Brighton and Sussex University Hospitals NHS Trust

Termination of Pregnancy Under 14 Weeks

The Care and Management of Termination of Pregnancy for Women with underlying Medical and Anesthetic risks and for Fetal Abnormality

Gynecology Protocol: GP010
Date agreed: March 2016

Guideline Reviewer:	Tosin Ajala
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Contents

Key Principles

A protocol is a set of measurable, objective standards to determine a course of action. Professional judgement may be used in the application of a protocol.

Scope

This protocol applies to:

- All women requesting a Termination of Pregnancy with underlying Medical and Anesthetic risks and for Fetal Abnormality

Responsibilities

Nurses, Midwives, Obstetricians & Gynaecologists

- To access, read, understand and follow this guidance
- To use their professional judgement in application of this protocol

Management Team:

- To ensure the protocol is reviewed as required in line with Trust and National recommendations
- To ensure the protocol is accessible to all relevant staff

1.0 Referral Criteria For Women From BPAS

1.1 BSUH will act as a referral centre for termination of pregnancies that cannot be safely carried out by BPAS. These cases will be those that fall into ASA PS physical classification system of 3 and above (Appendix A). Most patients will be ASA PS 1 or ASA PS 2 and can be treated at BPAS.

- **ASA PS 1:** A normal healthy patient, entirely free of disease.
- **ASA PS 2:** A patient with mild systemic disease which is adequately treated and controlled and does not limit activity.
- **ASA PS 3:** A patient with severe systemic disease that limits activity but is not life threatening.
- **ASA PS 4:** A patient with incapacitating systemic disease that is a constant threat to life.
- **ASA PS 5**: A moribund patient who is not expected to survive for 24 hours or less with or without an operation.

1.2 Exclusion criteria will include:
ASA physical classification 1 & 2

- Request for second trimester surgical termination (dilatation and evacuation) i.e. above 13 weeks gestation.

2.0 Specific Organ Systems and Diseases

Women with the following conditions should be accepted for treatment from BPAS:

2.1 Respiratory system

- Any person who uses home oxygen.
- Uncontrolled asthmatic patients.
- Patients with unstable or severe COPD.
- Patients suffering from sleep apnoea under the care of the sleep apnoea clinic.

2.2 Cardiovascular system

- Poorly controlled hypertension (systolic BP>160mmHg and or diastolic BP of greater than 110mmHg
- Patients with unstable angina.
- Patients with a pacemaker or implanted defibrillator.
- Previous MI and open heart surgery within the last 12 months.
- Anyone with a coronary stent in situ
- Currently on anticoagulant therapy

2.3 Endocrine system

- Poorly controlled diabetic patient.
- Poorly controlled Thyroid disease (hyperthyroidism or hypothyroidism)

2.4 Renal System

- Patients receiving renal replacement therapy.

2.5 Liver Disease

- Patients with poorly controlled liver disease (Patients with no functional limitations and stable liver function test are exempt).

2.6 Neurological disease

- Patients who have previously suffered a CVA or Transient Ischemic Attack.
- Any patient with significant neurological disease.
- Uncontrolled seizures by therapy (seizures within the last 1 year while on therapy)
- Recent changes to antiepileptic drugs without interval review by GP or neurology consultant.

2.7 Haematology

- Anaemia : Hb less than 9g/dL
- Bleeding disorders; whether due to coagulation defect (e.g. haemophilia, von Willebrands disease) or a disorder of blood vessels (e.g. uterine arteriovenous malformation)
- Patients suffering from Leukaemia.
- Sickle cell disease and thalassaemia major.
- Porphyria

2.8 Anaesthetic History

- Patients who have had a severe reaction or problem with a previous anaesthetic.
- Patients who have severe Rheumatoid Arthritis must be discussed with an anaesthetist, as this can affect neck movement and compromise the airway.
- Patients unable to extend their neck and have unrestricted opening of their jaw.
- Patients who have previously experienced or suspected to have experienced malignant hyperthermia.

2.9 Other

- I.V Drug users with poor venous access.
- Poor venous access
- Women under 18 years of age should be managed within the gynaecology department. The paediatric liaison nurse at Royal Alexandra Children's Hospital (RACH) must be informed of the admission.
- Women under 16 years should be managed at RACH
- Women with a BMI of greater than 35.

- Women weighing more than 160 kg

3.0 Referral Pathway

3.1 Referrals are to be e-mailed to Sami Nair (samantha.nair@bsuh.nhs.uk) for initial review. This must include a copy of the ultra sound scan confirming intrauterine pregnancy. GOPD outpatient appointment to be arranged next available suitable consultant through the hub.

3.2 Patient is booked an appointment in gynae out-patient clinic via Patient Access Clerk Carl Hussey ext 7963

3.3 All accepted referrals must be seen in the gynae out-patient clinic within 5 working days. Treatment must start within a 5 working day period from the clinic date. Therefore all referrals must receive treatment within 10 working days.

3.4 For surgical TOP a provisional date is booked via Patient Access Clerk Clare Halton on ext 4155 before the patient is seen in clinic.

3.5 For in-patient medical TOP (up to 14 weeks) an appointment is booked in the gynae assessment unit (GAU) via Ward Manager or the ward co-ordinator in her absence on ext 4013 or 4022. Patient to be given a TCI 48 hours following the administration of 200mg Mifepristone orally.

4.0 Management of a Pregnancy with Fetal Abnormality

4.1 Women requesting a termination for a fetal abnormality at less than 14 weeks must be managed using the clinical guidance in these guidelines.

4.2 Pregnancy Loss midwife must be informed of all TOP's for fetal abnormality

4.3 If having medical management the patient may be managed and cared for on the on the labour ward if felt appropriate following discussion with the midwife in charge.

5.0 Clinical Assessment

5.1 To be seen in clinic by consultant/registrar gynaecologist in gynae out-patient department

5.2 A copy of the ultra sound scan must be available to confirm intrauterine pregnancy. If this is not available then an ultrasound scan must be arranged.

5.3 During the consultation the consultant must ensure a full clinical assessment including medical history is carried out and the following documents are completed:

- **Form HSA1; abortion act certificate A (Appendix B)**
  (To be signed by 2 qualified medical practitioners) with the indication for TOP

- **BSUH NHS Trust consent form (Yellow)**
  Patients can only be consented for TOP by those clinicians competent to perform the procedure (designated consent is not permitted)

- **BSUH NHS Trust P1 consent for cremation for form**
  Must be signed by both the doctor and patient. This form acts as a histology request form hence a separate one is not required. It also acts as a legal document to allow cremation of fetal tissue. Ensure all clinical details and the qualification of the completing doctor is included on the form.

5.4 All women must have a pre-op assessment and admission booklet completed by the nursing staff in gynae outpatients department.

5.5 Take blood for full blood count and 2 separate group and save samples, 2nd sample must be within 5 days of admission.

5.6 Anti- D immunoglobulin G 500iu IM must be given to all nonsensitised RhD negative women within 72 hours of evacuation. Hence it is essential that all these women have their blood group checked at the initial consultation

5.7 All women must be screened for Chlamydia and paired bacteriology swabs (HVS and endocervical) are indicated. Antibiotic prophylaxis must be prescribed:
- Doxycycline 100 mg orally twice daily for 7 days starting on the day of abortion, **plus**
- Metronidazole 800 mg orally prior to or at the time of abortion

5.8 If pre-op nurse requires anaesthetic advice they are to contact the anaesthetic department on extension 4307 or request that the Doctor in clinic dictates a letter requesting urgent anaesthetic review and e-mail to: anaesthetic.admin@bsuh.nhs.uk

5.9 All women undergoing a termination of pregnancy must have a VTE risk assessment

5.10 Notes to be sent directly to the Day surgical unit for surgical TOP or L11 for medical TOP

6.0 Surgical Management of Termination of Pregnancy

6.1 Women should be counselled regarding the risks of the procedure including those of perforation (1 in 1000), bleeding (1 in 1000), infection (1 in 10) and repeat procedure (2 in 1000) as a result of incomplete evacuation.

6.2 Sample of products of conception must be sent to histology on all surgical terminations.

6.3 If no products are obtained at ERPC, contact the Consultant on-call whilst patient still anaesthetised and if after review no products are obtained, then follow-up with serial biochemistry is indicated.

6.4 The routine use of oxytocin for surgical TOP is not routinely recommended.

6.5 All Surgical TOP on women over 12 weeks of pregnancy should be discussed with the operating surgeon.

6.6 Form HSA 4 (Yellow Booklet): this form is to be completed immediately post TOP by the practitioner terminating the pregnancy. It must not be filed in the notes and should be and sent to Gynae Secretary Denise Hemsley on L11, this is then sent in a sealed envelope to:

The Chief Medical Officer,
Department of Health,
Richmond House,
79 White Hall,
London,
SW1A 2NS

6.7 Evidence

No accurate high quality data relating to individual risks of surgical evacuation of pregnancy. Overall complications rates are ~2%.

7.0 In-Patient Medical Management Of Termination Of Pregnancy 14 Weeks Or Less

7.1 Routine history and examination must be carried out, ruling out possible contra-indications to medical management;

- Uncontrolled severe asthma
- Suspected ectopic pregnancy
- Chronic adrenal failure
- Porphyria,
- Severe diarrhoea
- Anaemia (less than 9g/dl)

7.2 Severe uncontrolled asthma is classified as those cases not controlled with inhalers/medication and requiring hospital admission and /or steroids in the past year

7.3 Women with a pregnancy less than 14 weeks gestation should be given the option of in-patient medical management of termination of pregnancy unless clinically contra-indicated.

7.4 Before prescribing the Mifepristone (below) the prescribing doctor must check that certificate A has been completed.

7.5 Staff administering the mifepristone must both check certificate A has been completed with 2 signatures prior to administering Mifepristone.

7.6 Those with a pregnancy with a CRL measurement of greater than 8 week size but less than 12 weeks can be managed using the following regimen:

- *Mifepristone 200mg orally on day 1 followed by 800mcg of Misoprostol per vaginum on day 3 (48 hours later)*

7.7 Those women with a pregnancy over 12 (up to 14 weeks) weeks can be offered medical management using the following regimen:

- *Mifepristone 200mg orally on day 1 followed by 5 doses of 400mcg Misprostol per vaginum on day 3 (48 hours later)*

7.8 Arrange to readmit to L11/Horsted Keynes 36-48 hours following Mifepristone

7.9 Failure to deliver after the first course, can be managed with a second course the following day.

7.10 Failure to deliver after this interval requires a consultant opinion. A third course should not be started for 24 hours or induction can be undertaken with amniotomy and syntocinon.

7.11 Following delivery of fetus continue Misoprostol until placenta delivers

7.12 If placenta not delivered 6 hours after last Misoprostol patient needs ERPC

7.13 If bleeding heavy following delivery of fetus use syntocinon infusion

7.14 **Evidence**
Combinations of mifepristone and Misoprostol are more successful than Misoprostol alone

7.15 Misoprostol is more successful than Cervagem

7.16 Overall success rates are greater than 90%

7.17 200mg of oral mifepristone is prescribed and must be taken by the patient in the presence of two clinicians (nursing or medical).

7.18 Codydramol 2 tablets to be taken 4 to 6 hourly PRN, max of 8 tablets a day should be prescribed for 4 days

7.19 Ibuprofen 400mg TDS should be recommended, in suitable patients, for use only if required (care with asthmatic patients). Patient to be advised to purchase over the counter.

7.20 Due to the high success rates of medical management, formal follow up in EPU is not required. Patients should be advised to do a home pregnancy test three weeks after the medication is given. If this is positive then they should contact EPU for follow up.

7.21 If at 3 weeks pregnancy test is still positive then a transvaginal ultrasound scan is indicated.

- If endometrial thickness is **greater than 15mm,** offer one week of expectant management *or* 600mcg Misoprostol PV and rescan in 1 week or consider ERPC.

7.22 Evidence

Medical evacuation is a safe alternative management shown to be acceptable to some patients.

7.23 It empowers these patients the choice of an alternative method to surgical evacuation.

7.24 The regime of 200mg Mifepristone PO followed by 800mcg of vaginal Misoprostol is associated with:

- high efficacy rates (complete evacuation) ~ 97%
- low failure rates ~ 0.5% (5 in 1000)
- high patient acceptability rates, greater than 90%

7.25 There is limited specific data on the number of ERPCs required following medical management, but is likely to be small overall and less than is seen with conservative management.

7.26 Form HSA 4 (Yellow Booklet): this form is to be completed immediately post TOP by the practitioner terminating the pregnancy. It must not be filed in the notes and should be and sent to Gynae Secretary Denise Hemsley on L11, this is then sent in a sealed envelope to:

The Chief Medical Officer
Department of Health
Richmond House
79 White Hall
London
SW1A 2NS

8.0 Discharge & Follow Up For Women Referred From BPAS

8.1 Following completion of termination of pregnancy it is the responsibility of the clinician carrying out the procedure to complete an electronic discharge summary.

8.2 A copy of this discharge summary must be sent to Gynae Secretary Denise Hemsley on L11 to be faxed to BPAS within 24 hours of discharge. Fax to: 01273 562337

8.3 All women must be entered on the TOP Dentrite Database

8.4 All counselling services and contraception advice will be offered at BPAS prior to termination of pregnancy

8.5 No hospital follow up is required

8.6 Written and verbal discharge information must be given to the patient on discharge

9.0 References

1. American Society of Anesthesiologists
2. The care of women requesting induced abortion. Evidence based guideline No 7. RCOG press 2011
3. The management of early pregnancy loss. RCOG Clinical Green Top Guideline. No 25. Published 2006. Addendum 2011.
4. Use of Anti-D Immunoglobulin for Rh Prophylaxis. RCOG Clinical Green Top Guideline. No 22. Revised May 2002.

Appendix A: ASA PS Catagory

ASA PS Category	Preoperative Health Status	Comments, Examples
ASA PS 1	Normal healthy patient	No organic, physiologic, or psychiatric disturbance; excludes the very young and very old; healthy with good exercise tolerance
ASA PS 2	Patients with mild systemic disease	No functional limitations; has a well-controlled disease of one body system; controlled hypertension or diabetes without systemic effects, cigarette smoking without chronic obstructive pulmonary disease (COPD); mild obesity, pregnancy
ASA PS 3	Patients with severe systemic disease	Some functional limitation; has a controlled disease of more than one body system or one major system; no immediate danger of death; controlled congestive heart failure (CHF), stable angina, old heart attack, poorly controlled hypertension, morbid obesity, chronic renal failure; bronchospastic disease with intermittent symptoms
ASA PS 4	Patients with severe systemic disease that is a constant threat to life	Has at least one severe disease that is poorly controlled or at end stage; possible risk of death; unstable angina, symptomatic COPD, symptomatic CHF, hepatorenal failure
ASA PS 5	Moribund patients who are not expected to survive without the operation	Not expected to survive > 24 hours without surgery; imminent risk of death; multiorgan failure, sepsis syndrome with hemodynamic instability, hypothermia, poorly controlled coagulopathy
ASA PS 6	A declared brain-dead patient who organs are being removed for donor purposes	

Source: American Society of Anesthesiologists

Appendix B - Certificate A

IN CONFIDENCE

CERTIFICATE A

ABORTION ACT 1967

Not to be destroyed within three years of the date of operation

Certificate to be completed before an abortion is performed under Section 1(1) of the Act

I,

……
……

(Name and qualifications of practitioner in block capitals

of

……
……

……
……

(Full address of practitioner)

Have/have not* seen/and examined* the pregnant woman to whom this certificate relates at

……
……

……
……

(full address of place at which patient was seen or examined)

on

……
……

and I

……
……

(Name and qualifications of practitioner in block capitals)

of……
……

……
……

(Full address of practitioner)

Have/have not* seen/and examined* the pregnant woman to whom this certificate relates at

……
……

……
……
(Full address of place at which patient was seen or examined)

on
……
……

We hereby certify that we are of the opinion, formed in good faith, that in the case

of
……
……
(Full name of pregnant woman in block capitals)

of
……
……

……
…… (Usual place of residence of pregnant woman in block capitals)

(Ring appropriate letter(s))

A the continuance of the pregnancy would involve risk to the life of the pregnant woman greater than if the pregnancy were terminated;

B the termination is necessary to prevent grave permanent injury to the physical or mental health of the pregnant woman;

C the pregnancy has NOT exceeded its 24th week and that the continuance of the pregnancy would involve risk, greater than if the pregnancy were terminated, of injury to the physical or mental health of the pregnant woman;

D the pregnancy has NOT exceeded its 24th week and that the continuance of the pregnancy would involve risk, greater than if the pregnancy were terminated, of injury to the physical or mental health of any existing child(ren) of the family of the pregnant woman;

E there is a substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped.

This certificate of opinion is given before the commencement of the treatment for the termination of pregnancy to which it refers and relates to the circumstances of the pregnant woman's individual case.

Signed ..... **Date** .....

Signed ..... **Date**.....
* Delete as appropriate DdDH005329 4/94 C8000 CC38806

Form HSA1 (revised 1991)