Procedures For The Approval Of Independent Sector Places For The Termination Of Pregnancy

PROCEDURES FOR APPROVAL OF PRIVATE SECTOR PLACES FOR TERMINATION OF PREGNANCY UNDER THE ABORTION ACT 1967, AS AMENDED.

INTRODUCTION

1. **The Secretary of State for Health has a responsibility to approve private sector places for the purpose of treatment for termination of pregnancy. The Secretary of State also maintains a register of Pregnancy Advice Bureaux. Approved places may only accept patients referred from Bureaux on the register.**

2. **The Secretary of State will consider the approval of clinics or hospitals for the purposes of section 1(3) of the Abortion Act 1967 if proprietors undertake to comply with a set of Required Standard Operating Principles. Section 2 sets out these operating principles in detail. Proprietors seeking approval for the provision of late abortions will require separate approval. Principles related to the registration of Pregnancy Advice Bureaux will also require separate approval. A separate set of principles related to the registration of a Pregnancy Advice Bureau may be obtained from the address given below.**

3. **Once a clinic/hospital is approved, there will be regular unannounced inspections by departmental officers. The aim of inspections will be to assist proprietors in providing consistent standards of service. Inspectors will be available to provide advice and guidance on matters related to the conditions of the Abortion Act, the terms under which the premises are approved and standards of service.**

4. **Failure to comply with the Required Standard Operating Principles, or to maintain the standards required by the Secretary of State may lead to withdrawal of approval.**

5. **In approving and inspecting premises at which the termination of pregnancy may be conducted, the Department of Health has adopted the principles of the central and local government Concordat on Good Enforcement i.e.**

   - **performance will be measured against agreed standards;**
   - **there will be openness in dealing with business and others;**
   - **enforcers will be helpful, courteous and efficient;**
   - **complaints procedures will be publicised;**
   - **enforcement decisions will be taken in a proportionate manner; and**
   - **enforcement officers will strive for high standards of consistency.**

6. **A copy of the application form for the approval of clinics/hospitals may be obtained from the address given below. The Department will consider all applications. This process may include visits to the premises by its medical, nursing and administrative staff.**

7. **If you have any enquiries arising from this document, please contact:**

Sexual Health Team
Department of Health
Room 580d
Skipton House
80 London Road
London SE1 6LH **Telephone: 020 7972 26172/5002**

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Section 1 – Introduction

1. In July 1993, the Prime Minister announced an initiative to reduce burdens on business through the introduction of a code for enforcement agencies. This document contains the Department of Health's code of practice in respect of the regulation of places approved to carry out termination of pregnancy and registered pregnancy advice bureaux. The code was approved by Health Ministers prior to publication.

2. The Secretary of State for Health has a responsibility under Section 1(3) of the Abortion Act 1967, as amended by Section 37 of the Human Fertilisation and Embryology Act 1990, to approve and monitor private sector places for the purpose of treatment for termination of pregnancy. He also maintains a register of Pregnancy Advice Bureaux. No charge is made for this. Approval or registration depends upon compliance with conditions, known as 'required standard operating principles'.

3. The code sets out the level of service that approved places and registered bureaux in the private sector can expect from the Department of Health, including:-

* impartial and fair treatment of applications
* prompt response to enquiries
* clear, concise and unambiguous information and advice
* responsibility to uphold the Secretary of State's 'principles'
* independent review of complaints about the treatment of applications
* value for taxpayers' money in the application of regulations

The Department of Health's overall aims are to ensure that we give effective help and advice to those providing abortion services and to pregnancy advice bureaux to help them comply with the requirements of the Abortion Act and the 'principles', and to enable them to feel that they are and will be treated fairly, impartially and with courtesy.

How the Department of Health will help organisations providing services in connection with the Abortion Act

You are entitled to expect the Department of Health

To be objective

* By handling enquiries fairly
* By treating all our providers impartially

To help you

* To understand how and when the regulations and the 'principles' apply to you and how we may consult you
* By providing you with clear and unequivocal advice in reply to general or specific enquiries about the requirements of the Abortion Act 1967 and the 'principles'
* By being polite and courteous at all times

To provide an efficient service

* By dealing with your enquiries promptly and accurately
* By keeping your enquiries strictly confidential
* By requiring compliance with regulations, 'principles' and issued guidance
* By keeping your costs of compliance to a minimum and where possible consulting you in advance of any change

If you are not satisfied

* You can ask us to look at your complaint and for it to be examined at a senior level elsewhere in the Department (see paragraph 2 for address)
* You can ask your MP to put your case to the Parliamentary Commissioner for Administration (the Ombudsman)
* We will monitor the effectiveness of this complaints system

WORKING WITH BUSINESS

THE DEPARTMENT OF HEALTH'S CODE OF PRACTICE FOR APPROVING PLACES FOR TERMINATION OF PREGNANCY UNDER THE ABORTION ACT 1967, AS AMENDED, AND FOR REGISTRATION OF PREGNANCY ADVICE BUREAUX

1. All of the business conducted by the Department of Health in connection with approvals under Section 1(3) of the Abortion Act 1967, as amended, and with registration of Pregnancy Advice Bureaux, will be carried out fairly and impartially.

2. General or specific enquiries, written or oral, about the requirements of the Abortion Act will be acknowledged within 3 working days and dealt with as quickly as possible by named officials. Only exceptionally will a reply take more than three weeks from the date of receipt. We can be contacted at Room 580d, Skipton House, 80 London Road, London SE1 6LH or by `phone on 020 7972 6172/5002 (or fax on 020 7972 6196).

3. The conditions on which the Secretary of State's approval or registration depends - known as ‘principles’, will be clearly set out in writing and made available to those wishing to apply for approval to carry out termination of pregnancy under the Abortion Act, or for registration of a Pregnancy Advice Bureau.

4. It will be made clear to all applicants that failure to comply with any of those conditions could lead to withdrawal of the Secretary of State's approval or registration.

5. On receipt of a request for information in connection with approval or registration, the application forms will be dispatched to the applicant within 3 working days.

6. On receipt of a completed application form, an acknowledgement will be sent within 3 working days.

7. On receipt of an application for approval, the Department will send, within 14 days, a copy for comment to the health authority responsible under the Registered Homes Act 1984 for registering the applicant's premises.

8. On receipt of a response from the registering health authority, and all the necessary documentation and resolution of further enquiries into the application, arrangements for a visit will be made within 14 days to the applicant's premises by the Department's medical, nursing and administrative staff.

9. The visits are part of the approval and registration procedure and will be arranged for a time and date mutually convenient to the applicant and the visiting teams.

10. The applicant will be notified of the Secretary of State's decision by telephone within two working days and in writing within 14 days.

11. Once approval or registration is given, places are subject to unannounced inspection by the Department's medical, nursing and administrative staff.

12. Any matters requiring attention following inspection of approved places or registered bureaux will be discussed at the time and if necessary, notified to the proprietors within three weeks.

13. Prior to the end of the period of approval or registration, the Department will notify proprietors of the need to re-apply for Secretary of State's approval or registration. Proprietors will be required to apply for re-approval or re-registration within approximately one month, and the Department within 7 days will send an acknowledgement of receipt of the application.

14. Notification of the Secretary of States decision following application for re-approval or re-registration will be sent before the start of the new period of approval.

15. We will monitor the effectiveness of our complaints procedure and take any necessary remedial action.

16. Information about the Department of Health's performance in meeting the standards set out in this code will be made available on an annual basis, on request.

Department of Health
July 1999

Section 2

1. The Abortion Act 1967 requires that treatment for the termination of pregnancy must be carried out at a NHS hospital or at a place approved by the Secretary of State for Health. Wherever the treatment is provided, it must be based on a set of core principles the aims of which are to:

   - Ensure compliance with all legal requirements.
   - Provide the best quality of care for women.
   - Provide sound management and organisational arrangements.

2. Outside the NHS, proprietors of premises wishing to undertake induced abortions must:

   i. be registered under the Registered Homes Act 1984, and

   ii. indicate to the Authority (i.e. The Secretary of State) the range of termination methods that they expect to provide, the anticipated throughput of cases per year and number of beds available for patients who need overnight care.

3. The principles proprietors must undertake to observe are known as "Required Standard Operating Principles" (RSOPs).

REQUIRED STANDARD OPERATION PRINCIPLES

RSOP1 Compliance with the Abortion Act – Completion of Forms

Timely completion of the notices prescribed by the Abortion Regulations 1991.

Under the Abortion Act 1967, pregnancies are terminated to protect health. Other than in an emergency to save a woman's life, medical practitioners must give their opinions on the reasons under the Act for the termination following consultation with the woman. The Act also requires the practitioner who terminates a pregnancy to provide information about the termination to the Chief Medical Officer.

Completion of Abortion Act forms is the responsibility of the registered medical practitioners who certify that in their opinion a termination is necessary (HSA1 or2) or who carry out a termination (HSA4). Notwithstanding this, proprietors must have arrangements in place to ensure that required documentation has been completed and safely stored or, in the case of the form HSA4, sent to the Chief Medical Officer.

RSOP2 **Notification of Change of Proprietor**

All prospective proprietors must undertake to inform the Secretary of State of any change in the ownership of the controlling business or premises. This is because a new approval is required in every case where the ownership of an approved place changes. Proprietors must also notify any significant deviation from the accommodation or business details applicable when the approval was granted (e.g. changes of senior management and nursing staff, services provided).

RSOP3 **Professional Guidelines**

Clinical practice and good quality care should be guided by authoritative clinical guidelines and professional opinion such as that provided by relevant Royal Colleges.

The Royal College of Obstetricians and Gynaecologists (RCOG) have issued a number of documents on the care of women undergoing induced abortion. It is expected that further clinical guidelines will be published during 1999. The Royal College of Anaesthetists has issued good practice guidance[1] that sets out standards which the Royal College of Anaesthetists and Association of Anaesthetists recommend should characterise anaesthetic departments throughout the country. The Royal College of Nursing has also published guidelines for nurses and midwives working with women undergoing the termination of pregnancy[2]

RSOP4 **Advice / Consent / Counselling**

All clinics/hospitals must demonstrate that they have effective services providing advice, medical assessment and counselling. The primary function of medical assessment is to establish whether a woman referred or referring herself for termination has grounds for the termination under the Act. The medical assessment can be assisted by trained, non-medically qualified, clinic staff who help by defining problems the pregnancy would cause, assist the woman to understand and assimilate the new information she needs to make her final decision and provide her with information on associated health matters. There should be information on sources of advice and support for women following termination.

There should also be literature and information on alternatives to abortion – for instance adoption and motherhood – from sources independent of the clinic for women who decide to continue with the pregnancy.

Practice will be monitored as a part of the DH inspection process.

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[1] Good Practice – A Guide for Departments of Anaesthesia. The Royal College of Anaesthetists and The Association of Anaesthetists of Great Britain and Northern Ireland. London 1998
[2] Guidelines on the Termination of Pregnancy. The Royal College of Nursing. London 1997

Consent

The principles of good practice which all registered medical practitioners are expected to follow when seeking patients' informed consent to investigations, treatment, screening or research are set out in documents prepared by the General Medical Council and sent to all doctors[3].

For women over aged 16 who do not have the capacity to give consent, one of the doctors who expresses an opinion on the abortion should, ideally, have experience of dealing patients with mental incapacity.

Counselling

A person trained and experienced in counselling in this field must be available to attend clinics / hospitals if required. Counselling must be offered to women who request or who appear to need help in deciding on the management of pregnancy or who are having difficulty in coping emotionally. Counselling should be offered to women under 16 and to those with a history of psychiatric illness, who lack social or emotional support or whom their partner, family or employer is possibly coercing into having an abortion. All staff must realise that a woman may not resolve ambivalence about a pregnancy during a counselling session. Rather, the session helps her clarify her thoughts and facilitates constructive discussion during the next few hours or days. This is often through more effective communication with her partner or some other person who is emotionally close. Women who remain ambivalent after counselling can be given a provisional appointment for admission but must be told that the procedure can be postponed or cancelled and that she remains free to continue with the pregnancy if, on reflection, she decides this would be the most satisfactory outcome.

Girls under age 16

In the case of girls under 16, every effort should be made during the assessment session to persuade the girl to involve her parents whilst respecting the girl's wishes regarding confidentiality. Girls under 16 are vulnerable and may be under a great deal of pressure to resolve the situation. Safeguards must be in place to ensure that she is free from such pressure. An advocate, such as a General Practitioner (GP), social worker, or independent advocate, may be helpful.

[3] **Seeking Patient's Consent: The ethical considerations. General Medical Council 1999**

If a girl under the age of 16 has sufficient understanding and intelligence to comprehend fully what is proposed, including the consequences of the action, she is competent to consent to her own medical or surgical treatment.[4] It is for the registered medical practitioner who first interviews the girl to assess her capacity to consent to the treatment before it is provided. That practitioner is also responsible for ensuring that all other health staff who will be involved in the care of the girl know and accept the decision. The doctor must also ensure that all staff are aware of the extent to which the girl is willing for her treatment to be disclosed to parents, relatives, friends, social workers or her general practitioner. GMC guidance of 1999[5] and circular HC(FP)(86)1 refers.

A registered medical practitioner who decides that a girl under 16 years old is not competent to give informed consent may find that she is unwilling to allow her parents or social services to be involved. Under these circumstances, while the doctor has a legal duty to obtain consent from a person with parental responsibility, the doctor must explain to the girl the necessity for breaching her confidentiality. She must be told the identity of the person (or people) the doctor will speak to on her behalf. These could be one or both parents or, in the case of a girl in care, the local authority. The person may refuse treatment where they consider that the treatment is not in the child's best interest and the registered medical practitioner is bound by such a refusal that can only be overturned by an order of the court.

RSOP5 Abuse of Children and the Vulnerable

There are special difficulties in managing suspected child abuse, incest or abuse of the very vulnerable in the non-NHS abortion services. The need for a decision on a termination may be urgent because of advanced gestation and both the girl and any accompanying adult usually conceal the truth from assessing staff. The girl may have travelled away from her home area to assist with the concealment. Clinic staff must be alert to the possibility of abuse, particularly when the girl refuses to involve her parents or general practitioner or is accompanied by a controlling adult such as a male relative who wishes to remain particularly close to a girl. When abuse is suspected, the primary concern must be the wellbeing of the girl and any siblings. Clear protocols must be in place for all assessors, medical staff, nurses or counsellors on action to be taken should abuse be suspected. It is suggested that all places should designate a small number of doctors and counsellors to assess all girls under 16. Within the terms of confidentiality, it would be their responsibility to liase with the appropriate social services child protection group when there is strong evidence that a girl has been abused or when other children are likely to be at risk. Further guidance has been issued as an addendum to

[4] **Gillick v West Norfolk and Wisbech Health Authority [1985] 3 AER 402**
[5] **Seeking Patient's Consent: The ethical considerations. General Medical Council 1999**

"Working Together – Under the Children Act 1989."[6] Similar considerations can arise in the case of vulnerable women (perhaps because of mental handicap).

RSOP6 Performance Standards and Audit

Have in place clear locally agreed standards against which performance can be audited. Although these will be guided by appropriate national standards, it is important that local standards are agreed, applied and audited. Subjects which proprietors may wish to audit include: -

Waiting times and the conditions in which patients (and when appropriate, their partners) wait before consulting advisors, medical practitioners or counsellors.

The consultation process. For example: the result of consultations; the number of women who do not proceed to a termination.

The availability of 24-hour helplines and response times. The qualifications and expertise of those responding to requests for advise and support. The availability of expert advisors; the nature of the calls received; the number of calls requiring further action.

The provision of services for women with special needs. For example: the availability of trained counsellors for those women at risk of particular psychological or emotional difficulties; the availability of a female doctor for woman who wish to consult a woman - especially those from certain cultural backgrounds and ethnic minorities, arrangements for non-English speaking women.

Indicators of good practice could include locally developed strategies for minimising avoidable morbidity. These might encompass: the number of women known to require antibiotics four weeks after the procedure; cervical preparation; availability of blood tests. Other measures that could include: the number of "incidents"; the number of women known to require repeat surgical procedures within four weeks of the procedure; the use of local anaesthesia where this is clinically indicated; medical complications or the use of ultrasound equipment.

RSOP7 Disposal of Fetal Tissue

Confirmation that fetal tissue will be treated with dignity and respect in accordance with standing national and local instructions. The wishes of women should be taken into account.

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[6] Child Protection: Medical Responsibilities. Guidance for doctors working with child protection agencies. Department of Health, BMA, Conference of Medical Royal Colleges. London 1994

A small number of places have been approved to provide fetal material for research purposes. Fetal material must not be supplied for research purposes without the express permission of the Department of Health. In every case, the Department will expect compliance with the "Polkinghorne Code of Practice on the Use of Fetuses and Fetal Material in Research and Treatment.[7]"

RSOP8 Patient Confidentiality

Measures must be in place to safeguard patient confidentiality and all staff must be familiar with them. Information for women and professionals must emphasise the duty of confidentiality.

RSOP9 Printed Information

Oral information should be supported by leaflets that the person requesting an abortion can take away and read before the procedure. Clear leaflets containing accurate, impartial information should be provided including possible adverse reactions following abortion and alternatives to a termination. Depending upon local requirements, these may need to be available in languages other than English. The needs of those unable to read should be considered and appropriate arrangements made to ensure that they are empowered to make an informed choice (e.g. audiotapes). Information provided to women will be monitored as a part of the DH inspection programme. Inspectors will consider the availability, clarity, content, balance and tone in which the information is presented.

RSOP10 Admission Registers

Patient registers are required by Regulation 7 made under the Registered Homes Act 1984. A separate register should be kept for patients having medical terminations.

These records, including theatre registers where these are kept separately, must be completed at the time procedures are conducted. Clinical and staffing records, including all registers required by the Registered Homes Act, must also be available for inspection at any reasonable time. Inspectors will treat all records in strict confidence and only DH appointed medical and nursing officers would inspect clinical notes.

[7] **Report of the Committee to Review the Guidance on Research Use of Fetuses and Fetal Material. HMSO 1989**

RSOP10a Data Requirements

To assist with the monitoring and inspection process, a return must be sent to the Department from each approved place giving non-attributable details of the numbers of terminations conducted and number of women who decide not to proceed to a termination. This return must relate to a calendar year and be sent to the Department of Health by the 1st February of the following year. All information provided will be treated as confidential.

RSOP11 Patient Records

There must be adequate clinical records. For all terminations, there must be clearly understood arrangements for recording comprehensive details of the patient's identity. Her notes should record documentation (for instance on possible adverse reactions, 24 hour contact numbers etc) given on leaving.

RSOP12 Staffing

There must always be sufficient trained staff (including support staff) of the appropriate grades to provide care of a high quality for patients on the premises taking into account the actual and anticipated number of terminations and methods planned for each session. Annex A outlines suggested staffing standards.

RSOP13 Emergency Medical Cover

Arrangements must be in place to provide emergency medical and consultant cover. Annex A indicates appropriate levels and qualifications for local consultant gynaecologist and anaesthetist cover if the NHS is unwilling, or unable, to provide cover.

RSOP14 Duty Records

Records of duty and shift rotas must be available for inspection. A named senior manager should be responsible for ensuring that these are complete and accurate and that staff attends according to the rota.

RSOP15 Confirmation of Professional Status

A named senior manager, director or proprietor must be responsible for ensuring that qualifications, experience, GMC registration / UKCC PIN reference are confirmed for all medical, midwifery and nursing staff. The senior manager, director or proprietor should also be responsible for ensuring that all medical, midwifery and nursing staff continue to fulfil PREP (Post Registration Education and Practice)

requirements (as appropriate) and hold current qualifications or experience. See Annex A.

RSOP16 Risk Management

We would expect proprietors to have in place systems to identify and minimise any risks to patients and staff within their premises. Protocols should exist on action to be taken should incidents occur. There should be opportunities for medical, midwifery and nursing staff to contribute to risk appraisal including the reviews of incidents that may occur to see what lessons can be learnt. Examples of subjects for risk appraisal may include:

- arrangements for women being treated on a day care basis that (unexpectedly) require overnight care;
- the use of local anaesthetic techniques where this is clinically indicated;
- the management of anaesthetic emergencies (e.g. anaphylaxis and malignant hyperpyrexia);
- the stage at which emergency support services must be summonsed;
- the ready availability of blood / blood products relative to the procedures being conducted and when these should be used etc. See Annex B.

RSOP16a Maintenance of Equipment

Risks and emergencies can also be minimised through a programme of regular checking and servicing of equipment. This is particularly the case with anaesthetic and patient monitoring equipment. Health Authority and DH inspections will include confirmation of regular and routine servicing. Inspectors will also wish to confirm that staff receive approved training in the use of equipment - particularly emergency equipment which may be rarely used. Guidelines for checking anaesthetic machines are available from the Association of Anaesthetists[8]. The Royal College of Anaesthetists encourages their prominent display at any site where anaesthetics are given.

[8] **9 Bedford Square, London, WC1B 3RA**

RSOP17 Training in Emergency Procedures

These procedures and protocols must be underpinned by regular training in emergency procedures – especially basic resuscitation. Evidence must be available that training has taken place. This must be available for examination and staff may be questioned by DH inspectors on their participation in emergency training.

RSOP18 Death of a Patient

Arrangements must be in place to immediately inform the Department of Health by telephone in the event of the death of a patient. A record must be kept of the date, time, cause and place of death. Verbal information must be confirmed in writing within 24 hours.

RSOP19 Complaints Policy

There must be a recognised and clearly defined complaints policy and a procedure that is made known to all clients. A senior manager, director or proprietor must regularly monitor complaints.

RSOP20 Payment of Fees

Women must be free of any fear of exploitation. For instance, DH inspectors may require confirmation that fees are not being demanded or accepted for an abortion either directly or indirectly (e.g. through the agency of a pregnancy advice bureau) until two certificates of opinion necessary for a legal abortion under the Act have been given on form HSA1. Similarly, patients must not be admitted for an abortion in a clinic / hospital before full and proper completion of form HSA1 (i.e. two certificates of opinion have been given).

RSOP21 Patient Questionnaires

All approved places must recognise the rights of women to confidentiality. Nevertheless, all places should undertake post care patient satisfaction surveys and questionnaires aimed at identifying women's experiences and views on the treatment they have received. A senior manager, proprietor or director should monitor these. Proprietors should be prepared to make the results of these surveys available to DH inspectors on a confidential basis. All information would, for reasons of confidentiality, be aggregated and anonymised.

RSOP22 Referrals from Bureaux

Premises approved for the termination of pregnancy must not accept patients from any bureau that is not on the register of approved Pregnancy Advice Bureaux. Premises that provide abortions under agency agreements with the NHS may accept patients under the terms and conditions of the local NHS contract.

RSOP23 Access to Staff

Subject to clinical duties, proprietors of premises should assist DH inspectors to have access to clinical staff (medical, nursing and midwifery) on duty at the time of a visit (including unannounced visits).

Maintaining Standards

4. The approval process will provide a framework for maintaining the safety and quality of care in the independent sector. In keeping with the concept of clinical governance, the DH will be responsible for ensuring that these are maintained through a system of monitoring within the premises and a programme of inspection visits. In addition, any cases of alleged malpractice or sub-standard care will be investigated.

5. Many professional organisations are moving towards a system of continuous professional accreditation involving peer group scrutiny of clinical practice requiring regular attendance for post-graduate training and including recognised standards of professional conduct. Proprietors of approved premises will need to ensure that clinical staff (doctors, nurses and midwives) for whom they are responsible are participating in this process and are monitored to ensure that they maintain their professional standards. When necessary, proprietors are encouraged to make time available for continuous professional development.

6. Within the NHS, clinical practice will be increasingly influenced through national service frameworks and guidance such as that issued by the National Institute of Clinical Excellence (NICE) alongside professional bodies. As outlined in *"A First Class Service"*[9] – it is expected that NICE will produce clinical guidance against which performance can be assessed. The independent Commission for Health Improvement (CHI) will, through a rolling programme of spot checks, monitoring the uptake of guidance or of the audit tools involved. CHI will also conduct systematic service reviews in which it will follow through the implementation of NICE guidance.

[9] **"A First Class Service – Quality in the NHS," Department of Health, London, June 1998**

7. NICE and CHI will only apply to the NHS in England and Wales. However, for abortion services, clinical standards endorsed by NICE for the NHS will influence the requirements set for the independent sector by the Secretary of State as a part of the approval process and through the operation of locally negotiated agency contracts. They will be monitored during the inspection programme required by the Secretary of State.

8. It is the responsibility of local practitioners, in consultation with proprietors, to develop good clinical practice within their local settings. DH inspectors will wish to be assured that good professional practice is being maintained at individual premises and that appropriate indicators of good practice are in place.

9. It will be for proprietors to formulate local policies on these and other issues aimed at the delivery of high quality care within their premises. However, proprietors are urged to have in place arrangements for obtaining professional advice covering the range of relevant specialities. This advice should encompass:

- appointments of clinical staff;
- continuing professional education and training;
- clinical practice;
- clinical audit arrangements;
- service arrangements;
- patient complaints;
- patient views;
- the data and evidence necessary to carry out the management of these functions to achieve quality assurance and outcomes.

10. In formulating local policies, proprietors are recommended to liase with specialist NHS consultants, supervisors of midwives and nursing officers when their expertise and statutory duties can be utilised.

Patterns of Service

11. Evidence is available that the earlier the termination takes place in the pregnancy, the smaller the risk to the woman. Therefore, for the reasons of safety, terminations should always be conducted as early as possible consistent with the woman being fully informed of possible consequences of an abortion and having had time to reflect upon the options available to her.

12. For early gestations there should be a choice of surgical and medical terminations at the discretion of the relevant medical practitioner in consultation with the woman.

Day Care

13. Evidence is also available that for many women, procedures may be safely performed as day care treatment. This must be for the clinical discretion of the registered medical practitioner in consultation with the woman. However, places must either retain a number of beds for those women for whom day care treatment is unsuitable or arrange onward referral of these women to alternative premises.

Medical Terminations - Delegation of Duties

14. The Abortion Act requires that a registered medical practitioner (RMP) only may terminate a pregnancy. However, provided the RMP personally decides upon, initiates and takes responsibility throughout the process, the protection provided by the Act will apply to the RMP and to any other person participating in the termination under his or her authority.

15. The RMP is not required to personally perform every action. Certain actions may be undertaken by registered nurses or midwives (who are not RMPs) provided they are fully trained and work agreed protocols.

16. This does not affect the rights, provided under section 4 of the Act, of those with a conscientious objection not to participate in treatment authorised by the Act unless that treatment is immediately necessary to save life or prevent grave permanent physical or mental injury to the pregnant woman.

Terminations beyond the First Trimester

17. Terminations of pregnancy beyond the first trimester require additional training and particular skills for medical, midwifery and nursing staff. Therefore they must be conducted by practitioners who can demonstrate that they have sufficient regular and recent experience of these later terminations to ensure that their specialist skills are maintained.

18. Terminations after 20 weeks gestation raise particular public and professional concern because of the possibility of a viable birth. Therefore, premises wishing to carry out terminations at 20 weeks gestation or more must have separate approval from the Secretary of State. No operations for the termination of pregnancy must be carried out after the end of the 24th week of gestation. In addition to meeting all the relevant RSOPs outlined above, they must demonstrate:

    i. That all medical, midwifery and nursing staff involved in the care of patients undergoing late terminations have appropriate recent experience and skills.

ii. That they have in place emergency arrangements for the event of a live birth (however remote). This requirement may be achieved by demonstrating that there is close and willing co-operation, **at all times**, between the independent provider and a closely located NHS maternity / neonatal unit. This unit must have experienced neonatal and paediatric staff able and willing to provide advice, support and emergency admission facilities throughout the 24 hours. Closely located means within 30 minutes taking account of traffic densities etc.

iii. That if the requirements of (ii) cannot be met, the place must have the following specialist neonatal equipment always available: an incubator, a neonatal laryngoscope and endotracheal tubes, suction apparatus including mucus catheters and an oxygen supply.

iv. That medical, midwifery and nursing staff are skilled in neonatal resuscitation techniques. It is recognised that the Royal College of Obstetricians and Gynaecologists[10] recommend that feticide is carried out and that therefore a live birth in an independent sector abortion clinic / hospital should be an extremely rare event but may be possible. It will therefore be a condition of approval that staff must show evidence of regular training in neonatal resuscitation and, if the place cannot demonstrate close working with the NHS (ii above), the use of specialist equipment.

19 The provision of a registered midwife to undertake the specialised care of a women whose pregnancy is terminated at a later stage of gestation by medical induction is now accepted as good practice as her training, knowledge and skill ensure the safety of the patient during treatment.

General

20. It is recommended that, wherever possible, the woman's GP should be informed about any treatment for the termination of pregnancy. Then, in the event of a woman requiring care in the longer term, the GP would be aware of all treatments provided and be in a better position to determine the appropriate therapy. All women should be told of their right to confidentiality if they do not want their GPs informed.

Pregnancy Advice Bureaux (PABx)

21. Women may obtain advice on pregnancy matters and access to abortion services through a GP, NHS clinic/hospital or a PAB.

22. A PAB may be defined as a "place that provides advice and help to women who may be pregnant". Services provided include pregnancy testing, medical advice, assessment, counselling and contraceptive advice.

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[10] Fetal Awareness: Report of a Working Party, Royal College of Obstetricians and Gynaecologists. London. October 1997

23. Separate approval is required of places wishing to be registered as a PAB. More information on the criteria for registration as a PAB may be obtained from the guidance “Procedures for the Registration of Pregnancy Advice Bureaux” obtainable from the Department of Health.

Annex A

Staffing

1. The overall safety and well being of patients is paramount in assessing staffing requirements at all times.

2. Staffing must at all times be sufficient for the number of women to be admitted and the procedures to be undertaken.

3. Women should not be admitted or procedures commence if there are insufficient trained staff.

4. Inspectors from the Department of Health will expect to see evidence that the professional status of medical, midwifery and nursing staff have been confirmed and experience verified.

Nursing and Midwifery Staff

5. One first level registered general nurse or registered midwife should be on duty in the clinic / hospital at all times. The person in charge of each shift throughout the 24 hour period should be a first level registered nurse or registered midwife able to accept professional responsibility for the smooth running of the clinic, of other staff and of patients.

6. The first level nurse or registered midwife should at all times be supported by at least one other first or second level registered nurse or registered midwife. Nursing and midwifery staff levels should reflect factors such as:

    i. the anticipated throughput of patients and abortion methods to be used;

    ii. the incidence of complications (which must be routinely assessed / reassessed);

    iii. the support required for dealing with a patient;

    iv. other emergencies that may arise as well as the continued observation of patients;

    v. the residence or otherwise of a medical officer.

7. Particularly where late (i.e. 20 to 24 week gestation) terminations are being undertaken, staffing levels should be calculated with reference to case mix, anaesthesia used, room layouts and skill mix. The particular emotional and psychological support of women undergoing these late terminations should not be overlooked. As a guide, there should be at least one midwife for up to every five patients available from the time treatment commenced to the time treatment ended. Midwifery and nursing staff must be competent in the use of all the equipment required to be available in places approved for late terminations.

8. Each nurse or midwife should have the appropriate knowledge and training on which to base observations and to detect deviations from normal progress and to carry out medical instructions. Each nurse or midwife should have the ability to professionally assess a patient's condition and describe this accurately to a doctor.

9. Each nurse or midwife should have the appropriate knowledge, training and confidence to initiate immediate action in the event of an emergency and before medical help arrives.

10. Midwives and Nursing staff should not be asked to undertake duties for which they are not clinically competent.

11. An auxiliary or assistant nurse is not a nurse and should not be expected to carry out duties or responsibilities in excess of their capabilities or competence or which are those of a nurse or midwife. Arrangements must also be in place to ensure that all auxiliary and support staff are aware of the principles of good quality care and need to respect patient confidentiality.

12. All nursing and midwifery staff are expected to undertake continuing professional education and training to retain skills and gain familiarity with on-going clinical developments.

Medical Staff

13. No doctor should be expected to undertake duties or responsibilities for which they are not clinically competent. They should be able to provide appropriate information to women about possible complications and sequelae of the course proposed.

14. Doctors must be fully registered medical practitioners and be able to show evidence of current membership of a medical defence body.

15. Immediate medical cover must be provided by the residential medical officer or (in an emergency) any other fully registered medical practitioner and must be available at the clinic or hospital within 10 minutes (taking into account traffic conditions or other hazards).

16. All medical staff must undertake continuing post-graduate medical education in association with their respective specialist College or Faculty. All anaesthetists (and, it is recommended, other clinicians who may be called on in an emergency) must be proficient in Advanced Cardiac Life Support in accordance with the advice of the Resuscitation Council.

17. The Royal College of Anaesthetists (RCA) makes the following recommendations for staffing standards when anaesthetics are given at sites remote from general hospitals and on occasions when the doctor administering anaesthesia is not part of a recognised departmental structure. In these situations, RCA recommend that anaesthetists should be one of the following:

- Individuals on the Special Register (Anaesthetics) of the General Medical Council. They should meet the RCA's Continuing Medical Education (CME) requirements.

- Trainees working under supervision (as defined in current College training documents) in programmes accredited by the RCA.

- Non-consultant career grade doctors (NCCG) with NHS appointments working under line responsibility of a named consultant anaesthetist. This named consultant should be a member of the NHS department where the NCCG is based and must have ultimate clinical and medico-legal responsibility for the work of the NCCG, who should comply with RCA's CME requirement.

18. It is recommended that only anaesthetists holding a higher qualification give all general anaesthetics for abortion. Anaesthetists who do not meet this standard must demonstrate that they possess lengthy and current experience including dealing with emergencies.

19. Depending upon case mix, caseload, room layout etc, anaesthetists should have appropriately trained assistance.

Emergency Cover

20. Consultant cover for both gynaecology and anaesthetics must be available to assist operating surgeons and anaesthetists in an emergency. It is important that serious gynaecological complications are managed by a consultant gynaecologist with extensive on-going experience in gynaecological emergencies. When on call, they must be able to reach the clinic or hospital within 30 minutes (taking into account traffic conditions or other hazards). It is also required that arrangements are in place whereby there can be an urgent telephone discussion between the consultant and the clinic clinician in an emergency.

21 The aim in an emergency should be to stabilise the patient and, when safe, to transfer to a specialised unit where, if needed, there is immediate access to intensive care, laboratory services and other specialist disciplines.

22. Anaesthetic emergencies are a special problem. These often arise quickly and require immediate attention. Therefore, it must be possible to contact a consultant anaesthetist with widespread current experience immediately by telephone.

23. Consultant cover should be available on a 24-hour basis and the consultant(s) should hold a substantive post (not a locum) as a consultant in the National Health Service.

24. Where a proposed consultant does not hold a current substantive post in the NHS, consideration will be given to the appointment of consultants who can demonstrate current and continuing practice in this speciality at a consultant level in the independent sector.

Annex B

Blood Testing and Emergency Cover – including the provision of Blood

Pre – operative Blood Testing

1. Pre-abortion assessment should include the determination of the blood group ABO and rhesus blood groups. Haemoglobin concentration should be measured routinely and other investigations performed if clinically indicated. Facilities should be available to enable testing for disorders of the blood according to the patients' needs.

2. Anti-D Immunoglobulin should be given to all non-sensitised rhesus negative women following abortion.

Emergency Blood Cover

3. Arrangements must be made with a local hospital blood bank or a private laboratory that can provide a 24-hour emergency service.

4. Supplies of blood should be obtainable within 60 minutes. This time must take account of the geographic distance, travel conditions at the busiest time of the day and other prevailing hazards – e.g. the weather. At the discretion of the proprietor, director or senior manager, clinics / hospitals may hold reserve stocks of blood for emergency use. Where this is done, stocks should be stored in accordance with the recommendations of the haematologist. Stored stocks must be regularly examined and records confirming monitoring.

5. A sample of serum held in advance by the hospital or private laboratory should be available for cross – matching.

Blood Supplies and Other IV Fluids required in an Emergency

6. Available immediately at all clinics or hospitals:

    i. Plasma Protein Fraction (minimum 2 units 500ml).

    ii. Plasma Protein Substitute (minimum 4 litres).

    iii. Crystalloid IV Solutions (including Dextrose Saline and electrolyte solutions).

    iv. Short acting volume expander (e.g. Haemaccel or Gelofusine) (minimum 2 litres).

7. If clinically indicated for women at risk of haemorrhage, 2 units of blood cross-matched in advanced before an operation commences, must be available at the clinic / hospital or at an adjacent blood bank or private hospital. Adjacent means within 15 minutes travel taking account of the worst possible travel conditions.

General Note

8. If any of the emergency blood / IV fluid supplies as per these guidelines have been used up, the operation list should be suspended until they have been replaced.

9. Clinics/ hospitals must have suitable storage facilities for blood, blood products and IV fluids, including blood refrigerators reserved solely for the storage of blood / blood products. Supplies and storage of blood / blood products should be supervised by a haematologist and made available for recycling as appropriate. Blood refrigerators and other equipment must be regularly checked for working efficiency and a log kept of the checks that must be available for regular inspection.