

Maternity - Management of Early Pregnancy Complications

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Summary Provides policy direction for Early Pregnancy Assessment Services and Emergency Departments in the management of early pregnancy complications.

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This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is **mandatory** for NSW Health and is a condition of subsidy for public health organisations.

MATERNITY - MANAGEMENT OF EARLY PREGNANCY COMPLICATIONS

PURPOSE

This is a policy for maternity services with respect to the management of early pregnancy complications in Early Pregnancy Assessment Services (EPAS). It also acts as a guide as to what is deemed suitable for ambulatory management.

This policy provides information related to the diagnosis and clinical management of women with early pregnancy loss, defined as a loss within the first 12 completed weeks of pregnancy. It mainly addresses the management of spontaneous miscarriage, but is also relevant to women affected by ectopic pregnancy and gestational trophoblastic disease, although specific guidelines for these conditions should be examined separately.

This policy recognises the importance and value of a dedicated outpatient EPAS within hospitals, as the EPAS has been shown to provide clinical benefits.

It is recognised that EPAS may care for women between 12 to 20 weeks gestation. However, the clinical and psychological needs of such women are often different compared to those with early pregnancy complications. Consideration needs to be given to a lower threshold for admission to hospital to ensure that such clinical and psychological needs can be met. The carers in environments to which such women are admitted need to be cognisant of the particular clinical and psychological needs of these women.

MANDATORY REQUIREMENTS

The place of the different diagnostic modalities must be clearly defined within service-specific algorithms (Appendix B), and the full range of therapeutic options (expectant and surgical) must be available to women who miscarry whenever possible. Apart from certain specific clinical circumstances, women should be able to choose their preferred method of management.

All maternity services must provide or be networked to a dedicated outpatient Early Pregnancy Assessment Service (section 2).

IMPLEMENTATION

Chief Executives or delegated officers are to ensure a written local protocol is in place and implemented as described in this policy.

Health professionals in all relevant health care settings must be familiar with the various diagnostic tools necessary to help delineate viable from non-viable pregnancy and ectopic from intrauterine pregnancy.

Maternity services and Emergency Departments must ensure that there are appropriate local policies and algorithms for each therapeutic intervention with clearly outlined pathways for each of the options available.

All health professionals must be aware of the psychological sequelae associated with pregnancy loss and must provide support, follow-up and access to formal counselling when necessary (section 5).

REVISION HISTORY

Version	Approved by	Amendment notes
September 2009 (PD2009_058)	Director-General	New policy addressing the management of early pregnancy complications
May 2012 (PD2012_022)	Deputy Director-General Population Health	Replaces PD2009_058 with updated clinical advice

ATTACHMENTS

1. Maternity – Management of Early Pregnancy Complications - Procedures.

**Maternity - Management of Early Pregnancy
Complications**



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1 INTRODUCTION

This Policy Directive is based on The Women's Hospitals Australasia's *Management of Early Pregnancy Loss Clinical Practice Guideline* (2008). The complete guideline can be found at

<http://www.midwives.org.au/lib/pdf/documents/Mgt%20of%20Early%20Pregnancy%20Loss%20CPG.pdf>

This policy directive should be read in conjunction with:

- PD2005_406 Consent to Medical Treatment – Patient information
- PD2005_341 Human Tissue - Use/Retention, including Organ Donation
- PD2005_066 Provision of folate – folic acid supplementation for pregnant women and prevention of neural tube defects.
- PD2006_074 RhD immunoglobulin (Anti D)

The Woman's Hospitals of Australasia Clinical Practice Guideline (2008) was adapted from the Green-top Guideline No. 25, Management of Early Pregnancy Loss, October 2006, produced by the Royal College of Obstetricians and Gynaecologists (RCOG) of the United Kingdom.

This policy has been recommended for use in NSW by the Maternal and Perinatal Health Priority Taskforce and the Early Pregnancy Assessment Service Clinical Advisory Group.

1.1 Types of Evidence defined

The definitions of the types of evidence used in the original RCOG Guideline, come from the US Agency for Health Care Policy and Research (AHCPR). Where possible, recommendations are based on, and explicitly linked to, the evidence that supports them. Areas lacking evidence are annotated as 'good practice' points. Refer Appendix A.

1.2 Purpose and scope

This is a policy for maternity services with respect to the management of early pregnancy complications in Early Pregnancy Assessment Services (EPAS). It also acts as a guide to Emergency Departments as to what is deemed suitable for ambulatory management.

This policy provides information related to the diagnosis and clinical management of women with early pregnancy loss, defined as a loss within the first 12 completed weeks of pregnancy. It mainly addresses the management of spontaneous miscarriage, but is also relevant to women affected by ectopic pregnancy and gestational trophoblastic disease, although specific guidelines for these conditions should be examined separately.^{2,3,4}

This policy recognises the importance and value of a dedicated outpatient Early Pregnancy Assessment Service (EPAS) within hospitals, as the EPAS has been shown to provide clinical benefits¹².

It is recognised that EPAS may care for women between 12 to 20 weeks gestation. However, the clinical and psychological needs of such women are often different to those with early pregnancy complications. Consideration needs to be given to a lower threshold for admission to hospital to ensure that such clinical and psychological needs can be met. The health professionals in the environment in which such women are

admitted must be cognisant of the particular clinical and psychological needs of these women.

The place of the different diagnostic modalities must be clearly defined within service-specific algorithms (refer Appendix B), and the full range of therapeutic options (expectant and surgical) must be available to women who miscarry whenever possible. And apart from certain specific clinical circumstances, women should be able to choose their preferred method of management.

Chief Executives or delegated officers are to ensure a written local protocol is in place and implemented as described in this policy.

Health professionals in all relevant health care settings must be familiar with the various diagnostic tools necessary to help delineate viable from non-viable pregnancy and ectopic from intrauterine pregnancy.

Maternity services must ensure that there are appropriate local policies and algorithms as above for each therapeutic intervention with clearly outlined pathways for each of the options available.

All health professionals must be aware of the psychological sequelae associated with pregnancy loss and must provide support, follow-up and access to formal counselling when necessary (section 5).

It is acknowledged that Specialist Obstetricians & Gynaecologists and GP Obstetricians have been and will continue to provide such services. The algorithms in this document are also appropriate for their use.

1.3 Background

Miscarriage occurs in 10 to 20% of clinical pregnancies⁵ and accounts for 55,000 couples experiencing early pregnancy loss each year in Australia.⁶

While the rate of miscarriage has remained fairly predictable, better diagnostic and therapeutic interventions have changed standard treatments; what once was 'routine surgical evacuation' has become less so.¹ In the last five years, with the advent of more refined diagnostic techniques and therapeutic interventions, treatment is now provided more and more on an outpatient basis, in both GP and outpatient hospital settings.⁷

In addition to the obvious medical (and possibly surgical) implications of miscarriage, research over the last two decades indicates that significant psychological effects can occur in women who suffer a miscarriage,^{8,1} while further research has shown that appropriate support during and after the event can have positive, lasting effects.⁸

Changes in medical terminology for miscarriage were recommended as early as ten years ago^{9,10} however many textbooks and research articles continue to use terminology which women find distressing. In this policy the medical terminology has been reviewed and the preferred terminology has been recommended.

This policy is primarily aimed at health professionals from all disciplines and managers who support women at the time of pregnancy loss.

1.4 Appropriate terminology

**The recommended medical term for pregnancy loss less than 20 weeks in Australia and New Zealand is ‘miscarriage’.
The word miscarriage should be used in clinical practice.**

C

The inadvertent use by health professionals of inappropriate terms such as ‘pregnancy failure’, or ‘**incompetent** cervix’ can contribute to women’s negative self-perceptions and worsen any sense of failure, shame, guilt and insecurity related to the miscarriage.⁹

Evidence
Level IV

It is important to note that the terminology that describes different types of clinical miscarriage (e.g. ‘incomplete’ or ‘missed’) remains relevant, as medical interventions vary depending on the type of miscarriage. Appendix C outlines both revised terms and terms recommended for use with women experiencing an early pregnancy loss.

2 SERVICE PROVISION

2.1 What is the ideal setting for assessment of women with possible diagnosis of early pregnancy loss?

All maternity services must provide or be networked to a dedicated outpatient early pregnancy assessment service (EPAS). There are clinical benefits associated with this type of service.

Management of women with threatened or actual early pregnancy loss can be streamlined with the implementation of EPAS, with improvement in the efficiency of the service and quality of care. Admission to hospital was shown to be avoided in the UK by 40% of women, with a further 20% requiring shorter hospital stay.¹²

Dedicated EPAS have been established in various locations across NSW. These services in general augment existing hospitals and non hospital services for women with early pregnancy problems. It is acknowledged that Specialist Obstetricians & Gynaecologists and GP Obstetricians have been and will continue to provide such services. It is recognised that lower role delineated facilities across the State will have established pathways for dealing with early pregnancy problems. For such services networking to a dedicated EPAS for consultation is recommended with referral only where required.

2.2 What are the requirements for running an effective early pregnancy assessment service (EPAS)?

To be effective, an EPAS requires the following:

- an appointments system,
- a discrete waiting area and appropriate consultation room
ultrasound equipment (including transvaginal probes) or access to ultrasound evaluation,
- easy access to laboratory facilities for rhesus antibody testing, selective serum human chorionic gonadotrophin (hCG), and ideally progesterone estimation.¹³

Evidence
Level IV

The EPAS should be available on a daily basis during the normal working week, and if possible, services available on weekends and after hours.

There must be written pathways for clinical management, clearly defined lines of communication, governance, and accountability for clinical practice.

Inclusion and/or exclusion criteria for the EPAS should be delineated by the facility and should include guidance for appointment booking (i.e. with referral only or self-referral).

Standardised patient information leaflets, referral and transfer of care (discharge) letters must also be readily available, utilised, and regularly reviewed.

√

3 DIAGNOSIS AND INVESTIGATION

Diagnosis is made through a combination of patient history, physical examination and clinical investigation.

√

3.1 What is the role of transvaginal ultrasound in the EPAS setting?

EPAS should have access to transvaginal ultrasound with staff appropriately trained and credentialed in its use.

C

Transvaginal scanning will be required in the majority of women referred to an EPAS. Ultrasound assessment is particularly reliable in confirming the diagnosis of complete miscarriage (positive predictive value 98%).¹⁴ The sonographer should be formally trained in the use of both transabdominal (TAS) and trans-vaginal ultrasound (TVS), as TAS and TVS are complementary and the appropriate modality should be used.

Ideally, ultrasound reports should use standardised documentation (see Appendix D for sample report). Ultrasound practice is guided by the Australian Society of Ultrasound in Medicine, RANZCOG, other professional bodies, and local governance policies.

√

Appropriate infection control measures must be taken when disinfecting transvaginal ultrasound probes and facilities must ensure that there is strict adherence to current standards for disinfection.

√

3.2 How should cases of suspected early pregnancy loss be managed in the EPAS?

EPAS must use diagnostic and therapeutic algorithms of care. In particular, these must be available for the management of suspected ectopic pregnancy, intrauterine pregnancy of uncertain viability and for pregnancy of unknown location.

C

The use of the term ‘indeterminate’ is confusing and more specific definitions should be used, that is, ‘pregnancy of unknown location’ and ‘pregnancy of uncertain viability’.

✓

‘Indeterminate’ is a term used in clinical practice that has led to confusion. Some practitioners have used the term to mean ‘pregnancy of indeterminate site’ or ‘pregnancy of indeterminate viability’. Therefore the term ‘indeterminate’ should no longer be used, and replaced with the two separate terms ‘pregnancy of unknown location’ and ‘pregnancy of uncertain viability’ (see table 1 for definitions). Both terms should only be used after assessment by TVS.

Evidence Level IV

Even with expert use of TVS using agreed criteria, it may not be possible to confirm if a pregnancy is intrauterine or extra uterine in 8 – 31% of cases in the first visit. These women should be classified as having a ‘pregnancy of unknown location.’¹³ In specialised scanning services, the overall incidence of pregnancy of unknown location is as low as 8 – 10%.

Evidence Level IV

The number of cases falling into these two groups can be kept to a minimum by using a thorough and critical approach to TVS in conjunction with strict diagnostic criteria.¹⁷ The sonographer should record whether an ‘apparently empty’ sac is eccentrically placed in the fundus, whether it exhibits a ‘double-ring’ pattern, and so on. These findings will help to delineate whether this is likely to be an intra- or extra uterine pregnancy.

Evidence Level IV

A basic ultrasound diagnostic algorithm can be found in Appendix B. It includes terminology described above, with the aim of encouraging a consistent approach across EPAS. TVS is only one part of the diagnostic process in the assessment of potential early pregnancy loss. Women should be managed within a service-specific policy that includes the use of serum hCG assay. Several published guidelines for the diagnosis, management, and treatment of early pregnancy are available on which to base clinical practice.^{13,18}

Evidence Level IV

Serial serum hCG assay is particularly useful in the diagnosis of asymptomatic ectopic pregnancy.

B

3.3 What is the role of serial hCG assessment in predicting pregnancy outcome?

Modern monoclonal antibody based kits can detect hCG at 25 iu/l, a level reached nine days post conception (day 23 of a 28-day cycle).¹⁹ Service-specific discriminatory zones for serum hCG should be defined to help exclude possible ectopic pregnancy. At levels above 1500 iu/l, an ectopic pregnancy will usually be visualised with TVS.¹³ However,

Evidence Level III

the importance of levels that plateau below 1000 iu/l must be recognised. In these cases, pregnancy of unknown location and miscarriage are both possible outcomes. The potential for rarer diagnoses, such as gestational trophoblastic disease or cranial germ cell tumour, must be considered although, in these cases, serum hCG levels are likely to be greater than 1000 iu/l.¹³ In a study of 152 women with a history and TVS findings suggestive of complete miscarriage, serial hCG assessment revealed a 5.9% incidence of ectopic pregnancy.²⁰

Early ectopic pregnancy can be difficult to diagnose and access to serial serum hCG estimation is essential, with results available within 24 hours.⁷ Staff must be familiar with what is an acceptable normal rise in 48 hours. Although a doubling of hCG titre is often expected, this can vary depending on gestation.



Serum hCG levels need caution in interpretation. In cases of twin pregnancy or heterotopic pregnancy, a suboptimal rise may be misleading.

Women with miscarriage or ectopic pregnancy who are managed expectantly may also require serial serum hCG monitoring.

3.4. Does serum progesterone assay have a role in predicting pregnancy outcome?

Serum progesterone can be a useful adjunct when ultrasound suggests pregnancy of unknown location. TVS, serial serum hCG levels and progesterone may all be required in order to establish a definite diagnosis.

B

When ultrasound findings suggest pregnancy of unknown location, serum progesterone levels below 25 nmol/l are associated with pregnancies subsequently confirmed to be non-viable.^{13,21–24} However, care must be taken in terms of active intervention, and uterine evacuation should not be undertaken based on a low initial progesterone. Viable pregnancies have been reported with initial levels less than 15.9 nmol/l. In the presence of pregnancy of unknown location, a serum progesterone less than 20 nmol/l predicts spontaneous pregnancy resolution with a sensitivity of 93% and specificity of 94%. One advantage is that the need for formal uterine evacuation can be reduced if a policy of expectant management is adopted.

Levels above 25nmol/l are 'likely to indicate' and above 60 nmol/l are 'strongly associated with' pregnancies subsequently shown to be normal. Overall, it is not possible to define a specific discriminatory value for a single serum progesterone result that will allow absolute clinical confirmation of viability or non-viability.

If the pregnancy test is positive yet ultrasound is unable to visualize the pregnancy, this is by definition a "pregnancy of unknown location." There are threshold hCG levels whereby an intrauterine pregnancy would not be expected to be seen with ultrasound (approximately 1500i/u for T/V and 2000i/u for T/A) and the role of progesterone in the assessment of pregnancy nonviability is less important than hCG in the acute setting.

3.5. Should all women with early pregnancy loss receive anti-D immunoglobulin?

Non-sensitised rhesus (Rh) negative women must receive anti-D immunoglobulin in the following situations: ectopic pregnancy and any miscarriage, regardless of gestational age of the fetus or uterine evacuation method.

C

Rh D Immunoglobulin (Anti-D) must be administered in accordance with NSW Health Policy Directive PD2006_074.

The National Blood Authority guidelines⁷⁷ on the prophylactic use of Rh D immunoglobulin (anti-D) in obstetrics recommends the following:

General

For successful immunoprophylaxis, Rh D immunoglobulin should be administered as soon as possible after the sensitising event, but always within 72 hours. If Rh D immunoglobulin has not been offered within 72 hours, a dose offered within 9–10 days may provide protection. Blood should be taken from the mother before administration of the Rh D immunoglobulin to assess the magnitude of fetomaternal haemorrhage (FMH). Where FMH quantitation shows that FMH greater than that covered by the dose already administered has occurred, administration of an additional dose/s sufficient to provide immunoprophylaxis must be administered and preferably within 72 hours.

Evidence
Level I

Sensitising events in the first trimester

- A dose of 250 IU (50 µg) Rh D immunoglobulin should be offered to every Rh negative woman with no preformed anti-D to ensure adequate protection against immunisation for the following indications up to and including 12 weeks gestation (level IV evidence):
 - miscarriage; (level IV)
 - termination of pregnancy; (level IV)
 - ectopic pregnancy; and (Level IV)
 - chorionic villus sampling. (level III)
- A dose of 250 IU (50 µg) Rh D immunoglobulin is sufficient to prevent immunisation by a fetomaternal haemorrhage of 2.5 ml of fetal red cells (5 ml whole blood) (Level IV evidence).
- There is insufficient evidence to support the use of Rh D immunoglobulin in bleeding prior to 12 weeks gestation in an ongoing pregnancy, although if the pregnancy then requires curettage, Rh D immunoglobulin should be given. If miscarriage or termination occurs after 12 weeks gestation, 625 IU (125 µg) Rh D immunoglobulin should be offered.

Sensitising events beyond the first trimester

- Although some of the recent evidence related to the use of immuno-prophylaxis is based upon studies of potentially sensitising events occurring up to 20 weeks gestation, for practical purposes the working party recommends that a dose of 250 IU (50 µg) be used for first trimester events (up to and including 12 weeks gestation) and 625 IU (125 µg) be used beyond first trimester. Future revisions of

these guidelines may, in the face of further recommendations, extend the use of the 250IU (50µg) dose beyond 12 weeks gestation.

- A dose of 625 IU (125 µg) Rh D immunoglobulin should be offered to every Rh D negative woman with no preformed anti-D to ensure adequate protection against immunisation for the following indications after 12 weeks gestation (Level IV evidence):
 - Genetic studies (chorionic villus sampling, amniocentesis, cordocentesis);(Level III)
 - Abdominal trauma considered sufficient to cause fetomaternal haemorrhage; (Level IV)
 - Each occasion of revealed or concealed antepartum haemorrhage (where the patient suffers unexplained uterine pain the possibility of concealed antepartum haemorrhage should be considered, with a view to immunoprophylaxis); (Level IV)
 - External cephalic version (performed or attempted); (Level III)
 - Miscarriage or termination of pregnancy. (Level IV)
 - As evidence for the efficacy of this dose for these indications is not available, it is recommended that the magnitude of fetomaternal haemorrhage be assessed and further doses of Rh D immunoglobulin administered if required, especially where transplacental access or puncture of fetal blood vessels occurs.

Upon transfer of care (discharge) from the EPAS, documentation that clearly states whether or not anti-D was given and the dosage must be annotated.



4 TREATMENT

The options for treatment include: expectant management and/or surgical uterine evacuation. To the fullest extent possible, a woman should be given the choice of treatment option.

Protocols must be developed locally with selection criteria, therapeutic regimens, and arrangements for follow-up.



Concerns have been raised about the infective risks of non-surgical management⁵⁸ but published data suggest a reduction in clinical pelvic infection and no adverse affects on future fertility.^{28,57,66}

Evidence Level Ia

Expectant management should be offered by EPAS where women have access to a telephone and emergency hospital admission, if required. A plan to access medical assistance when required should be developed in consultation with each woman in areas where there is geographical and /or social isolation.

Expectant management may be followed by minimal bleeding, as any retained tissue will usually undergo reabsorption. Occasionally, the passage of tissue may be associated with significant bleeding (i.e. >spotting). It is important that all women undergoing expectant management have direct telephone access to staff for advice and support. Hospital beds must be available should admission be required.

Evidence Level IV

Expectant management is an effective method to use in selected cases of confirmed first-trimester miscarriage. This means no specific intervention is undertaken and allows spontaneous passage of fetal tissue.

A

4.1 Expectant Management

Expectant management is an effective and acceptable method to offer women who miscarry. Patient counselling is particularly important for those women **with an intact sac** who wish to take an expectant approach. They should be aware that complete resolution may take several weeks and that overall efficacy rates are lower. They may wish to consider a medical approach or to commence expectant management with the option of surgical evacuation at a later date, if required. Expectant management for incomplete miscarriage is highly effective.

Evidence
Level Ib

Observational and controlled trials of expectant compared with surgical management also show wide variations in reported efficacy (25–100%).⁵⁵⁻⁶⁴ Similar factors affect the success rates; these factors include the type of miscarriage, duration of follow-up, and whether ultrasound or clinical assessment was used for review. A low serum progesterone level can be used to predict those pregnancies which are most likely to resolve spontaneously.⁶⁵

Evidence
Level Ib

Ultrasound criteria used to define ‘retained products’ varies between studies. One study included patients with an ‘AP tissue diameter of 15–50mm’ with ultrasound review at 3 days (efficacy 71%),⁵⁵ while another included all those with an ‘AP tissue diameter < 50mm’ and reviewed patients clinically on three occasions up to 6 months (efficacy 100%).⁵⁷ The mean anteroposterior (AP) diameter of tissue in those managed expectantly in the latter study was only 11 mm, which would have been defined as ‘complete miscarriage’ by the former study and therefore would have been excluded. When ultrasound assessment of the uterine cavity shows heterogenous shadows with a maximum AP diameter of 15 mm or less, genuine retained products are less likely to be confirmed histologically.¹⁴ These could, of course, include some cases of ‘incomplete miscarriage’ but are best managed conservatively as there is a trend towards a lower complication rate compared with surgical management (3.0 versus 5.8%, $P = 0.06$).⁵⁹

Evidence
Level Ib

Several randomised trials have compared expectant with surgical management. In a trial with 122 women, efficacy rates were confirmed at six weeks of 47% (expectant) and 95% (surgical).⁶¹ After seven days, 37% of women managed expectantly had achieved a complete miscarriage. A meta-analysis of 13 trials comparing expectant with medical management⁶³ showed that the type of miscarriage was a significant factor affecting the efficacy with an expectant approach. For missed miscarriage, complete evacuation rates for expectant versus surgical management were 28% (49/173, range 14–47%) and 81% (242/298, range 60–83%), respectively. For women with incomplete miscarriage, the rates were 94% (31/33, range 80–100%) and 99% (75/76, range 99–100%).

Evidence
Level Ia

4.2 When should surgical uterine evacuation be used?

Clinical indications for offering surgical evacuation include: persistent excessive bleeding, haemodynamic instability, evidence of infected retained tissue and suspected gestational trophoblastic disease.
Surgical uterine evacuation should be offered to women who prefer that option.

C

Surgical uterine evacuation (ERPC) has been the standard treatment offered to women who miscarry. Until recently, up to 88% of women who miscarried were offered ERPC. This was based on an assumption that retained tissue increases the risks of infection and haemorrhage and would not be passed spontaneously. It remains the treatment of choice if there is excessive and persistent bleeding, if vital signs are unstable or in the presence of retained infected tissue. Studies suggest that these complications affect less than 10% of women who miscarry.²⁷ At least 34% of women express a 'strong' preference for a surgical approach to uterine evacuation.²⁸

Evidence
Level IV

4.3 How should surgical uterine evacuation be performed?

Surgical uterine evacuation for miscarriage should be performed using suction curettage.

A

Vacuum aspiration has been used as the method of choice for management of miscarriage where there is an intact intrauterine sac. A Cochrane review concluded that vacuum aspiration is preferable to sharp curettage in cases of incomplete miscarriage. Two trials were included: vacuum aspiration was associated with statistically significantly decreased blood loss (mean difference -17 ml, 95%CI -24 to -10ml), less pain (RR 0.74, 95% CI 0.61 to 0.90) and shorter duration of procedure (mean difference -1.2 minutes, 95% CI -1.5 to -0.87 minutes).²⁹ Routine use of a metal curette after suction curettage is not required. Use of oxytocin is associated with a statistically significant (but not clinically significant) difference in median blood loss (17.6 ml versus 24.5 ml).³⁰ Where infection is suspected, delaying surgical intervention for 12 hours is recommended to allow intravenous antibiotic administration.

Evidence
Level Ia

Reported serious complications of surgery include perforation, cervical tears, intra-abdominal trauma, intrauterine adhesions and haemorrhage. The incidence of serious morbidity using a similar surgical technique in induced pregnancy termination is 2.1%³¹ with a mortality of 0.5/100 000.³²

Evidence
Level III

The advantages of prostaglandin administration prior to surgical evacuation are well established, with significant reductions in dilatation force, haemorrhage and uterine/cervical trauma. There is no randomised evidence to guide practice in cases of first-trimester miscarriage, particularly in the presence of an intact sac. Practitioners may consider oral or vaginal cervical preparation based on individual patient circumstance. 'Timing' of the administration should be considered to allow for maximum effect whilst minimising the possibility of the loss of uterine contents into the bed or toilet.

Curettage under local anaesthesia is well described. It is used commonly in the USA³³ and many European, Asian and African countries. In a UK study of 58 women with incomplete and missed miscarriage, uterine evacuation was achieved in all cases using a manual vacuum aspiration technique under systemic analgesia or patient-controlled anaesthesia. Levels of patient satisfaction and acceptability were high.³⁴

Evidence Level III

4.4 Which women should be screened for genital tract infection?

Screening for infection, including *Chlamydia trachomatis*, should be considered in women undergoing surgical uterine evacuation.

C

Consider vaginal swabs to diagnose bacterial vaginosis if clinically indicated or population prevalence dictates.

✓

Women with *C. trachomatis*, *Neisseria gonorrhoea* or bacterial vaginosis in the lower genital tract at the time of induced pregnancy termination are at an increased risk of subsequent pelvic inflammatory disease;²⁶ until further research is published, no definitive recommendations can be made for women undergoing surgical evacuation for miscarriage management.

Evidence Level IV

4.5 Should prophylactic antibiotics be given prior to surgical evacuation?

There is insufficient evidence to recommend routine antibiotic prophylaxis prior to surgical uterine evacuation.

A

Antibiotic prophylaxis must be given based on individual clinical indications.

✓

A randomised trial of prophylactic doxycycline in curettage for incomplete miscarriage did not demonstrate an obvious benefit but the study was of insufficient power to detect a clinically meaningful change in infectious morbidity. Until further research is available, antibiotic prophylaxis should only be given based on individual clinical indications.

Evidence Level Ib

4.6 What are the advantages of arranging histological examination of tissue passed at the time of miscarriage?

Tissue obtained via surgical evacuation should be histologically examined / evaluated to confirm pregnancy and to exclude ectopic pregnancy or unsuspected gestational trophoblastic disease.

C

Heath, et al., suggested that there is no obvious benefit in routine histological investigation of tissue obtained from cases of pregnancy termination and miscarriage.⁶⁸ However, within a subgroup of 468 undergoing surgical evacuation for miscarriage, there were two cases of ectopic pregnancy diagnosed 25 and 28 days post-evacuation (an incidence of 0.42%). Neither was suspected on scan, but histology had reported 'decidua only'. In view of the maternal risks associated with ectopic pregnancy and molar pregnancy, it is recommended that practitioners send tissue obtained at the time of surgical uterine evacuation for histological examination. This may confirm the diagnosis of miscarriage and can help to exclude ectopic pregnancy or gestational trophoblastic disease.⁷

Evidence Level IV

Practitioners must be aware of their local public health requirements or guidelines related to the appropriate disposal of fetal remains, should the woman request to take the remains home. Medical, nursing and midwifery staff must provide current and sensitive information to ensure proper burial or cremation.

√

5 PSYCHOLOGICAL ASPECTS OF EARLY PREGNANCY LOSS

5.1 Is there potential benefit from support and follow-up after pregnancy loss?

All professionals must be aware of the psychological sequelae associated with pregnancy loss and must provide support, follow-up and access to formal counselling when necessary. Appropriate support can result in significant positive psychological gain.

C

Plans for follow-up must be clearly recorded in the referral or transfer of care (discharge) letter from the EPAS or ward.

√

A system must be in place for informing all relevant primary health care professionals in cases of pregnancy loss.

√

The negative psychological impact of early pregnancy loss can be both severe and protracted and affects both women and their families⁷¹⁻⁷³ and may be different for every couple. Information should be made available which highlights the options available for appropriate and sensitive disposal of fetal tissue⁶⁹. Each woman's (and couple's, as appropriate) needs should be identified and acknowledged, assistance and referral given to facilitate the grieving process. The provision of information on miscarriage should be offered to each woman or couple.

Evidence Level III

A randomised trial assessing the effects of caring-based counselling on women's emotional wellbeing in the first year after miscarriage found a significant beneficial effect with reduction in overall emotional disturbance, anger and depression.⁸ A continuing awareness of the potential effects of miscarriage is required, with a willingness to involve appropriate support and counselling services when needed. The needs of the partner should also be considered. The opportunity for follow-up should be offered to all women after pregnancy loss but unfortunately this does not always occur. In a recent national audit study in the UK, 38% of women reported that

Evidence Level III

there had been no offer of or arrangement for follow-up.⁷⁴ Follow-up can involve any member of the multidisciplinary team based in hospital or community practice.

5.2 Should informed choice be encouraged in deciding which intervention to use to achieve uterine evacuation?

In terms of therapeutic intervention, the woman's choice should be encouraged, as it is associated with positive quality-of-life outcomes.

A

Objective assessment of psychological morbidity in a controlled trial of expectant versus surgical management of miscarriage revealed no differences related to the procedure itself.⁷⁵ However, women with miscarriage who chose their own treatment had the best health-related quality-of-life (HRQL) assessments compared with women who were randomised to one or other treatment modality.⁷⁶ This confirms the importance of allowing and encouraging patient choice in the management of early miscarriage.

6 RECOMMENDED AUDITABLE STANDARDS

- Patient satisfaction with elements of the EPAS
- Appropriate use of anti-D prophylaxis
- Appropriate screening for genital tract infection
- Appropriate use of serial serum hCG/serum progesterone assessment
- Uptake rates for expectant, and surgical interventions
- Complications of the various interventions (including failure rates)
- Involvement of patient in choice of treatment
- Number of visits required to reach definitive diagnosis
- Standards of documentation

7 SUPPORT GROUP WEBSITES

Association of Early Pregnancy Units, www.earlypregnancy.org.uk

Small Miracles Foundation, <http://www.smfoundation.org.au/>

SIDS and Kids, www.sidsandkids.org

Stillbirth and Neonatal Death Support, www.sands.org.au

Bears of Hope, <http://www.bears of hope.org.au/>

Stillbirth Foundation, <http://www.stillbirthfoundation.org.au/>

8 REFERENCES

1. Royal College of Obstetricians and Gynaecologists. *The Management of Early Pregnancy Loss*. Guideline No. 25. London: RCOG; 2006. (including addendum released October 19th 2011)
2. Royal College of Obstetricians and Gynaecologists. *The Management of Tubal Pregnancy*. Guideline No. 21. London: RCOG; 2004.
3. Royal College of Obstetricians and Gynaecologists. *The Management of Gestational Trophoblastic Neoplasia*. Guideline No. 38. London: RCOG; 2004.
4. Royal College of Obstetricians and Gynaecologists. *The Investigation and Treatment of Couples with Recurrent Miscarriage*. Guideline No. 17. London: RCOG; 2003.
5. Alberman E. Spontaneous abortion: epidemiology. In: Stabile S, Grudzinkas G, Chard T, editors. *Spontaneous Abortion: Diagnosis and Treatment*. London: Springer-Verlag; 1992. p. 9–20.
6. Sands Australia, <http://www.sands.org.au>, Accessed 11 November, 2011
7. Recommendations from the 33rd RCOG Study Group. In: Grudzinkas JG, O'Brien PMS, editors. *Problems in Early Pregnancy: Advances in Diagnosis and Management*. London: RCOG Press; 1997. p. 327–31.
8. Swanson KM. Effects of caring, measurement, and time on miscarriage impact and women's well-being. *Nurs Res* 1999;48:288–98.
9. Chalmers B. Terminology used in early pregnancy loss. *Br J Obstet Gynaecol* 1992;99:357–8.
10. Hutchon D. Understanding miscarriage or insensitive abortion: time for more defined terminology? *Am J Obstet Gynecol* 1998;179:397–8.
11. Farquharson RG, Jauniaux E, Exalto N. ESHRE Special Interest Group for Early Pregnancy (SIGEP). Updated and revised nomenclature for description of early pregnancy events. *Hum Reprod* 2005;20:3008–11.
12. Bigrigg MA, Read MD. Management of women referred to early pregnancy assessment unit: care and effectiveness. *Br Med J* 1991;302:577–9.
13. Condous G, Okaro E, Bourne T. The conservative management of early pregnancy complications: a review of the literature. *Ultrasound Obstet Gynecol* 2003;22:420–30.
14. Rulin MC, Bornstein SG, Campbell JD. The reliability of ultrasonography in the management of spontaneous abortion, clinically thought to be complete: a prospective study. *Am J Obstet Gynecol* 1993;168:12–15.
15. Royal College of Radiologists, Royal College of Obstetricians and Gynaecologists. *Guidance on Ultrasound Procedures in Early Pregnancy*. London: RCR/RCOG; 1995.

16. Hately W, Case J, Campbell S. Establishing the death of an embryo by ultrasound: report of public inquiry with recommendations. *Ultrasound Obstet Gynecol* 1995;5:353–7.
17. Jauniaux E, Johns J, Burton GJ. The role of ultrasound imaging in diagnosing and investigating early pregnancy failure. *Ultrasound Obstet Gynecol* 2005;25:613–24.
18. Royal College of Obstetricians and Gynaecologists. *Problems in Early Pregnancy: Advances in Diagnosis and Management*. London: RCOG Press; 1997.
19. Braunstein GD, Razor J, Adler D, Danzer H, Wade ME. Serum human chorionic gonadotrophin levels throughout normal pregnancy. *Am J Obstet Gynecol* 1976;126:678–81.
20. Condous G, Okaro E, Khalid A, Bourne T. Do we need to follow up complete miscarriages with serum human chorionic gonadotrophin levels? *BJOG* 2005;112:827–9.
21. Hahlin M, Thorburn J, Bryman I. The expectant management of early pregnancy of uncertain site. *Hum Reprod* 1995;10:1223–7.
22. Banerjee S, Aslam N, Woelfer B, Lawrence A, Elson J, Jurkovic D. Expectant management of pregnancies of unknown location: a prospective evaluation of methods to predict spontaneous resolution of pregnancy. *BJOG* 2001;108:158–63.
23. McCord ML, Muam D, Buster JE, Arheart KL, Stovall TG, Carson SA. Single serum progesterone as a screen for ectopic gestation: exchanging specificity and sensitivity to obtain optimal test performance. *Fertil Steril* 1996;66:513–16.
24. Mol BWJ, Lijmer JG, Ankum WM, van der Veen F, Bossuyt PMM. The accuracy of a single serum progesterone measurement in the diagnosis of ectopic pregnancy: a meta-analysis. *Human Reprod* 1998;13:3220–7.
25. Royal College of Obstetricians and Gynaecologists. *Use of Anti-D Immunoglobulin for Rh Prophylaxis*. Guideline No. 22. London: RCOG; 2002.
26. Royal College of Obstetricians and Gynaecologists. *The Care of Women Requesting Induced Abortion*. Evidence-based Clinical Guideline No.7. London: RCOG Press; 2004.
27. Ballagh SA, Harris HA, Demasio K. Is curettage needed for uncomplicated incomplete spontaneous abortion? *Am J Obstet Gynecol* 1998;179:1279–82.
28. Hinshaw HKS. Medical management of miscarriage. In: Grudzinkas JG, O'Brien PMS, editors. *Problems in Early Pregnancy: Advances in Diagnosis and Management*. London: RCOG Press; 1997. p. 284–95.
29. Forna F, Gülmezoglu AM. Surgical procedures to evacuate incomplete abortion. *Cochrane Database Syst Rev* 2001;(1):CD001993.
30. Ali PB, Smith G. The effect of syntocinon on blood loss during first trimester suction curettage. *Anaesthesia* 1996;51:483–5.

31. Joint Study of the Royal College of General Practitioners and the Royal College of Obstetricians and Gynaecologists. Induced abortion operations and their early sequelae. *J R Coll Gen Pract* 1985;35:175–80.
32. Lawson HW, Frye A, Atrash HK, Smith JC, Shulman HB, Ramick M. Abortion mortality, United States, 1972 through 1987. *Am J Obstet Gynecol* 1994;171:1365–72.
33. Farrell RG, Stonington DT, Ridgeway RA. Incomplete and inevitable abortion: treatment by suction curettage in the emergency department. *Ann Emerg Med* 1982;11:652–8.
34. Gazvani R, Honey E, MacLennan FM, Templeton A. Manual vacuum aspiration (MVA) in the management of first trimester pregnancy loss. *Eur J Obstet Gynecol Reprod Biol* 2004;112:197–200.
35. Winikoff B. Pregnancy failure and misoprostol – time for a change. *N Engl J Med* 2005;353:834–6.
36. El-Refaey H, Hinshaw K, Henshaw R, Smith N, Templeton A. Medical management of missed abortion and anembryonic pregnancy. *Br Med J* 1992;305:1399.
37. Henshaw RC, Cooper K, El-Refaey H, Smith NC, Templeton AA. Medical management of miscarriage: nonsurgical uterine evacuation of incomplete and inevitable spontaneous abortion. *Br Med J* 1993;306:894–5.
38. Chung TKH, Cheung LP, Lau WC, Haines CJ, Chang AM. Spontaneous abortion: a medical approach to management. *Aust N Z J Obstet Gynaecol* 1994;34:432–6.
39. de Jonge ET, Makin JD, Manefeldt E, De Wet GH, Pattinson RC. Randomised clinical trial of medical and surgical curettage for incomplete miscarriage. *Br Med J* 1995;311:662.
40. Chung T, Cheung LP, Leung TY, Haines CJ, Chang AM. Misoprostol in the management of spontaneous abortion. *Br J Obstet Gynaecol* 1995;102:832–5.
41. Creinin M, Moyer R, Guido R. Misoprostol for medical evacuation of early pregnancy failure. *Obstet Gynecol* 1997;89:768–71.
42. Nielsen S, Hahlin M, Platz-Christensen J. Unsuccessful treatment of missed abortion with a combination of an antiprogesterone and a prostaglandin E1 analogue. *Br J Obstet Gynaecol* 1997;104:1094–6.
43. Chung T, Leung P, Cheung LP, Haines C, Chang AM. A medical approach to management of spontaneous abortion using misoprostol. *Acta Obstet Gynecol Scand* 1997;76:248–51.
44. Demetroulis C, Saridogan E, Kunde D, Naftalin AA. A prospective RCT comparing medical and surgical treatment for early pregnancy failure. *Hum Reprod* 2001;16:365–9.
45. Zalanyi S. Vaginal misoprostol alone is effective in the treatment of missed abortion. *Br J Obstet Gynaecol* 1998;105:1026–8.

46. Tang OS, Lau WNT, Ng EHY, Lee SWH, Ho PC. A prospective randomized study to compare the use of repeated doses of vaginal with sublingual misoprostol in the management of first trimester silent miscarriages. *Hum Reprod* 2003;18:176–81.
47. Ngoc NT, Blum J, Westheimer E, Quan TT, Winikoff B. Medical treatment of missed abortion using misoprostol. *Int J Gynecol Obstet* 2004;87:138–42.
48. Reynolds A, Ayres-de-Campos D, Costa MA, Montenegro N. How should success be defined when attempting medical resolution of first-trimester missed abortion? *Eur J Obstet Gynecol Reprod Biol* 2005;118:71–6.
49. Hughes J, Ryan M, Hinshaw K, Henshaw R, Rispin R, Templeton A. The costs of treating miscarriage: a comparison of medical and surgical management. *Br J Obstet Gynaecol* 1996;103:1217–21.
50. Wood SL, Brain PH. Medical management of missed abortion: a randomised controlled trial. *Obstet Gynecol* 2002;99:563–6.
51. Zhang J, Giles JM, Barnhart K, Creinin MD, Westhoff C, Frederick MM. A comparison of medical management with misoprostol and surgical management for early pregnancy failure. *N Engl J Med* 2005;353:761–9.
52. Graziosi GC, Bruinse HW, Reuwer PJ, Mol BW. Women's preferences for misoprostol in case of early pregnancy failure. *Eur J Obstet Gynecol Reprod Biol* 2006;124:184–6.
53. Johnson N, Priestnall M, Marsay T, Ballard P, Watters J. A randomised trial evaluating pain and bleeding after a first trimester miscarriage treated surgically or medically. *Eur J Obstet Gynecol Reprod Biol* 1997;72:213–15.
54. Davis AR, Robilotto CM, Westhoff CL, Forman S, Zhang J, NICHD Management of Early Pregnancy Failure Trial Group. Bleeding patterns after vaginal misoprostol for treatment of early pregnancy failure. *Hum Reprod* 2004;19:1655–8.
55. Nielsen S, Hahlin M. Expectant management of first trimester spontaneous abortion. *Lancet* 1995;345:84–6.
56. Nielsen S, Hahlin M, Platz-Christensen J. Randomized trial comparing expectant with medical management for first trimester miscarriages. *Br J Obstet Gynaecol* 1999;106:804–7.
57. Chipchase J, James D. Randomised trial of expectant versus surgical management of spontaneous miscarriage. *Br J Obstet Gynaecol* 1997;104:840–1.
58. Jurkovic D. Modern management of miscarriage: is there a place for non-surgical treatment? *Ultrasound Obstet Gynecol* 1998; 11: 161–3.
59. Chung TKH, Cheung LP, Sahota DS, Haines CJ, Chung AMZ. Spontaneous abortion: short-term complications following either conservative or surgical management. *Aust NZ J Obstet Gynaecol* 1998;38:61–4.
60. Jurkovic D, Ross JA, Nicolaidis K. Expectant management of missed miscarriage. *Br J Obstet Gynaecol* 1998;105:670–1.

61. Wieringa-De Waard M, Vos J, Bonsel GK, Bindels PJE, Ankum WM. Management of miscarriage: a randomized controlled trial of expectant management versus surgical evacuation. *Hum Reprod* 2002;17:2445–50.
62. Hurd WW, Whitfield RR, Randolph JF Jr, Kercher ML. Expectant management versus elective curettage for the treatment of spontaneous abortion. *Fertil Steril* 1997;68:601–6.
63. Graziosi GC, Mol BW, Ankum WM, Bruinse HW. Management of early pregnancy loss – a systematic review. *Int J Gynecol Obstet* 2004;86:337–46.
64. Bagratee JS, Khullar V, Regan L, Moodley J, Kagoro H. A randomized controlled trial comparing medical and conservative management of first trimester miscarriage. *Hum Reprod* 2004;19:266–71.
65. Elson J, Salim R, Taylor A, Banerjee S, Zosmer N, Jurkovic D. Prediction of early pregnancy viability in the absence of an ultrasonically detectable embryo. *Ultrasound Obstet Gynecol* 2003;21:57–61.
66. Blohm F, Hahlin M, Nielsen S, Milsom I. Fertility after a randomised trial of spontaneous abortion managed by surgical evacuation or expectant treatment. *Lancet* 1997;349:995.
67. Elson J, Taylor R, Hillaby K, Dew T, Jurkovic D. Expectant management of miscarriage – prediction of outcome using ultrasound and novel biochemical markers. *Hum Reprod* 2005;20:2330–3.
68. Heath V, Chadwick V, Cooke I, Manek S, MacKenzie IZ. Should tissue from pregnancy termination and uterine evacuation routinely be examined histologically? *BJOG* 2000;107:727–30.
69. Royal College of Obstetricians and Gynaecologists. *Disposal Following Pregnancy Loss Before 24 Weeks of Gestation*. Good Practice Guideline No. 5. London: RCOG; 2005.
70. Thapar AK, Thapar A. Psychological sequelae of miscarriage: a controlled study using the general health questionnaire and the hospital anxiety and depression scale. *Br J Gen Pract* 1992;42:94–6.
71. Neugebauer R, Kline J, O'Connor P, Shrout P, Johnson J, Skodol A, *et al*. Depressive symptoms in women in the six months after miscarriage. *Am J Obstet Gynecol* 1992;166:104–9.
72. Hopper E. Psychological consequences of early pregnancy loss. In: Grudzinkas JG, O'Brien PMS, editors. *Problems in Early Pregnancy: Advances in Diagnosis and Management*. London: RCOG Press; 1997. p. 296–308.
73. Moulder C. Guidelines for good practice. In: *Miscarriage: Women's Experiences and Needs*. 2nd ed. London: Harper Collins; 1995. p. 253–63.
74. Scottish Programme for Clinical Effectiveness in Reproductive Health. *Scottish Audit of the Management of Early Pregnancy Loss*. Aberdeen: SP CERH; 2003.

75. Nielsen S, Hahlin M, Möller A, Granberg S. Bereavement, grieving and psychological morbidity after first trimester spontaneous abortion: comparing expectant management with surgical evacuation. *Hum Reprod* 1996;11:1767–70.
76. Wieringa-De Waard M, Hartman E, Ankum W, Reitsma J, Bindels P, Bonsel G. Expectant management versus surgical evacuation in first trimester miscarriage: health-related quality of life in randomised and nonrandomized patients. *Hum Reprod* 2002;17:1638–42.
77. National Blood Authority, Guidelines on the prophylactic use of Rh D immunoglobulin (anti-D) in Obstetrics, Approved by the National Health and Medical research Council, 6 June, 2003, revision of guidelines funded by the Australian Government Department of Health and Ageing.
78. Trinder J., Brocklehurst R., Porter M., Read M., Vyas S., Smith, L. Management of Miscarriage: expectant, medical, or surgical? *BMJ* 2006 May 27; 332(7552): 1235-1240.
79. The Royal Australian and New Zealand College of Obstetrics and Gynaecology, College Statement: The use of misoprostol in obstetrics and gynaecology, Number C-Obs12, Nov 2007.
80. Statistics New Zealand; Births & Deaths, September 2006; <http://www.stats.govt.nz/NR> accessed 26 Sep 07.
81. Johnson MP, Puddifoot, JE. The grief response in the partners of women who miscarry. *BJ Medical Psychol* 1996 Dec;69:313-27.
82. Fervers B, Burgers J, Haugh M, Latreille J, Mlika-Cabanne N, Paquet L, Coulombe M, Poirier M, Burnand B. Adaptation of clinical guidelines: literature review and proposition for a framework and procedure. *Int J for Qual in Health Care* 2006; Vol 18, N 3: 167-176.
83. Shiffman RN, Dixon J, et al, The guideline Implementability Appraisal (GLIA): development of an instrument to identify obstacles to guideline implementation. <http://gem.yale.edu/eglia>

9 APPENDICES

Appendix A Evidence levels

Classification of evidence levels	Grades of recommendations
<p>Ia Evidence obtained from meta-analysis of randomised controlled trials</p> <p>Ib Evidence obtained from at least one randomised controlled trial</p> <p>IIa Evidence obtained from at least one well-designed controlled study without randomisation</p> <p>IIb Evidence obtained from at least one other type of well-designed quasiexperimental study</p> <p>III Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies</p> <p>IV Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities</p>	<p>A Requires at least one randomized controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation. (Evidence levels Ia, Ib)</p> <p>B Requires the availability of well controlled clinical studies but no randomised clinical trials on the topic of recommendations. (Evidence levels IIa, IIb, III)</p> <p>C Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality. (Evidence level IV)</p> <p>√ Good practice point Recommended best practice based on the clinical experience of the guideline development group.</p>

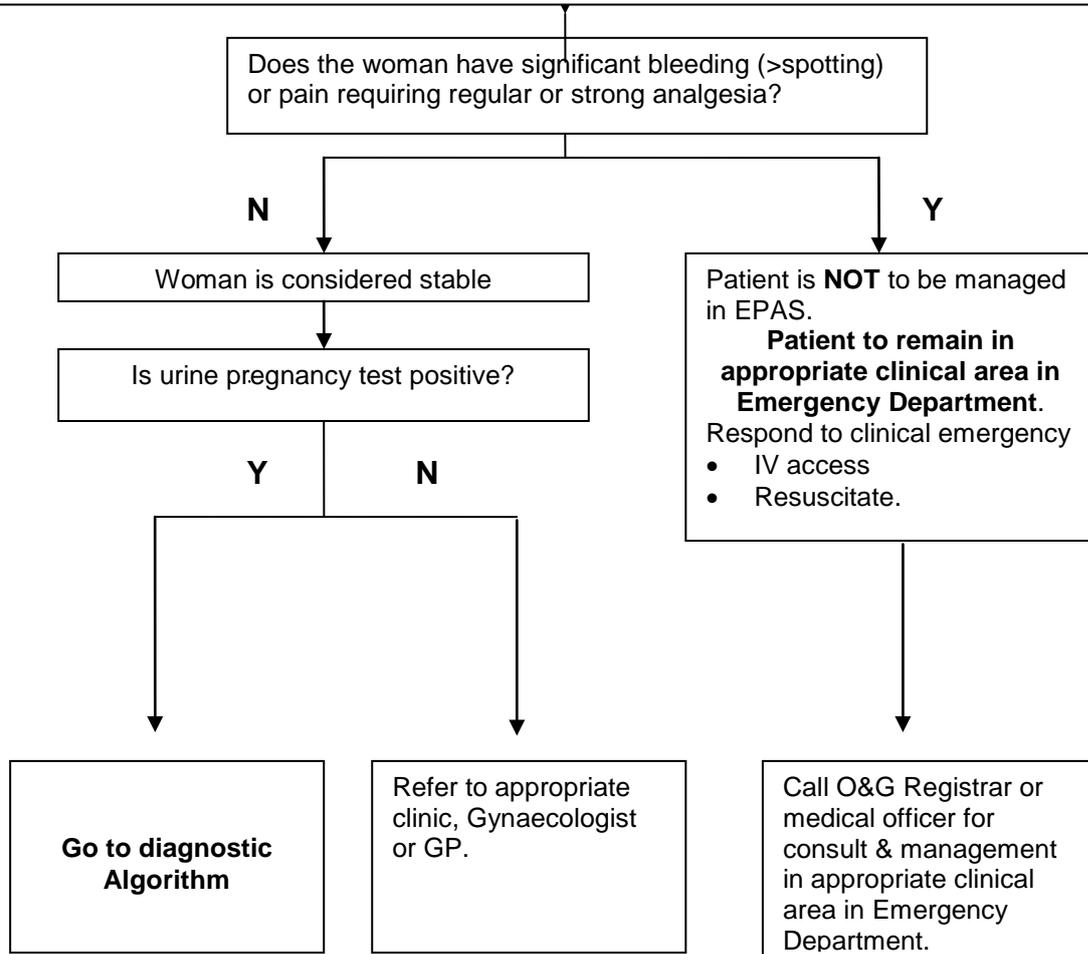
Appendix B Algorithms

Algorithms

Initial assessment and triage of women with bleeding/pain in early pregnancy less than 12 weeks gestation

Initial assessment: presentation to GP, Emergency Department (in an appropriate clinical area/Early Pregnancy Unit) Or Early Pregnancy Assessment Service

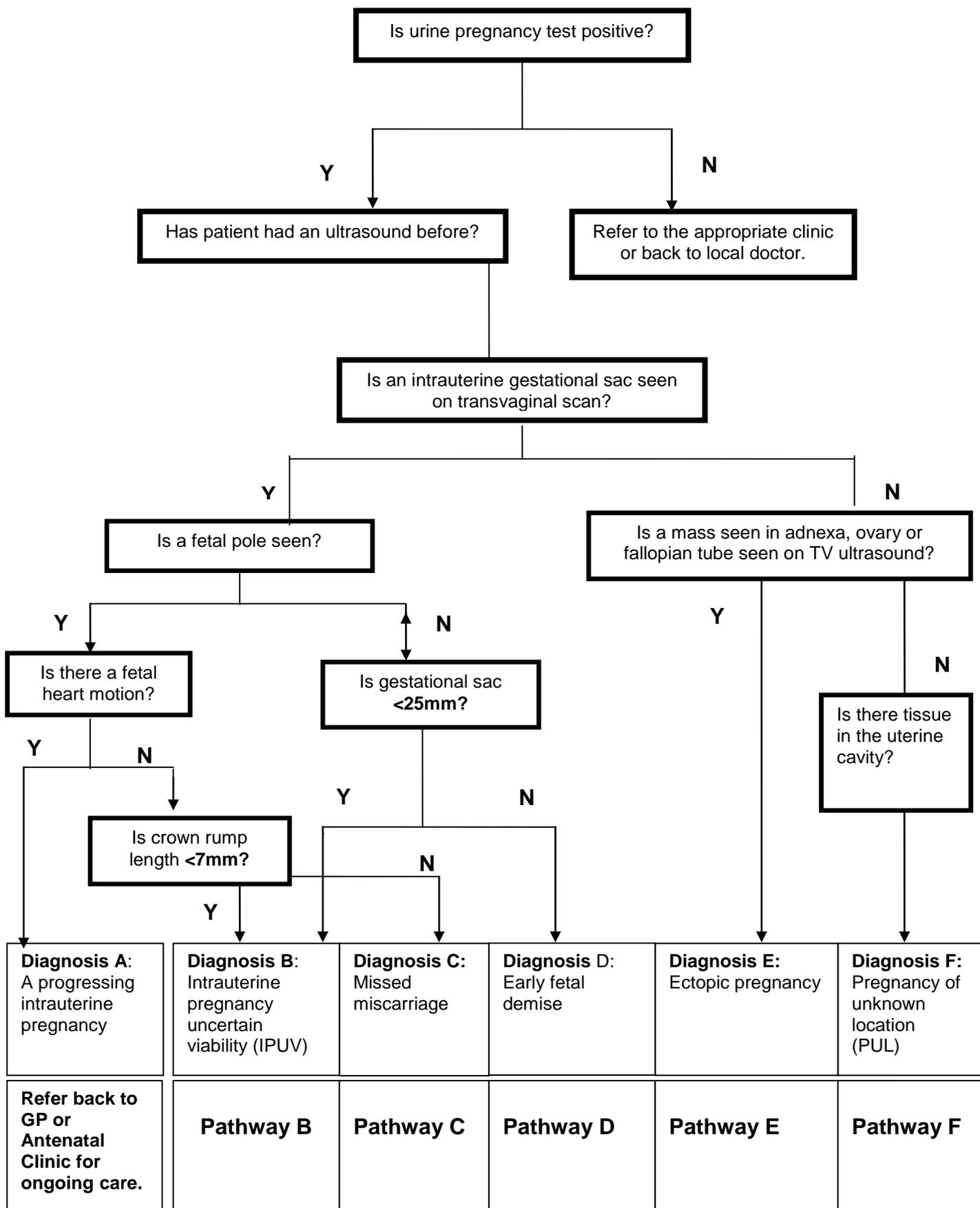
- History
- Current contraception/pap smear
- Vital signs
- Urinary pregnancy test (unless results already confirmed)
- Establish gestation based on LMP
- Abdominal palpation
- Speculum/bimanual assessment if significant bleeding (POC to histology, unless woman wants to retain).



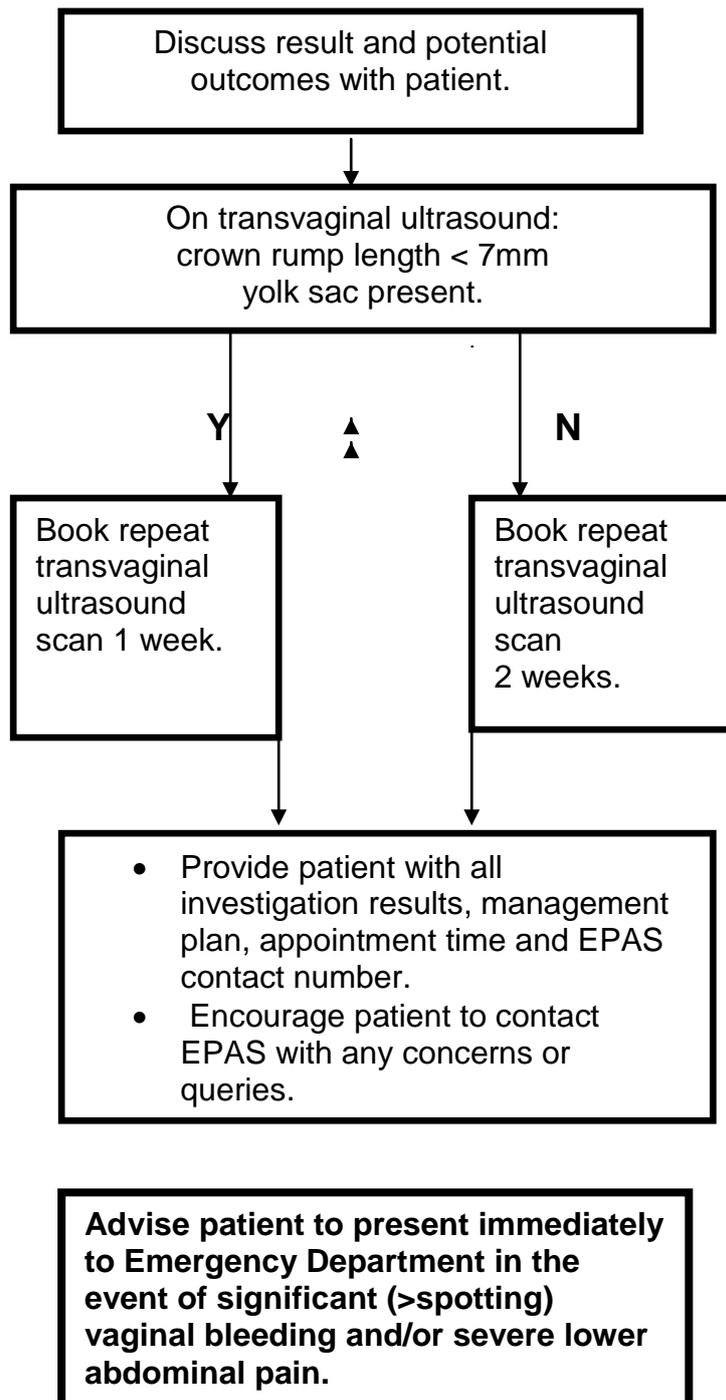
When referring to EPAS:

- Ensure that findings from initial assessment are documented and made available to EPAS. If possible, commence documentation on the EPAS record.
- Advise woman:
 - what time to attend EPAS and where to go
 - that she is likely to have a vaginal ultrasound scan
 - if possible to come with partner or friend/relative
 - if possible avoid bringing children to EPAS.
 - to be prepared to stay for up to 3 hours in the EPAS, as blood tests may be required
- Provide EPAS information leaflet.

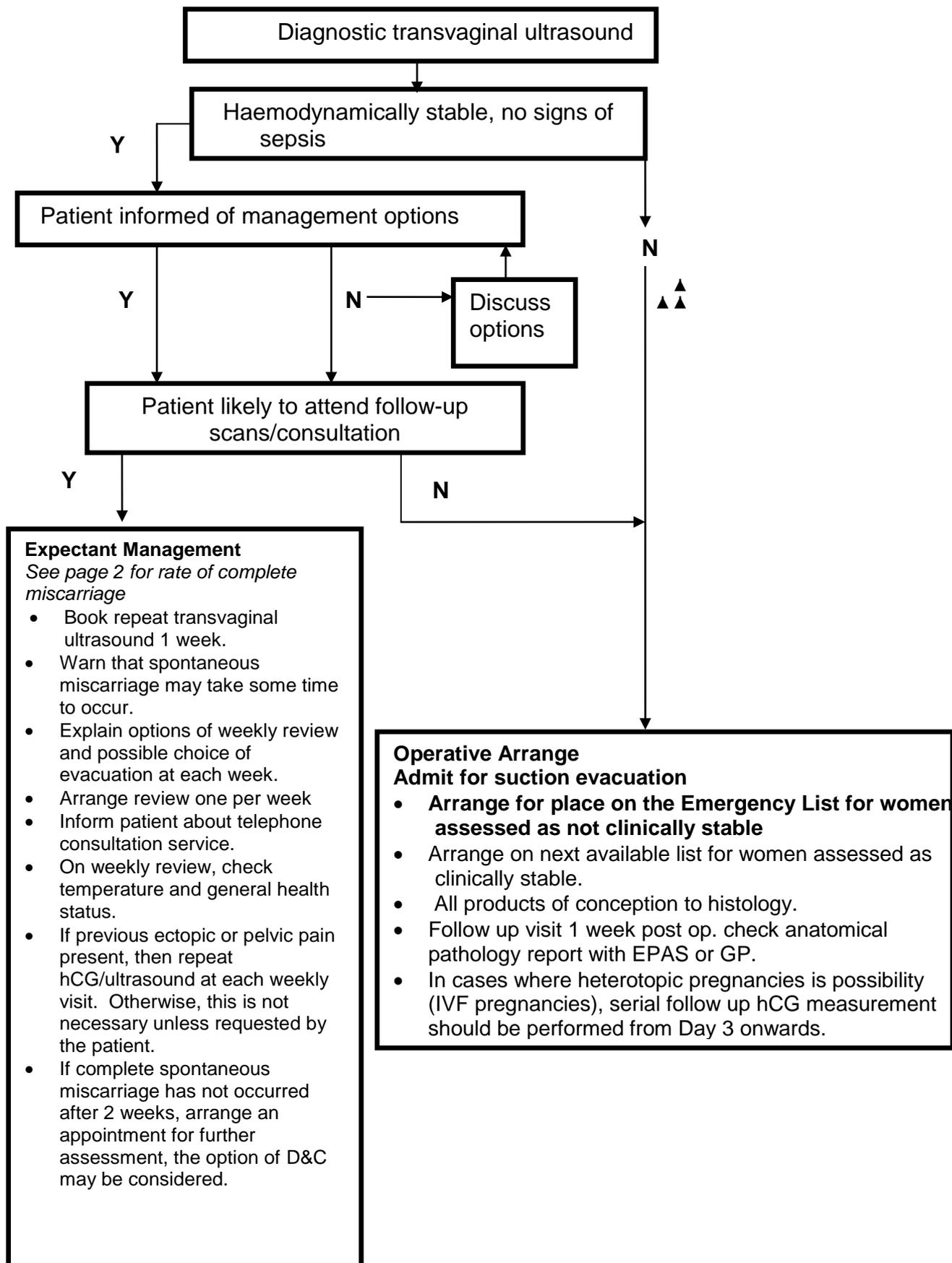
EPAS Diagnostic Algorithm



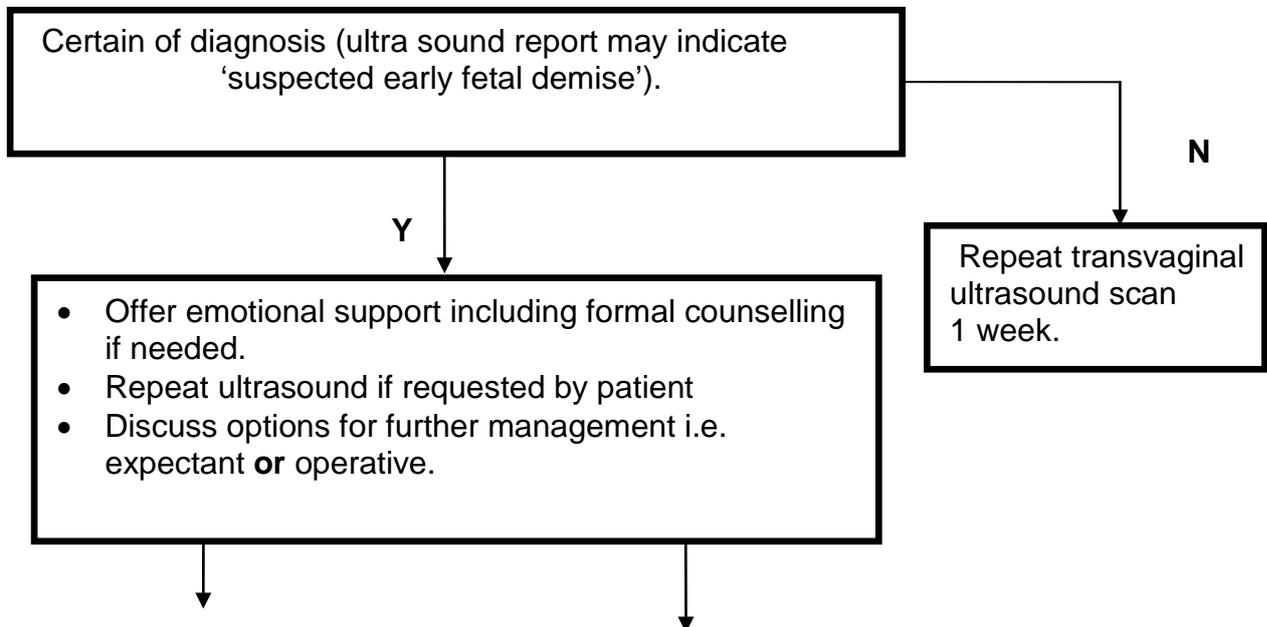
EPAS Algorithm: Pathway B
Intrauterine Pregnancy Uncertain Viability (IPUV)
Gestational sac < 20mm



EPAS ALGORITHM: PATHWAY C
Missed Miscarriage



EPAS ALGORITHM: PATHWAY D
Early fetal demise



Expectant See page 2 for rate of complete miscarriage

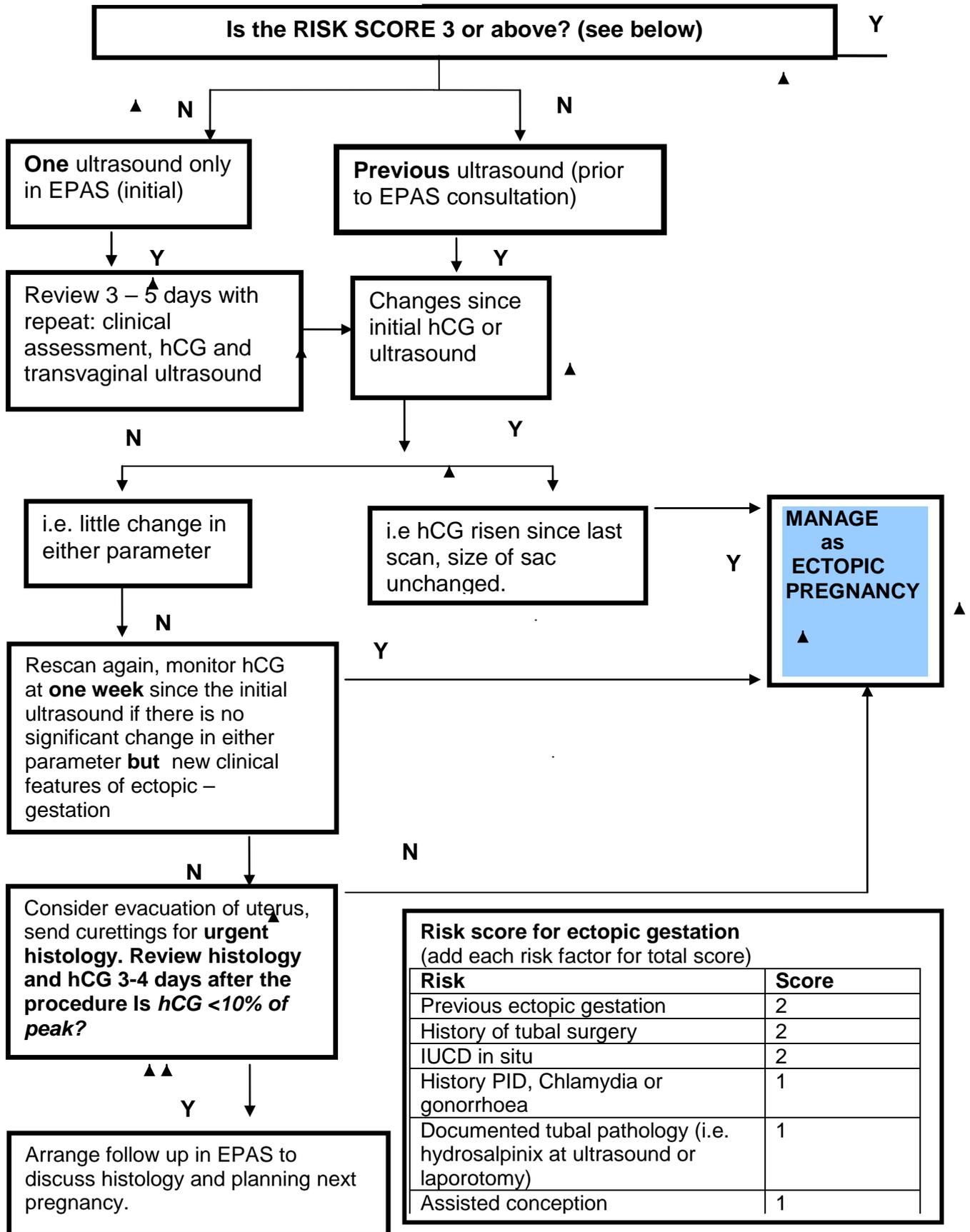
- Book repeat transvaginal ultrasound 1 week.
- Warn that spontaneous miscarriage may take some time to occur
- Explain options of weekly review and possible choice of evacuation at each week.
- Arrange review one per week
- Inform patient about telephone consultation service.
- On weekly review, check temperature and general health status.
- If previous ectopic or pelvic pain present, then repeat hCG/ultrasound at each weekly visit. Otherwise, this is not necessary unless patient requests it.
- If complete spontaneous miscarriage has not occurred after 2 weeks, arrange an appointment for further assessment, the option of D&C may then be considered.

Operative arrange Admission for suction evacuation

- Arrange on next available list.
- All products of conception to histology.
- Follow up visit 1 week post op. check anatomical pathology report with EPAS or GP.
- In cases with increased heterotopic pregnancy risk (IVF pregnancies), serial follow up hCG measurement should be performed from Day 3 onwards.



EPAS ALGORITHM: PATHWAY E
Management of Ectopic Pregnancy

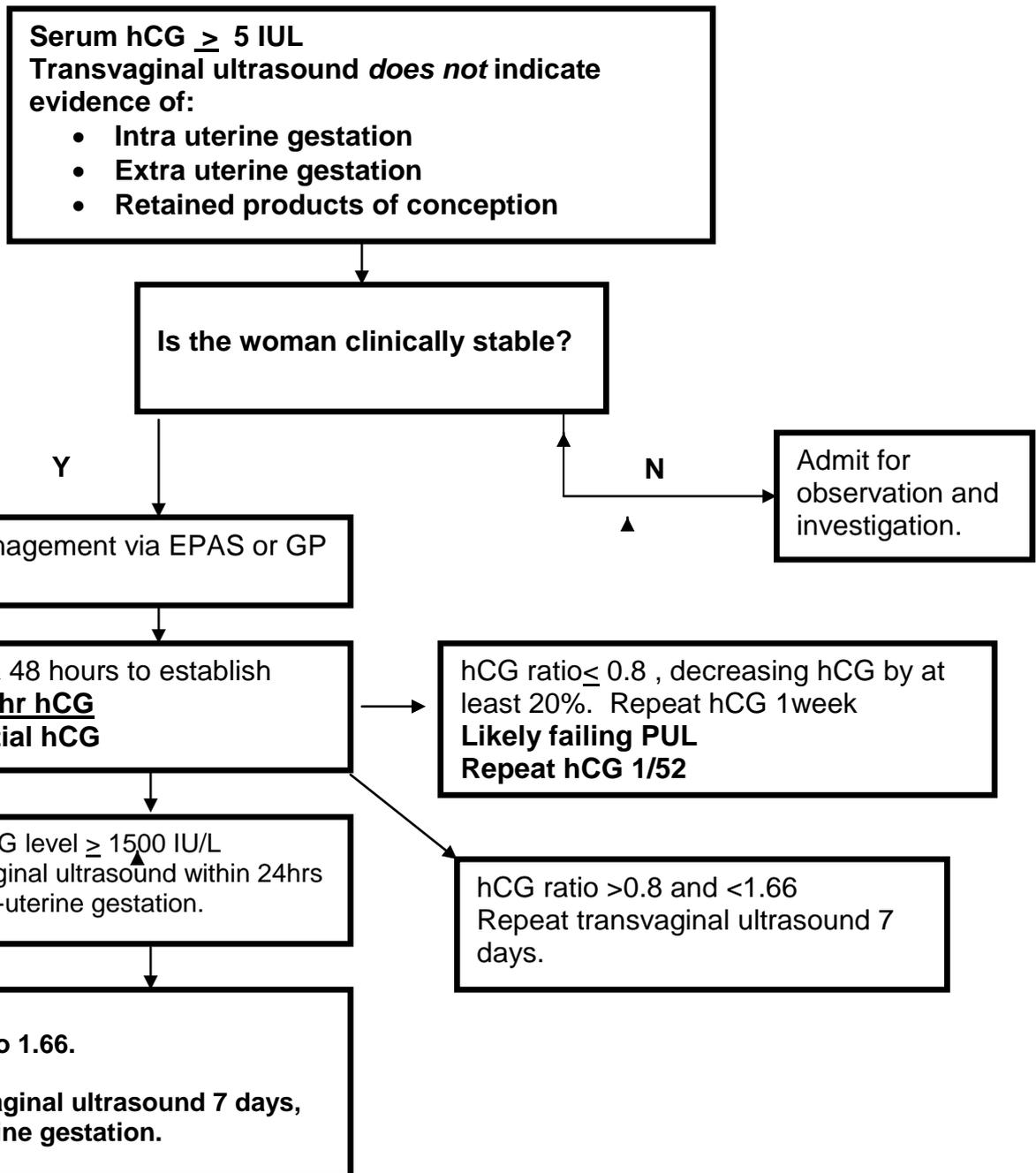


Risk score for ectopic gestation (add each risk factor for total score)	
Risk	Score
Previous ectopic gestation	2
History of tubal surgery	2
IUCD in situ	2
History PID, Chlamydia or gonorrhoea	1
Documented tubal pathology (i.e. hydrosalpinx at ultrasound or laporotomy)	1
Assisted conception	1

**EPAS Algorithm: Pathway F
Pregnancy of unknown location (PUL)**

Pregnancy of unknown location can be defined when:

- Serum hCG is positive i.e. ≥ 5 IU/L
- Transvaginal ultrasound (performed by a Senior Sonographer or Trained Sonologist) indicates no sign of either intra or extra uterine gestation or evidence of retained products of conception



All women must be advised to contact EPAS or present to Emergency Department if an increase in lower abdominal pain and /or vaginal bleeding, experiences faintness or shoulder tip pain.

Management of Ectopic Pregnancy

Ectopic pregnancy affects approximately 1 in 80 pregnancies. Statistics indicate the incidence is rising, however the associated mortality is decreasing due to improved diagnostic performance of transvaginal sonography and biochemical sensitivity and establishment of Early Pregnancy Services and Clinics.

Ectopic pregnancies are most commonly situated in the fallopian tube (approximately 95%). Less common sites are: interstitial, cervix, ovary, caesarean scar or rarely abdomen.

Risk factors may only be present in 25% - 50% of patients diagnosed with an ectopic pregnancy. These include:

- Previous ectopic pregnancy
- Tubal surgery
- Assisted reproductive technology
- Intra uterine contraceptive device in situ
- Use of emergency contraception
- History pelvic inflammatory/sexually transmitted disease
- Documented Tubal Pathology.

Management

Will depend on:

- clinical state of the woman,
- size ectopic visualised on transvaginal ultrasound
- presence/absence of haemoperitoneum
- serum hCG level
- patient choice **and** potential compliance.

Surgical Management

Laparoscopy is the method of choice for stable women who are medically fit and of appropriate BMI.

Laparotomy is preferred in cases of haemorrhagic shock or:

If the surgeon has insufficient experience of operative laparoscopy or suboptimal quality of laparoscopic equipment.

Medical Management: Systemic Methotrexate

Methotrexate is an anti-metabolite which prevents the growth of rapidly dividing cells by interfering with DNA synthesis. A single intramuscular dose of Methotrexate 50mg/m² is well tolerated and effective.

Indications for Methotrexate use:

- Haemodynamically stable
- Baseline serum hCG < 5,000IU/L
- Ectopic pregnancy < 3cm diameter on transvaginal ultrasound
- Absence of fetal heart motion on transvaginal ultrasound
- No significant haemoperitoneum.

Exclusion criteria

- Evidence of significant haemoperitoneum on transvaginal ultrasound
- Presence of fetal heart motion
- Active liver disease, aplastic anaemia, thrombocytopenia
- Women on concurrent corticosteroids
- Contraindications to Methotrexate
- Woman potentially non compliant to prolonged follow up (35 – 109 days)
- Ectopic mass > 3.0cm.

Expectant Management

Spontaneous resolution will occur in approximately 18% of all ectopic pregnancies. This has been well documented in numerous reports.

Indications for Expectant Management

- Serum hCG < 1000IU/L and declining
- Tubal mass less than 3cm
- No signs of tubal rupture or haemoperitoneum on transvaginal ultrasound
- Patient clinically stable.

Exclusion criteria

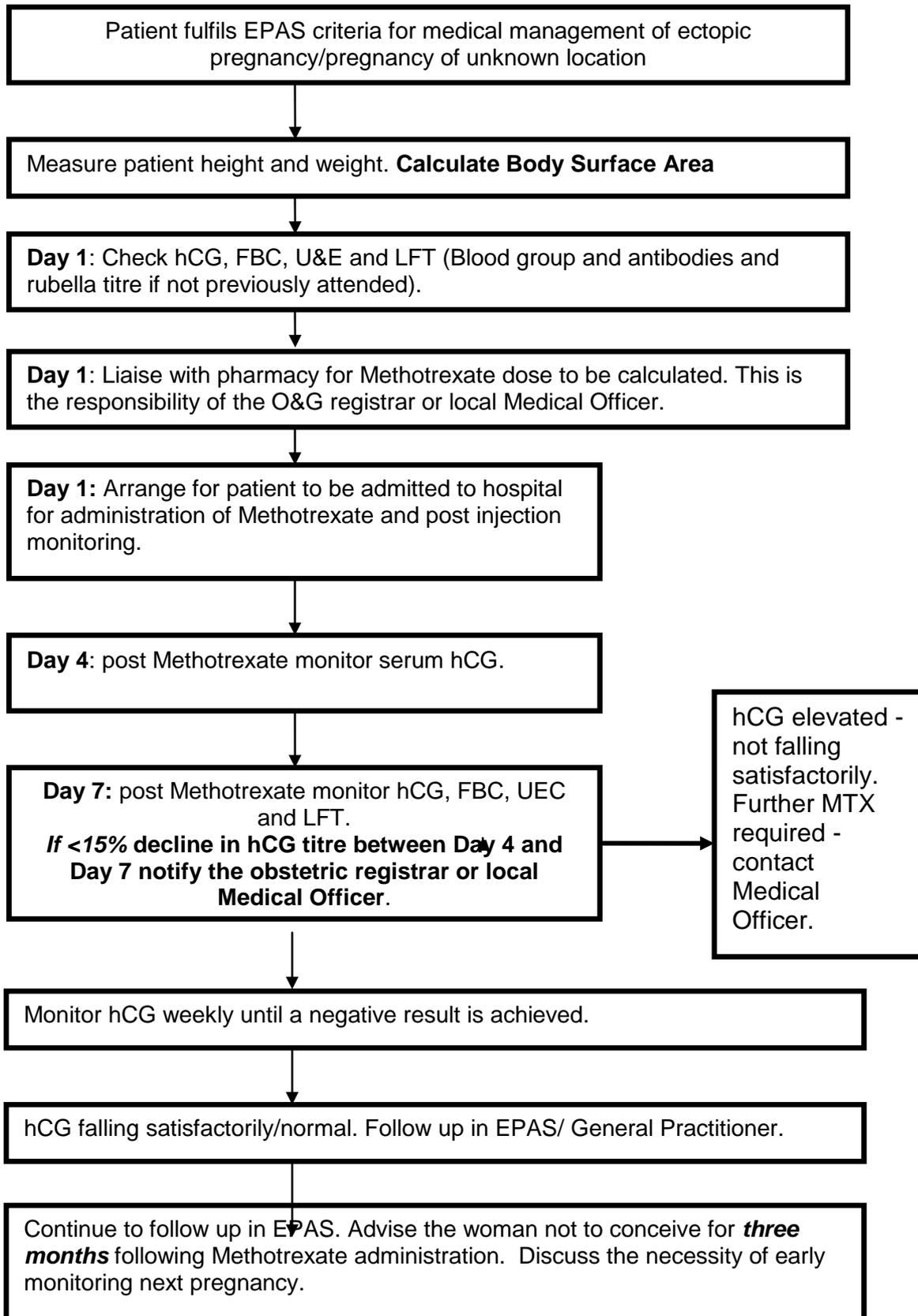
- Patient is potentially non compliant or not motivated to long term recovery.

Follow up

- Monitor serum hCG every 48 – 72 hrs until **less than 20 IU/L**
- **Once hCG levels less than 20 IU/L monitor once a week until negative.**
- Repeat transvaginal ultrasound if clinically indicated.

RUPTURE of ECTOPIC PREGNANCY can occur until hCG < 15 IU/L following expectant, medical or surgical management.

EPAS Algorithm: Methotrexate (MTX) Protocol



References for algorithms:

Association of Early Pregnancy Units: Guidelines 2007. Organisational, Clinical & supportive. Cardiff 2007

Condous G, Bleeding and pain in early pregnancy: what are the likely problems. Handbook for Early Pregnancy Care pp19-26 Chapter 3. Taylor and Francis London 2006

Condous G, Okaro E, Bourne T. The conservative management of early pregnancy complications: a review of literature. Ultrasound Obstet Gynaecol. 2003;22:420-430

Kirk E, Condous G, Bourne T, The non-surgical management of ectopic pregnancy. Ultrasound Obstet Gynecol 2006 271: 91 -100

Luise C, Outcome of expectant management of spontaneous first trimester miscarriage: observational study. 2002 April 13:324 (7342): 873-5.

Nepean Hospital Department of Obstetrics and Gynaecology: Acute Gynaecology Unit (AGU) Protocols, 2006

Royal College of Obstetricians and Gynaecologists (RCOG) The management of early pregnancy loss. (Green-top guideline: no 25) 2006 (including addendum released October 19th 2011)

Royal Prince Alfred Hospital: Early Pregnancy Assessment Service: Management Protocol for Early Pregnancy Assessment Service. November 2004.

Royal Women's Hospital: Algorithm: Initial assessment and triage of women with bleeding and pain in early pregnancy. Melbourne 2007

Royal Women's Hospital Early Pregnancy Assessment Service (EPAS) assessment, diagnosis, and management planning. Melbourne 2007

Sairam S, The role of ultrasound in the expectant management of early pregnancy loss. Ultrasound Obstet Gynaecol. 2001 Jun; (6) 506-9

Stovall and Ling. Single dose Methotrexate: An Expanded clinical trial. American Journal of O&G 1993.

Western Sydney Area Health Service (WSAHS): Registrars Guide for Bleeding in Early Pregnancy. 2003

Women's Hospitals Australasia: Management of Early Pregnancy Loss. Clinical Practice Guideline 2008

Appendix C Terminology

Table of appropriate terminology

Previous Term	Recommended Term	Definition	Notes
Spontaneous abortion	Miscarriage	Pregnancy loss occurring before 20 completed weeks of gestation or of a fetus less than 400gm weight if gestation is unknown [#]	
Threatened abortion	Threatened miscarriage	Any vaginal bleeding other than spotting before 20 completed weeks of gestation [#]	
Inevitable abortion	Inevitable miscarriage	Miscarriage is imminent or is in the process of happening [#] Threatened miscarriage with an open cervical os and/or rupture of the membranes [#]	
Incomplete abortion	Incomplete miscarriage	A miscarriage where some of the fetus or placenta are unable to be naturally expelled by the mother [#] A confirmed non-viable pregnancy on ultrasound with bleeding. Some products of conception remain in the uterus [#]	
Complete abortion	Complete miscarriage	A miscarriage needing no medical or surgical interventions [#] Products of conception have been passed; USS shows no apparent products; bleeding generally settles [#]	
Missed abortion	Missed miscarriage or Silent miscarriage	A confirmed, non-viable pregnancy on USS with no bleeding [#] Signs of this would be a loss of pregnancy symptoms and the absence of fetal heart tones found on an ultrasound [#]	A 'missed miscarriage' is when the fetus dies but the woman's cervix stays closed, there is no bleeding and the fetus continues to stay inside the uterus [#]

Previous Term	Recommended Term	Definition	Notes
Anembryonic pregnancy* or Blighted ovum*	Early fetal demise or Delayed miscarriage	Also called an <i>anembryonic pregnancy</i> . A fertilized egg implants into the uterine wall, but fetal development never begins. Often there is a gestational sac with or without a yolk sac, but there is an absence of fetal growth [#]	*these reflect different stages in the same process
Septic abortion	Miscarriage with infection (sepsis)	A miscarriage complicated by a pelvic infection [#]	
Recurrent abortion	Recurrent miscarriage	3 or more consecutive miscarriages by the same woman [#]	
	Biochemical pregnancy loss ¹¹	Pregnancy not located on scan ⁺	
	Empty sac ¹¹	Sac with absent or minimal structures ⁺	
	Fetal loss ¹¹	Previous CRL measurement with subsequent loss of fetal heart activity (FHA) ⁺	
	Early pregnancy loss ¹¹	Confirmed empty sac or sac with fetus but no FHA <12 weeks ⁺	
	Delayed miscarriage ¹¹	As 'early pregnancy loss' ⁺	
	Late pregnancy loss ¹¹	Loss of FHA >12 weeks ⁺	
Suspected ectopic	Pregnancy of unknown location ¹¹ (PUL)	No signs of either intra- or extra uterine pregnancy or retained products of conception in a woman with a positive pregnancy test. No identifiable pregnancy on scan with positive hCG ⁺	
	Viable pregnancy	Live ongoing embryonic pregnancy ⁺	
	Pregnancy of uncertain viability	Intrauterine sac (<25mm mean diameter) with no obvious yolk sac or fetus or Fetal echo <7mm crown–rump length with no obvious fetal heart activity.	In order to confirm or refute viability, a repeat scan at a minimal interval of 1 week is necessary. ¹⁶
	Ectopic pregnancy	A pregnancy located outside the uterus, usually in the fallopian tubes, but may be ovarian. [#]	

Previous Term	Recommended Term	Definition	Notes
	Molar pregnancy	The result of a genetic error during the fertilization process that leads to growth of abnormal tissue within the uterus. Molar pregnancies rarely involve a developing embryo, but often entail the most common symptoms of pregnancy including a missed period, positive pregnancy test and severe nausea. [#]	
Incompetent cervix	Cervical weakness	The opening of the cervix before a fetus is mature enough to be born. It may lead to miscarriage or premature delivery.	Cervical weakness is not routinely evaluated and therefore not usually diagnosed until after a second trimester loss has occurred.
	Expectant miscarriage management	No specific intervention; allows spontaneous passage of fetal tissue. ⁷⁸	
	Surgical miscarriage management	Surgical evacuation (with or without curettage) of the retained fetal tissue. ⁷⁸	
Heterotopic pregnancy	Heterotopic pregnancy	Concurrent/simultaneous intra-uterine and extra uterine pregnancies	

Definitions from the Health Data Standards Committee. 2006. National Health Data Dictionary Version 13.2. <http://www.aihw.gov.au/publications/hwi/nhddv13-c00.pdf>

*Definitions from The European Society for Human Reproduction Special Interest Group for Early Pregnancy, who have revised the nomenclature for use in early pregnancy loss in order to improve clarity and consistency.¹¹

