



Standards in the Care of the Infertile

BFS/RCOG Joint Document

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Introduction

The aims of the **British Fertility Society** are to promote high quality practice in the provision of fertility treatment, to provide a common forum for members of various disciplines having an interest in the science and treatment of infertility, to promote high quality scientific and clinical research in the causes and treatment of infertility, to provide professional leadership in the provision and regulation of infertility services, and to promote the increase of NHS funding for, and equity of access to, fertility treatments.

The **Royal College of Obstetrics and Gynaecology** (RCOG) directs and supports the training and educational framework and core curriculum for trainee specialists as well as setting standards, in collaboration with professional organisations including the British Fertility Society, for robust competence assessment of clinical practice in Obstetrics and Gynaecology.

The RCOG and the BFS are keen to establish recognised standards for care provision of patients with infertility problems. This joint document aims to establish a grounded structure for service delivery, competence, clinical performance and provision of education within the multidisciplinary fertility service setting. It is recognised that this will be an evolutionary process that will require continuous updating and revision as new standards and core service improvements appear.

CARE PROVISION CHARTER

All people with infertility problems should have prompt access to an integrated multidisciplinary service that provides efficient and accurate assessment of the clinical situation. This should lead to individualised management founded on evidence based principles of care. Care should be reinforced by access to adequate information and appropriate counselling services. At all times, the infertile should be treated with respect, and supported in making informed choices about their care and management.

Standards in the Care of the Infertile

Standard	Core	Aspirational
PRIMARY CARE		
Organisation of services	Local protocols based on current guidelines e.g. RCOG, NICE, Professional Societies, should be agreed for the management of the infertile in general practice, as well as referral to secondary care	Dedicated liaison staff in the local fertility clinic should be available to assist with the referral process and guideline dissemination.
Initial investigation	Progesterone monitoring, rubella assessment, Chlamydia screening and semen analysis should be performed in line with current guidelines before referral to fertility clinic	Semen analysis should be performed by same laboratory servicing the fertility clinic.
SECONDARY CARE		
Location of services	Assessment, investigation and treatment (including ovulation induction, fertility enhancing surgery, and assisted conception services) should only be carried out in centres where there are appropriate facilities and trained staff.	Managed clinical networks should be established throughout the country facilitating equity of access to services.
Availability of Service	5 day opening during office hours. Sat/Sun clinic cover to cater for those requiring weekend supervision.	24/7 access to information and advice. Evening & weekend clinics to cater for those with difficulties attending regular clinics
Access to infertility clinics	People with infertility problems should be seen within the same NHS waiting times as are standard for any other medical condition.	Direct referral systems from the GP to the fertility clinic should be established
Patient Information	Verbal and written information in a range of languages should be available to people attending with fertility problems. An underlying principle should be the universal use of clear, understandable terminology.	Clear information on all aspects of infertility and its management available in language of choice.
Written information leaflets	Patients must be sent appropriately worded invitation with a contact name, telephone number and clinic times. There should be visible open access to written information leaflets in a range of languages in fertility clinics	Online external access to patient information leaflets should be available.
Consultation room	Initial interview should be in private facilities and should allow for discussion with men and women together and separately as required.	Dedicated infertility clinic facilities and staff should be available.
Competence of clinical and nursing staff	Clinics should be led by staff who have undergone training in the general management of the infertile and who will usually have been certified by the BFS/RCOG/RCN as appropriate.	Multidisciplinary meeting at conclusion of every clinic. Consultant should see all patients at least on alternate clinic visits.

Initial investigation	Semen analysis should be undertaken according to recognised WHO methodology and in laboratories that practice internal quality control and belong to an external quality control scheme.	All fertility clinics should be serviced by a dedicated andrology laboratory.
Pelvic assessment	Waiting time, from the initial appointment, for surgical assessment of the pelvis should be within agreed national targets.	All patients should be seen within 8 weeks of referral.
Patient choice of management	All patients should receive education relevant to diagnosis and management with open explanation of expectant and interventional options including success rates and risks of treatment.	Dedicated phone line for patient queries and electronic access to protocols from outside unit
Support services	Counselling should be made available throughout all stages of infertility investigation and treatment and also after the treatment process is complete.	Counsellors should be part of the staff complement at all fertility centres.
Support services	People who experience fertility problems should be informed that they may find it helpful to contact a fertility support group.	Clinics should have established links with local, regional and national support groups.
Support services	Lifestyle modification advice should be available to the infertile with access to smoking cessation and weight reduction programmes (where BMI is $>30\text{kg/m}^2$).	Dietician and smoking cessation services should be available at all centres.
Ovulation induction	Protocols of treatment should minimise the risk of multiple pregnancy and ovarian hyperstimulation.	Multiple pregnancy rates after infertility treatment should be $<10\%$.
Ovulation induction	Treatment with gonadotrophins should only be carried out in circumstances which permit daily monitoring of ovarian response	A 7 day a week clinical and laboratory service should be available in all centres.
Unexplained infertility	Expectant management (no treatment) should be considered where the duration of infertility is less than 3 years, taking in to account the woman's age.	Empirical treatment should only be offered in the context of clinical trials.
Unexplained infertility	Intrauterine insemination treatment should be carried out in centres licensed by the HFEA.	Patients should not have to travel > 2 hours from home to access IUI services.
Endometriosis	Medical treatment of minimal and mild endometriosis does not enhance fertility in subfertile women	Both laparoscopic and open surgery for endometriosis should be available to patients.
Endometriosis	Medical treatment of moderate and severe endometriosis, either alone or as an adjunct to surgery does not enhance fertility.	Both laparoscopic and open surgery for endometriosis should be available to patients.

TERTIARY CARE		
Location of services	Tertiary level care, including gamete donation services and IVF, should only be provided in centres holding licences in accordance with the EU Tissues and Cells Directive (2004).	Patients should not have to travel > 2 hours from home to access tertiary level services.
Organisational and management responsibility	A designated responsible person should direct ART services	Fertility clinic team should meet at least twice annually to discuss clinic policy and guidelines
Quality Management	All processes and procedures within the centre should be documented, based on contemporary guidance on best practice, and undergo regular review.	A quality manager should be employed in tertiary centres.
Resource management	Key elements in personnel management (staffing numbers, job descriptions, initial and update training, competence assessment, CPD, personnel records, internal communication) should be in place.	Study leave allocations should be adequate for CPD needs of all staff.
Resource management	All equipment and materials should be subject to procurement, verification, validation and traceability procedures in accordance with the current regulatory standards.	Responsible person at centres should have adequate session allocation in timetable to fulfil regulatory duties.
Assisted conception processes	Should be carried out in accordance with regulatory standards and best practice guidelines.	Centres should organise an annual review of audits with all staff.
Gamete donation	The British Andrology Society Guidelines for the recruitment, screening and selection of donors should be followed.	Centres should have access on a regional basis to adequate supplies of donated semen to meet clinical needs.
Evaluation and improvement	Lead clinician should co-ordinate key performance indicator monitoring for care periodically as appropriate. This will include assessment of user satisfaction, monitoring and resolution of complaints, staff suggestions, internal audit, inter-centre comparisons and inter-laboratory quality assurance. In addition identification, investigation, control, recording and notification of serious adverse events and reactions should be discussed.	Centres should conduct an annual review of management effectiveness involving senior staff within the unit. The results of such a review should be disseminated to all staff.
Continuing Professional Development	Infertility specialists must have adequate workload and attend at least one BFS/RCOG recognised fertility meeting every 5 years.	Study leave allocations should be adequate for CPD needs of all staff.

Auditable Standards

The Infertility Service should benchmark all audited activity against published series and adopt all evidence based practice recommendations for diagnosis and management of infertility problems.

Examples (not exhaustive) of Key Performance Indicators against which audit could be performed:

AUDITS

Infertility clinic

Patient satisfaction surveys of Infertility Unit service e.g. information, waiting, staff courtesy, communication)

Waiting times to new appointment

Adherence to Chlamydia & rubella screening protocols

% patients with completed first line investigations at GP

Clomifene (anovulation) pregnancy rate

Gonadotrophin (anovulation) pregnancy rate

Ovulation induction multiple pregnancy rates

Andrology laboratory

Waiting time for routine semen analysis result

DNA's as % of appointments

Average % motile sperm recovery in IUI treatment preps.

Sperm survival rates after cryopreservation

Assisted Reproduction Treatment

% cycles initiated reaching egg recovery

Average %2PN for all patients per eggs inseminated in IVF

Average % cleavage of 2PN's per patient

Embryo cryopreservation rates

Survival rate of cryopreserved embryos

Clinical pregnancies per cycle initiated

Multiple pregnancies as % of total pregnancies

References and relevant websites

Fertility: assessment and treatment for people with fertility problems. *National Collaborating Centre for Women's and Children's Health for the National Institute of Clinical Excellence*; RCOG Press, London. 2004

Implementation of the NICE Guideline - Recommendations of the British Fertility Society for national criteria for NHS funding of assisted conception. R Kennedy, C Kingsland, A Rutherford, M Hamilton, W Ledger *Human Fertility* 9 181-9 (2006)

British Andrology Society guidelines for the screening of semen donors for donor insemination. British Andrology Society. *Human Reproduction* 14 1823-6 (1999)

One child at a time: reducing multiple births after IVF. Human Fertilisation and Embryology Authority: Report of the expert group. (2006)

HFEA standards for Assisted Conception Centres. *Human Fertilisation and Embryology Authority* (2006)

British Fertility Society (<http://www.fertility.org.uk/>)

Human Fertilisation and Embryology Authority (<http://www.hfea.gov.uk>)