Outpatient Medical Management of Miscarriage in the First Trimester of Pregnancy using Mifepristone and Misoprostol

(This guideline is for use in women with gestations up to 9 weeks)

This guidance does not override the individual responsibility of health professionals to make appropriate decision according to the circumstances of the individual patient in consultation with the patient and /or carer. Health care professionals must be prepared to justify any deviation from this guidance.

Lead Clinician(s)

Mamta Pathak	Consultant Gynaecologist
Approved by *Gynaecology Governance Meeting* on:	12th January, 2024
Approved by Medicines Safety Committee on: *Where medicines included in guideline*	8th May, 2024
Review Date: This is the most current document and should be used until a revised version is in place	12th January, 2027

Key amendments to this guideline

Date	Amendment	Approved by:
29th December, 2023	Document extended for six months whilst under review	Alex Blackwell
12th January, 2024	Approved at Gynaecology Governance	Directorate
8th May, 2024	Approved at Medicine Safety Committee	MSC

Introduction

Miscarriage affects 10-20% of all pregnancies and therefore contributes significantly to the emergency gynaecology caseload. It is also a significant negative life event for many affecting both physical, emotional and psychological welfare.

After thorough clinical assessment including ultrasound scan and counselling, patients should be offered a choice in how their miscarriage is managed to support positive quality of life outcomes. Options for miscarriage management include; expectant, medical and surgical management. Surgical management may be either evacuation of retained products of conception (ERPOC) under a general anaesthetic or Manual Vacuum Aspiration (MVA) under local anaesthetic in Emergency Gynaecology Assessment Unit (EGAU).

Please also refer to the Guideline for the Management of Bleeding in Early Pregnancy and Early Pregnancy Loss.

In the last 10 years, management of miscarriage has changed, with more treatment on an outpatient basis and the development of more refined diagnostic techniques and therapeutic interventions. Medical management of miscarriage is an effective alternative for the management of confirmed first trimester miscarriage without any suspicion of molar pregnancy. Patients with missed, delayed or silent miscarriage or early fetal demise (previously known as an anembryonic pregnancy or blighted ovum) as well as those with retained products of conception after incomplete miscarriage should be offered medical management. For patients with chronically retained placental tissue >15 mm with symptoms, surgical treatment should be offered as medical treatment is unlikely to be helpful in these cases.

The advantage of medical management of miscarriage is that this can be carried out from an outpatient setting (EGAU) and hence this option avoids surgical intervention, hospital admission and associated anaesthetic complications.

Misoprostol has a proven efficacy for the medical management of miscarriage but it is not licensed for this indication. It is however widely known for its low incidence of side effects and cost effectiveness. It is widely available and easy to store since it does not need refrigeration. The success rate for completing a miscarriage using Misoprostol is roughly 75-80%[1]. In the most recent WAHT audit, the success rate was 64%.

New evidence suggests that the combination of Mifepristone and Misoprostol in missed miscarriage reduces the failure of the gestational sac to spontaneously pass by 7 days, and reduces the need for surgical intervention to complete the miscarriage up to and after 7 days, compared to Misoprostol alone.

1. Criteria for outpatient management

- Crown Rump Length (CRL) of 23 mm or less with confirmed diagnosis of miscarriage
- Mean sac diameter 5 cm or less
- Incomplete miscarriage with AP diameter of >3 cm

NB. In borderline cases where the patient is keen for outpatient management of miscarriage discuss with the consultant on-call before offering treatment

NB. Patients above 9 weeks who are keen to avoid surgery and would prefer medical management should be admitted in a bereavement room.
Please follow the pathway WAHT-TP-027 (Medical management of mid-trimester miscarriage)

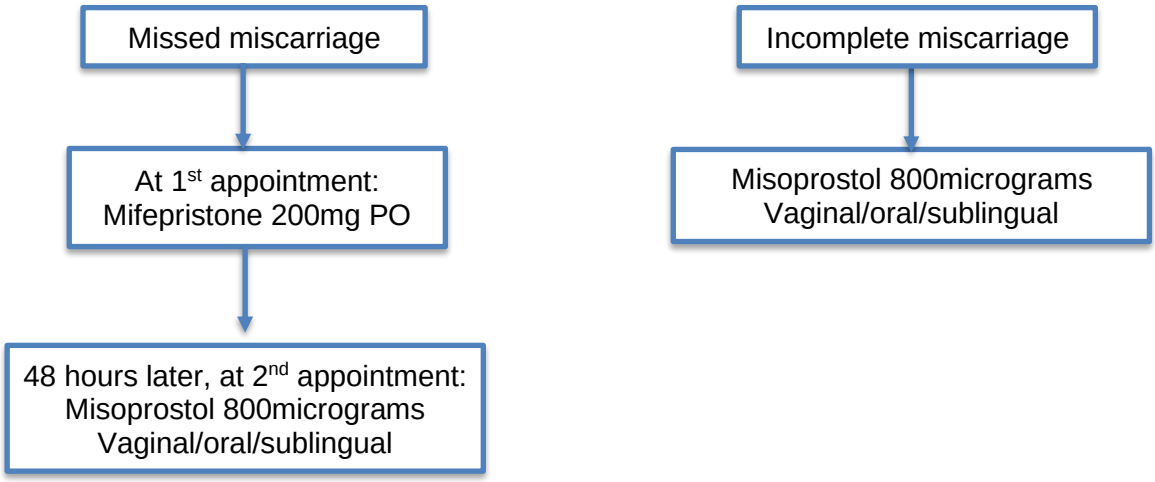
Details of Guideline

Diagnosis of a missed, delayed or silent miscarriage may be given by:

- Early Pregnancy Assessment Unit (EPAU)
- Emergency Gynaecology Assessment Unit
- Ultra Sound Scan Department (USS)
- Antenatal Clinic (ANC)

The patient (+/- partner as per patient choice) will be reviewed by EGAU/EPAU staff who will:

- Explain the diagnosis and treatment options
- Provide the patient with written information and details of The Miscarriage Association
- Explain the procedure, including the fact that this is an unlicensed indication for Mifepristone and Misoprostol and answer any questions that patient may have
- Explain the success rate, potential complications and side effects
- Take bloods for Full Blood Count and Group and Save
- Obtain informed consent, completing the consent form with the patient (including information on the unlicensed use of Misoprostol)
- Consent form to state “Medical management of miscarriage with Misoprostol”.
- If missed miscarriage, **at first appointment, administer Mifepristone 200mg PO stat** and make a further appointment for 48 hours’ time to administer Misoprostol as per below flowchart
- If incomplete miscarriage, do not offer Mifepristone, proceed to dose of Misoprostol as per below flowchart



- On-call doctors for Gynaecology to prescribe medications including regular analgesia and anti-emetics

- At **second appointment, administer 800 micrograms** (4 tablets) of Misoprostol, vaginally (into posterior fornix), to reduce Gastro-intestinal side-effects. Misoprostol may be administered orally or sublingually if patient declines vaginal route. This can be carried out in the EPAU or EGAU
- Misoprostol is currently stored in the Controlled Drugs cupboard on EGAU
- Observe patient for 30 minutes following administration of medications, record blood pressure, pulse rate and temperature before allowing home
- Open access to EGAU and contact number with safety-net advice to be given before the patient is allowed home
- Provide information pack and To Take Out (TTO) pack of Ibuprofen, Co-Codamol and Cyclizine
- Where suitable, and if TTO packs of Misoprostol are available, these may be dispensed from the clinical area to the patient to take home, according to MedPolSOP01

2. Contraindications and Cautions

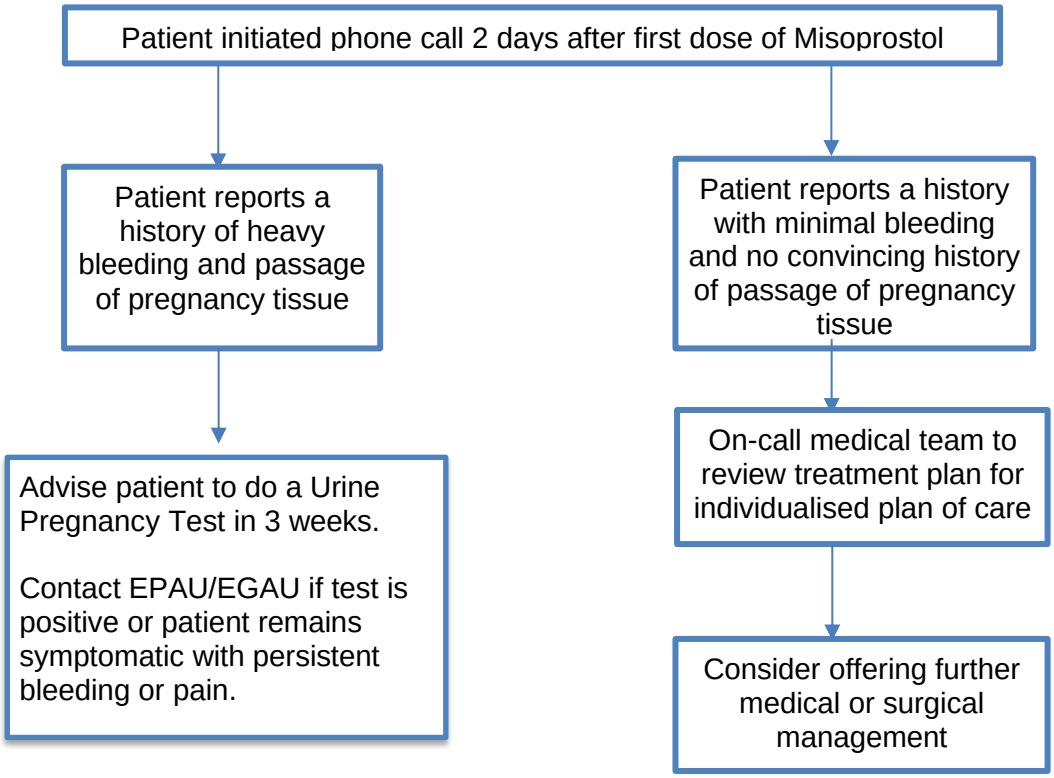
- Suspected molar pregnancy
- Ectopic pregnancy or pregnancy of unknown location
- Haemodynamically unstable with significant anaemia i.e. Hb<100
- Uncontrolled severe asthma
- Chronic adrenal failure
- Known or suspected heart disease
- Glaucoma
- Haemoglobinopathies
- Haemorrhagic disorders and anti-coagulation therapy (aspirin accepted)
- Adrenal suppression and long term glucocorticoid therapy (may require corticosteroid)
- Patient living in remote areas with difficulty in accessing hospital
- Inflammatory bowel disease
- Previous classical Caesarean section or uterine surgery

3. Serious or frequent risks

- With advanced gestation and increased size of gestation sac, pain and bleeding may be more severe
- Occasionally, patients may need to be admitted for stronger pain relief (2-32%)
- Common side effects include fever, shivering, nausea (1.4–30%) or diarrhoea (4-65%)
- Patients may have excessive bleeding requiring blood transfusion
- Emergency surgical treatment may be required

4. Follow-up

Patient to be advised to call EPAU/EGAU 2 after days after initiation (first dose) of Misoprostol



5. Examination of Products of Conception (POC) Consent

- Use the Pregnancy Tissue Examination Consent Form to take consent for the examination of the POC as appropriate. All sections of this form should be completed in full
- A copy of this form must be emailed to the Bereavement Support Midwives (BSM) (wah-tr.bereavementmidwives@nhs.net) or put in the BSM folder on EGAU
- All POC's being sent to the Histopathology lab. for histological examination must be sent in Formalin and must have 2 accompanying forms:
    - an ICE request (under the histopathology tab). Please specify if the POC is for cytogenetic testing or histological examination
    - a copy of the 'Pregnancy Tissue Examination Consent Form'

- All POC sent for cytogenetic testing (after 3 or more consecutive miscarriage) must be sent in a dry pot and must have 3 accompanying forms:
    - an ICE request (under the histopathology tab). Please specify that the POC are for cytogenetic testing
    - a West Midlands Regional Genetics Laboratory 'Rare Disease and Reproductive Genomics Test Request Form' (appendix 2)

- a copy of the 'Pregnancy Tissue Examination Consent Form'

- A copy of the Pregnancy Tissue Examination Consent Form should be scanned into the medical notes and a copy retained by the patient

Anti-D

- Routine Anti-D prophylaxis is not required if miscarriage management is solely medical without uterine instrumentation in the first trimester.

Discharge of Patients

- Nursing staff to ensure patient has the opportunity to discuss any concerns and be advised about indications for follow up. Open access to EGAU and contact number with safety-net advice to be given before the patient is allowed home
- Following diagnosis of miscarriage, nursing staff must:
  - The pregnancy is closed on Badgernet
  - Pregnancy related appointments are cancelled on PAS (IT system)
  - Miscarriage notification form (Appendix 4)
  - Miscarriage check list is completed (Appendix 3)

Appendices

1. Telephone follow-up for outpatient medical management of miscarriage
2. Nursing protocol for the medical management of first trimester miscarriage
3. Miscarriage check list
4. Miscarriage notification form
5. Instruction on administration of Misoprostol sublingually

Appendix 1

Telephone follow-up for outpatient medical management of miscarriage. Please complete this while performing the telephonic follow-up

Patient name:
Hospital number:
Date of birth:
NHS No:
Consultant:
Hospital: KTC WRH ALX

Parity:
Gestation: Maximum sac diameter: CRL

Initial attendance date :

Diagnosis on scan: Incomplete miscarriage
Missed miscarriage
Blighted ovum

Treatment:
Mifepristone 200mg PO date:
Misoprostol 800microgram PV dose 1 date:
Misoprostol 800 microgram PV dose 2 date:

Follow up Day 2 (Phone) EPAU/Gynae ward

	Day 2		
Likely complete miscarriage	Yes		No
Pain	Mild	Moderate	Severe
Bleeding	Light	Moderate	Heavy
2nd line treatment offered	Conservative	Medical	Surgical

Appendix 2

GYNAECOLOGY SERVICES
WORCESTERSHIRE ACUTE HOSPITALS NHS TRUST

NURSING PROTOCOLS FOR THE MEDICAL MANAGEMENT OF FIRST TRIMESTER MISCARRIAGE

ADMINISTRATION OF CERVICAL PREPARATION PRIOR TO MEDICAL (OR SURGICAL) MANAGEMENT OF FIRST TRIMESTER MISCARRIAGE

Having a miscarriage is an extremely traumatic experience, both emotionally and physically. Our aim as nurses within gynaecology is to provide a service that is dedicated to promoting a safe, comfortable environment for our patients from admission to discharge to ensure that everyone is treated in a professional manner and with respect at all times.

Cervical preparation is an invasive procedure and can be very distressing for the patient. It is apparent that if administration of the cervical preparation could be delivered by nursing staff as part of the continuous care it would minimise the number of contacts the patient receives and promote this as a nurse led service.

In 1992 the Nursing Standard stated

"Administration of abortifacient drugs by the nurse is seen as an extended role. The individual nurse must take responsibility for ensuring and maintaining his or her competence"

It is therefore necessary to establish a protocol to protect both the patient and nurse with regards to the administration of cervical preparations prior to medical management of miscarriage (or the cervical priming prior to surgical management of miscarriage).

These protocols should be used in conjunction with existing guidelines for practice.

PROTOCOL 1

NURSE INSERTION OF CERVICAL PREPARATIONS (MISOPROSTOL)

Criteria for undertaking the procedure:
1. The nurse must be a first level registered nurse with a minimum of 6 months experience in Gynaecology.
2. An experienced gynaecology nurse with a relevant women's health qualification must assess the nurse as competent.
3. Prior to assessment the nurse must have read and understood the protocol and have documented evidence of their competency.
4. Prior to administration the nurse must check that the consent form is signed and that the patient is fully aware of the procedure.

GUIDELINES FOR PRACTICE
NURSE INSERTION OF CERVICAL PREPARATIONS (MISOPROSTOL)

Process:

PROCEDURE	RATIONALE
The nurse will explain the procedure and include the possible side effects of the drugs prior to administration.	To reduce patient anxiety through information and obtain the patients consent and co-operation.
Initial observations of temperature, pulse and blood pressure will be recorded prior to the administration of cervical preparations.	To obtain baseline recordings.
Collect all equipment for the procedure: Gloves, tray, water for lubrication, incontinence sheet, sanitary towel, disposable pants and tissues.	To be prepared and organised thus preventing delays to procedure.
Ask patient to empty her bladder prior to commencing the procedure.	To prevent discomfort during procedure and allow the drugs to be absorbed post insertion.
Position patient supine with knees drawn up and legs parted.	To facilitate insertion of the pessary/tablets and ensure patient comfort.
Wash hands with bactericidal soap and water. Dry hands well. Put on gloves.	To minimise the risk of cross infection in accordance with the Trust Infection Control Policy.
Moisten tablets in water as per manufacturer's recommendations	To facilitate insertion of drug and ensure patient comfort.
Separate the labia and insert the drug using the middle finger along the posterior vaginal wall into the posterior fornix, or as far as able to ensure tablets are inserted high into the vagina.	To ensure the medication is retained and can reach its maximum efficiency.
Offer to wipe away excess water and provide patient with sanitary pad and disposable pants if required.	To maintain patient comfort.
Record drug administration on drug chart.	According to Trust Drug Policy.
Advise patient to stay in bed for ½ hour post insertion of tablets.	To retain medication and maximise absorption.

Appendix 3
Miscarriage Checklist

Worcestershire NHS
Acute Hospitals NHS Trust

MISCARRIAGE CHECKLIST

This form should be completed by the nurse discharge a patient following both first and second trimester pregnancy loss (surgical or medical management), and following ectopic pregnancy.

Please attach patient sticker here or record:

Name:.....

Unit No:

NHS No:

D.O.B: ...../...../.....

Gender: Female Male Cons: .....

CHECK	YES	NO	SIGN and DATE/TIME
Has the patient been back from theatre for 3-4 hours?			
Are the patient's systemic observations within normal limits?			
Check PV loss. Ensure this is not heavier than the patient's normal period.			
Is the patient passing clots?			
Has the patient taken diet and fluids without any nausea and vomiting?			
Has the patient passed urine?			
Does the patient feel dizzy or faint whilst mobilising?			
Have diet and fluids been tolerated?			
Has the cannulae been removed?			
Has the patient got a responsible adult to collect and escort her home?			
Adult to remain with patient over night.			
Relevant information leaflet given: • Miscarriage Association Pregnancy Loss • Late Miscarriage			
TTOs given to patient as required.			
Explanation of how to administer TTOs given			
Miscarriage notification form completed			
Discharge advice given prior to discharge relating to surgery and anaesthetic			
OP appointment arranged			
Check blood group			
Anti-D given if appropriate			
Contact and cancel any appointments: • Antenatal Clinic • Ultrasound Scan • Community Midwife			
Patient aware of Book of Remembrance/Pebble Pool			

Signature of Nurse: ..... Designation: .....

To be filed with : .....

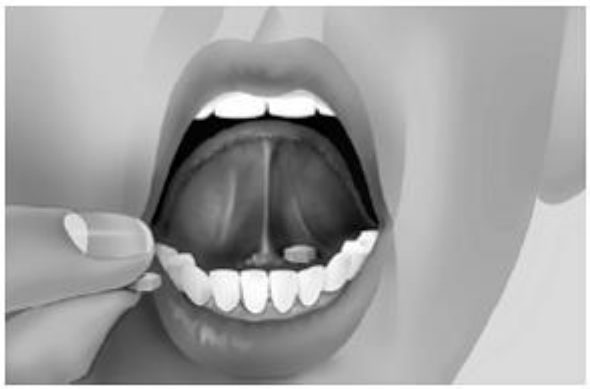
Miscarriage checklist/June 2008

Appendix 4
Miscarriage Notification

Miscarriage notification (to be sent to WRH ANC)		
First Name:	Surname:	NHS Number:
Date of Birth: Telephone number:	Address:	
GP Details:		
Gestation of pregnancy:	Management of miscarriage:	
If registered on Badgernet, please confirm pregnancy closed: Sign …… Print …… Date…….		
Additional notes e.g. any onward referrals made?		

Miscarriage notification (to be sent to GP)		
First Name:	Surname:	NHS Number:
Date of Birth: Telephone number:	Address:	
GP Details:		
Gestation of pregnancy:	Management of miscarriage:	
Notes to GP:		

Appendix 5
Instruction on Administration of Misoprostol Sublingually



1. Make sure the patient is seated

- The person taking sublingual misoprostol should be in an upright, comfortable seated position. This is important for ensuring proper administration of the dose and preventing accidental swallowing of the medication.

2. Rinse the mouth before administration

- Rinse the mouth out with clean water and spit the water out before administering the dose of sublingual misoprostol. This will aid the mucous membranes in the mouth in absorbing the medication faster.

3. Place two misoprostol tablets under each side of the tongue.

- Position the sublingual tablets of misoprostol under the tongue (two tablets of 200mcg misoprostol on either side of the tongue= total 800mcg dose misoprostol) so that they are completely covered by the tongue.
- If repositioning of the tablets are required, make sure under that the tablets are completely covered by the tongue
- Advise the patient that the tablets of misoprostol may cause a chalky taste in the mouth.
- Advise the patient that the tablets can cause headache, gastrointestinal effects, cramping in the pelvis and vaginal bleeding.

4. Allow the tablets to dissolve.

- Wait for the tablets to dissolve. The patient should remain in the GAU/EPAU for 30 minutes
- After 15 minutes any remaining fragments of the misoprostol can be swallowed with a drink of water.
- The patient may go home if no concerns.

Monitoring

Page/ Section of Key Document	Key control:	Checks to be carried out to confirm compliance with the Policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: *(Responsible for also ensuring actions are developed to address any areas of non-compliance)*	Frequency of reporting:
	WHAT?	**HOW?**	**WHEN?**	**WHO?**	**WHERE?**	**WHEN?**
	These are the 'key' parts of the process that we are relying on to manage risk. We may not be able to monitor every part of the process, but we MUST monitor the key elements, otherwise we won't know whether we are keeping patients, visitors and/or staff safe.	What are we going to do to make sure the key parts of the process we have identified are being followed? (Some techniques to consider are; audits, spot-checks, analysis of incident trends, monitoring of attendance at training.)	Be realistic. Set achievable frequencies. Use terms such as '10 times a year' instead of 'monthly'.	Who is responsible for the check? Is it listed in the 'duties' section of the Policy? Is it in the job description?	Who will receive the monitoring results? Where this is a committee the committee's specific responsibility for monitoring the process must be described within its terms of reference.	Use terms such as '10 times a year' instead of 'monthly'.

References

[You should include external source documents and other Trust documents that are related to this Policy]

Contribution List

Contribution List

This key document has been circulated to the following individuals for consultation;

Designation

This key document has been circulated to the chair(s) of the following committee's / groups for comments;

Committee

Supporting Document 1 - Equality Impact Assessment Tool

To be completed by the key document author and included as an appendix to key document when submitted to the appropriate committee for consideration and approval.

Please complete assessment form on next page;

NHS Worcestershire Acute Hospitals NHS Trust

Herefordshire & Worcestershire STP - Equality Impact Assessment (EIA) Form
Please read EIA guidelines when completing this form

Section 1 - Name of Organisation (please tick)

Herefordshire & Worcestershire STP		Herefordshire Council		Herefordshire CCG	
Worcestershire Acute Hospitals NHS Trust		Worcestershire County Council		Worcestershire CCGs	
Worcestershire Health and Care NHS Trust		Wye Valley NHS Trust		Other (please state)	

Name of Lead for Activity	

Details of individuals completing this assessment	**Name**	**Job title**	**e-mail contact**
Date assessment completed			

Section 2

Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.)	**Title:**			
What is the aim, purpose and/or intended outcomes of this Activity?				
Who will be affected by the development & implementation of this activity?	❑ Service User ❑ Patient ❑ Carers ❑ Visitors		❑ Staff ❑ Communities ❑ Other _____	
Is this:	❑ Review of an existing activity			

	❑ New activity ❑ Planning to withdraw or reduce a service, activity or presence?
What information and evidence have you reviewed to help inform this assessment? (Please name sources, eg demographic information for patients / services / staff groups affected, complaints etc.	
Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required)	
Summary of relevant findings	

Section 3

Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. **Please tick one or more impact box below for each Equality Group and explain your rationale**. Please note it is possible for the potential impact to be both positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Age				
Disability				
Gender Reassignment				
Marriage & Civil Partnerships				
Pregnancy & Maternity				
Race including Traveling Communities				
Religion & Belief				
Sex				
Sexual Orientation				
Other Vulnerable and				

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Disadvantaged Groups (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.)				
Health Inequalities (any preventable, unfair & unjust differences in health status between groups, populations or individuals that arise from the unequal distribution of social, environmental & economic conditions within societies)				

Section 4

What actions will you take to mitigate any potential negative impacts?	Risk identified	Actions required to reduce / eliminate negative impact	Who will lead on the action?	Timeframe
		.		
How will you monitor these actions?				
When will you review this EIA? (e.g in a service redesign, this EIA should be revisited regularly throughout the design & implementation)				

Section 5 - Please read and agree to the following Equality Statement

1. Equality Statement

1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9 protected characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation

1.2. Our Organisations will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.

1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carer's etc, and as such treat them and members of the workforce respectfully, paying due regard to the 9 protected characteristics.

Signature of person completing EIA	
Date signed	
Comments:	
Signature of person the Leader Person for this activity	
Date signed	
Comments:	

Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	
2.	Does the implementation of this document require additional revenue	
3.	Does the implementation of this document require additional manpower	
4.	Does the implementation of this document release any manpower costs through a change in practice	
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	
	Other comments:	

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval.