489&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
General Medical Council
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.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
General Medical Council Guidance
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

General Medical Council
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
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/probity/information_about_services.asp
HFEA Code of Practice 7th 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=j2Tt7C
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
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 7th 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
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/5_Self_assessment_In_vitro_fertilisation.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

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

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