NATIONAL GUIDELINES FOR MATERNAL CARE

VOLUME III

- Management of Pre Labour Rapture of the Membranes
- Management of Pre term Labour
- Investigation and Management of a Death in Utero
- Management of Anaemia in Pregnancy
- Gestational Age Assessment and Determination of Chorionicity
- Management of Pregnancy in the Presence of Uterine Scar
- Management of Rhesus Negative Mother
- Management of Puerperal Sepsis
- Management of Ectopic pregnancy

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Statement of Intent
The main Purpose of these guidelines is to improve the quality of clinical care provided by the health care providers at all levels. These parameters of practice should be considered as recommendations only. The ultimate judgment regarding a particular clinical procedure or a treatment plan must be made by the clinician in light of the clinical data gathered from the patient and the diagnosis and treatment options available.
Preface

This national guideline on maternal care is very well-timed, as a greater emphasis is being given for improving the quality of maternal care services for further reduction of maternal and newborn mortality and morbidity in Sri Lanka. This set of guidelines has addressed the relatively rare but important disease entities which are matching with the epidemiological transition of causality of maternal deaths from direct causes to indirect causes. This is an attempt to improve the quality and uniformity of clinical care with efficiency, cost effectiveness and accountability.

I highly appreciate the contribution made by Ceylon College of Physicians, Sri Lanka College of Obstetricians and Gynaecologists and relevant public health programmes in developing these guidelines. Their experience and updated scientific knowledge is reflecting in the guidelines.

Further, these guidelines have been developed considering the policies, facilities, and resources available in the country. As such this set of guideline will be considered as national guidelines for the conditions described.

Dr. P. G. Mahipala
Director General of Health Services,
Ministry of Health,
Sri Lanka

October 2015
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Disclaimer
This guidance is intended to provide general advice to streamline the management and maintain overall quality of patient care. It should never be relied on as a substitute for proper clinical assessment with respect to the particular circumstances and needs of each patient under your care. It is the responsibility of each Practitioner to have regard to the particular circumstances of each individual patient, and the application of this guidance.
This guidance has been prepared having regard to the information available at the time of its preparation. Medicine is a continually evolving science and the users must have regard to relevant information, research or material, which may have been published or become available subsequently.
Introduction

Clinical Guidelines are systematically developed statements which assist clinicians and patients in making decisions about appropriate treatment for specific conditions based on the best scientific evidence at the time of development. Guidelines are not intended to limit the clinical freedom; however, clinicians are expected to follow these recommendations as the basis for their decisions. Availability of resources, the existing situations, and the expectations of individual client needs to be considered. The guidelines are intended to guide all health care workers in all levels of institutions where maternity care is provided. Although these guidelines are mainly targeted for the government sector institutions, use in the private sector institutions where maternity care is provided, is also encouraged.

These guidelines are developed by expert group from the Sri Lanka College of Obstetricians and Gynaecologists in consultation with other relevant specialists such as anaesthesiologists, physicians, endocrinologists, and haematologists etc. The existing national and international guidelines, and WHO guidelines were perused and mixed with the local scenarios and expert opinion. The latest available scientific evidences were considered and included where ever necessary. Then, the draft guidelines were presented to the wider forum of experts and consensuses were reached. After that the guidelines were handed over to the Ministry of Health and consensus were built with the participation of multi-disciplinary team including medical administrators, provincial health authorities, representatives from SLCOG and other relevant professional colleges, and national programme managers.
Management of Prelabour Rupture of Membranes
1. Management of Prelabour Rupture of Membranes

1.1. Definitions
Prelabour rupture of membranes (PROM) is defined as the rupture of membranes prior to the onset of labor. This can occur at term (term PROM after completion of 37 weeks), or preterm (PPROM from 24 – 37 weeks) or prior to viability (pre-viable PROM less than 24 weeks).

1.2. Background
It is vital that prelabour rupture of membranes is recognized due to its association with cord accidents, sepsis and preterm birth. All these in combination or independently are capable of causing morbidity and mortality both in the mother and the neonate.

1.3. Diagnosis
The diagnosis is mainly based on the history and a sterile speculum examination. While the diagnosis may be obvious in the majority, in some cases, it may be difficult. In these situations it is recommended that the woman is reexamined after a minimum period 30 minutes of lying down.

During the initial speculum examination the approximate cervical length and dilatation, the colour of liquor, any offensive smell and the presence of cord prolapse should be noted.

A high vaginal swab for culture and antibiotic sensitivity must be taken at the time of the speculum examination.

If the diagnosis is still not confirmed, examination of the sanitary pad after a minimum of four hours of being ambulant may help come to a conclusion.

Ultrasound is not confirmatory, but may be useful.

It is important that digital vaginal examination is avoided in those who are suspected of pre-labour rupture of membranes, unless a decision for delivery has been made.
1.4. Management

1.4.1. Initial management
- Confirm the period of gestation and size, lie and presentation of the fetus
- Assess the maternal heart rate, respiratory rate, temperature and look for tenderness over the uterus
- Assess fetal condition with cardiotocograph if the period of gestation is > 28 weeks (especially note a persistent baseline tachycardia, which may indicate chorioamnionitis)
- Perform a full blood count and where it is available, a CRP

1.4.2. PROM at term
- There are two approaches to managing a woman who develops PROM at term.
  - Immediate induction of labor
  - Conservative management for approximately 24 hours, with close monitoring of maternal and fetal wellbeing followed by induction of labour
- There is no consensus as to which out of these two is the better method. A choice may be made between these two approaches depending on the preference of the Consultant and the wishes of the mother.
- In mothers who have proven colonization with group B streptococci (GBS) or a past history of an infected baby the following are recommended:
  - Immediate induction of labor.
  - Administration of prophylaxis against GBS with crystalline penicillin 3 Grams stat and 1.5 Grams four hourly intravenously until delivery. Those who have allergies to penicillin, clindamycin 900 mg i.v. 8 hourly until delivery.
- Induction of labor may be carried out either with the use of intravenous oxytocin or prostaglandin pessaries, depending on preference.
1.4.3. Preterm PROM

- Consider in utero transfer to a center with facilities appropriate for gestation and fetal weight.
- The parents must be counseled about the possible long stay in the hospital and prognosis.
- Inform the neonatal/pediatric team.
- There are three indications for delivery
  - Chorioamnionitis (see Box 1.1)
  - Fetal compromise
  - Completion of 36 weeks of gestation
- Use of antibiotics
  - Erythromycin 250 mg 6 hourly for 7 days
  - In addition, as per the ACOG Guideline, ampicillin 2 G iv 6 hourly for 48 hours followed by amoxicillin 500 mg orally 8 hourly for next 5 days
  - Change antibiotics depending on the culture and sensitivity report of the high vaginal swab
- Corticosteroids – refer preterm labor guideline
- Tocolysis – refer preterm labor guideline
- It is recommended that to woman’s pulse, respiratory rate and temperature is monitored and uterine tenderness and change in nature of amniotic fluid observed.
- Fetal tachycardia is one of the best indicators of chorioamnionitis.
- Regular assessment of fetal growth and wellbeing by ultrasound is required.
- The mode of delivery has to be individualized.

**Box 1.1. Diagnosis of Chorioamnionitis**

<table>
<thead>
<tr>
<th>The presence of at least three of the following will suggest a diagnosis of chorioamnionitis</th>
</tr>
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<tbody>
<tr>
<td>a. Maternal pyrexia &gt;38° c</td>
</tr>
<tr>
<td>b. Fetal tachycardia &gt;160 bpm</td>
</tr>
<tr>
<td>c. Maternal tachycardia &gt;100/min</td>
</tr>
<tr>
<td>d. Uterine tenderness</td>
</tr>
<tr>
<td>e. Offensive vaginal discharge</td>
</tr>
<tr>
<td>f. CRP &gt;3times the upper limit of normal</td>
</tr>
</tbody>
</table>
1.4.4. Preivable PROM

- Preivable PROM results in an extremely poor prognosis. The resulting early onset oligohydramnios leads to severe pulmonary hypoplasia, leading to a very high neonatal mortality rate. The few infants who survive have major contracture deformities.
- Parents must be informed about the poor prognosis.
- Inform the neonatal team.
- Tocolysis, magnesium sulphate for neuroprotection and prophylactic antibiotics are not indicated.
- The pregnancy may be managed conservatively until delivery, unless chorioamnionitis develops, which warrants delivery.
- A decision may be made not to resuscitate depending on the maturity, associated anomalies, views of the neonatal/pediatric team and the views of the parents. The neonate may be allowed to pass away with dignity and minimum resuscitation in this situation.

1.4.5. Management of premature rupture of membranes in the presence of a cervical cerclage

- There are no randomized data regarding this aspect.
- Management depends on the period of gestation, presence or absence of infection and labor.
- Retention of the cerclage is associated with a higher risk of infection, although it may result in prolongation of pregnancy.
Algorithm for management of Prelabour rupture of membranes (PROM)

1. **Women with a history suggestive of PROM**
   - Assess history of a gush of fluid and dampness.
   - Do a sterile speculum examination to see presence of liquor in vagina
     * Also look for cervical length and dilation, colour of liquor, any offensive vaginal discharge, and presence of cord prolapse.
   - Take a high vaginal swab for culture & AST

2. **Confirm the diagnosis**
   - If no fluid is seen, repeat speculum examination after 30 min of lying down

3. **Initial assessment**
   - If still negative, ask to wear a clean pad.
   - Inspect the pad after 4 hrs of ambulation
   - An USS maybe useful though not diagnostic.
   - Avoid digital examination unless delivery is planned.
   - If not suggestive of PROM, reassure and discharge home.
   - Ask to come back if further loss noted

4. **Confirm the period of gestation, EFW, lie and presentation**
   - Assess maternal heart rate, respiratory rate, and temperature
   - Look for tenderness over the uterus.
   - Assess fetal condition with CTG if >28 weeks. Do FBC and CRP if available

### PROM at term
- 2 approaches to the Mx
  - Immediate IOL OR
  - Conservative management up to 24 hrs and IOL
  - Decide according to patient preference after counselling.
- IOL either with IV Oxytocin or vaginal PG according to preference of the clinician and the woman.
- In known GBS carriers or a previous GBS infected baby
  - Offer immediate IOL
  - Antibiotic prophylaxis for GBS all delivery
    - (Crystalline penicillin IV, 3g stat and 1.5g four hourly OR clindamycin IV 900mg 8 hourly)

### Preterm PROM
- Inform the neonatal team. Consider in utero transfer if required.
- Steroids and tocolysis – as per PTL guidelines
  - Start on prophylactic antibiotics - Erythromycin orally 250mg 6 hourly for 7 days AND ampicillin IV 2g 6 hourly for 48 hours followed by amoxicillin orally 500mg 8 hourly for next 5 days
  - Monitor for evidence of infection. Fetal tachycardia is an early sign of chorioamnionitis.
  - Serial monitoring of fetal growth and wellbeing by USS should be carried out.
- The mode of delivery has to be individualised. The main indications for delivery include
  - Completion of 36 weeks of gestation
  - Evidence of fetal compromise
  - Chorioamnionitis

### Pre-viable PROM
- Inform the neonatal team
- The parents should be informed of the very poor prognosis due to lung hypoplasia and major contracture deformities
- Manage conservatively till labour ensues (unless there is evidence of chorioamnionitis, which warrants delivery)
- A decision for not carrying out resuscitation should be made, after consultation with the neonatal team, considering the maturity and other anomalies.
- Severe chorioamnionitis can occur even in preivable PROM and therefore appropriate monitoring is required.

**Fact box – Features of Chorioamnionitis**
- Presence of three or more of the following is strongly suggestive of chorioamnionitis.
  - Maternal pyrexia > 38°C
  - Maternal tachycardia > 100/minute
  - Offensive vaginal discharge
  - CRP > 10 times the upper limit of normal
Management of Preterm Labour
2. Management of Preterm Labour

2.1. Definition and background

- Onset of labor between 24 to 37 completed weeks.
- Approximately 10% of Sri Lankan babies are born preterm.
- It is the leading cause of perinatal morbidity & mortality and long term disability.

2.2. Classification of preterm birth

<table>
<thead>
<tr>
<th>Extreme</th>
<th>Early</th>
<th>Moderate</th>
<th>Mild</th>
</tr>
</thead>
<tbody>
<tr>
<td>24 – 27+6</td>
<td>28 – 31+6</td>
<td>32 – 33+6</td>
<td>34 – 36+6</td>
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</table>

- The mild category accounts for 30 – 50% of preterm births. In them, a good outcome can be achieved with basic measures.
- Short and long term adverse outcomes are greater with extreme preterm birth.

2.3. Presentation

The mother may present with non-specific symptoms such as uterine cramping, backache, increased vaginal discharge and show.

2.4. Diagnosis

A careful attempt must be made to diagnose preterm labor correctly. A wrong diagnosis of preterm labor could result in unnecessary interventions and psychological morbidity.

The following should be looked for:

- Palpable regular uterine contractions > 1 : 10 min
- Cervical findings on vaginal examination
  - Length < 2cm
  - Cervical dilatation > 2cm
  - Change in dilatation in four hours > 1cm
- One of the most important assessments in a woman with threatened preterm labor is measurement of cervical length by trans vaginal ultrasound. (See Annexure 1 for the technique of measuring the cervical length).
Table 2.1. Cervical length & risk of preterm birth

<table>
<thead>
<tr>
<th>Cervical length</th>
<th>Risk of delivery &lt;48 hours</th>
<th>Risk of delivery &lt;7 days</th>
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<tbody>
<tr>
<td>≥ 30 mm</td>
<td>1.9%</td>
<td>2.8%</td>
</tr>
<tr>
<td>≤ 15 mm</td>
<td>36.7%</td>
<td>56.7%</td>
</tr>
</tbody>
</table>

Therefore it is recommended that where facilities are available, transvaginal ultrasound to measure the cervical length be given high priority to base decisions on management of women in threatened preterm labor.

Where neonatal facilities are not adequate to deal with the period of gestation, a cut-off of 20 mm is suggested to base a decision to transfer to a center with suitable facilities.

It must be remembered that women with abruptio placentae, which requires a totally different management strategies is often misdiagnosed as having preterm labor. A conscious effort must be made to exclude this condition when diagnosing preterm labor.

**Cervical-vaginal fetal fibronectin test:** Patients with threatened preterm labour can be offered cervical-vaginal fetal fibronectin test. If test is negative, her chance of preterm delivery is extremely low. However, a positive test has a low predictive value for preterm delivery. This is presently not available in Sri Lanka.

**2.5. Management of a woman in preterm labour**

- Confirm gestational age
- Recognize coexisting illnesses
- Establish fetal lie, presentation and engagement of the presenting part
- Estimate fetal weight by ultrasound
- Assess fetal wellbeing
- Perform a sterile speculum examination to detect unsuspected rupture of membranes
• Perform a sterile vaginal examination for assessment of progress
• Inform senior staff
• Check availability of neonatal facilities with pediatric/neonatal team
• Consider situations in which, due to maternal or foetal reasons, it may be beneficial to allow the labor to continue
  Consider the need for
  a. Steroids
  b. Tocolysis
  c. Magnesium sulphate for neuroprotection of the neonate

2.5.1. Steroids
• Steroids must be administered between 24 – 34+6 weeks in an appropriately grown foetus. In the presence of fetal growth restriction, administration up to 35+6 is beneficial.
• There is no evidence of benefit beyond these time limits. The current evidence suggests that the risk of mortality may increase if steroids are administered beyond 37 weeks gestation.
• Diabetes mellitus is not a contraindication to administration of steroids.
• Either intramuscular Dexamethasone or Betamethasone ( total 24 mg in divided doses over 48hrs ) is recommend. In the WHO as well as Sri Lankan essential drugs list include 2ml vial of Dexamethazone 8 mg and this can be given 12 hourly for 3 doses .Betamethasone suspension containing acetate & sulphate (Not phosphate), 12 mg i.m. two doses 24 hours apart may be administered. Dose of betamethazone phosphate is 12mg 12hrly X 24 hrs
• Optimal effects are seen from within 24 hours upto 7 days after the completion of treatment. It is important therefore that steroids are administered only if delivery in anticipated within the next seven days.
• Routine administration of repeat doses is not recommended.
• A single rescue course / dose is recommended if pre term birth does not occur within the next 7 days or when the clinical assessment demonstrates a risk of pre term birth exists.
Further repeat courses may be considered up to a maximum of four courses in total.

Corticosteroids are recommended in women with prelabour rupture of membranes before 34+6 weeks with no clinical evidence of chorioamnionitis.

2.5.2. Tocolysis

- Tocolysis is beneficial to maximize the benefits of steroids or for delaying delivery for in utero transfer.
- Tocolysis is not recommended for management of preterm labor in the following situations:
  - Abruptio placentae
  - Suspected intrauterine infection
  - Maternal hypotension (Systolic blood pressure <90 mmHg)
  - Lethal congenital anomalies
  - Gestation ≥ 34+6 weeks with adequate neonatal facilities
  - Labor too advanced
  - Suspected fetal compromise
  - Preeclampsia

- The loading dose is Nifedipine 20 mg orally and 10 mg half-hourly orally till contractions cease (to a maximum total of 40 mg loading dose). Continue 20 mg 8 hourly up to 48 hours.

  Contraindications are:
  - Maternal cardiac disease
  - Hepatic dysfunction
  - Concurrent use of beta sympathomimetics, nitrates or antihypertensive medications

- The immediate release form of Nifedipine must be used (included in the WHO essential drugs list) and not the sustained release form. While Nifedipine is being administered in the above manner, maternal pulse and blood pressure must be measured half hourly for two hours and before the administration of the 8 hourly doses.

- Maintenance therapy is not recommended.
2.5.3. **Magnesium sulphate for neuroprotection of the neonate**

- Magnesium sulphate must be considered when extreme or early preterm birth is imminent (i.e. <32 completed weeks gestation)
- The dose is 4 Grams intravenously over 10 minutes, followed by a maintenance dose of 1G/hour up to a maximum of 24 hours or until delivery, whichever comes first.
- Intramuscular magnesium sulphate may be considered in situations where there are problems with i.v. administration. For details refer guideline on severe preeclampsia
- The loading dose will suffice birth occurs within four hours of its administration

2.6. **Labour & Delivery**

- The woman and her husband/partner must be informed of the situation
- Inform paediatric/neonatal team regarding imminent delivery
- Cephalic presentation may be managed similarly to high-risk labour at term. Continuous fetal heart rate monitoring is preferred.
- Vacuum extraction is contraindicated if the period of gestation is less than 34 weeks.
- The mode of delivery in a breech presentation must be decided after discussing with a Consultant.
- Episiotomy may be needed.
- Epidural analgesia is preferable to pethidine.
- A member/s of the paediatric team must be present at the delivery.
- Where it is necessary, a person experienced in preterm cesarean delivery must carry out cesarean section. Especially in extreme and very preterm infants the delivery must be affected with minimum trauma to the baby. En-caul delivery i.e. delivery with membranes intact is recommended to achieve this. This method of delivery is particularly important when the fetus presents by the breech or is not in longitudinal lie. A longitudinal incision in the lower segment must be considered where it is poorly formed.
- Delayed cord clamping for two minutes from delivery is recommended unless there is a contraindication (refer guideline on normal labor).
2.7. **Immediate management of the preterm neonate**

- Every effort must be made to deliver extremely preterm infants centers with tertiary neonatal care facilities. In-utero transfer is the best way to ensure better outcomes.
- Parents should be counseled about baby’s possible outcome and course of hospital stay.
- Discuss all potential extreme and very preterm deliveries with Neonatologist/Paediatrician as availability of intensive care cots may decide the need for in-utero transfer.
- Inform the neonatal team well in advance and ensure their attendance at delivery.
- An experienced neonatal clinician should attend deliveries <32 weeks gestation.

**Resuscitation**

- Preterm babies must be delivered into a warm environment. Air conditioners must be switched off and the resuscitaire warmed prior to birth.
- Preterm babies <32 weeks of gestation should be placed inside a food-grade plastic wrap or bag (freezer bags) up to their necks without drying, immediately after birth. Where there are practical difficulties in doing this, it may be done once the baby is transferred with the minimum delay under a preheated resuscitaire /radiant warmer. The bag is held open by an assistant and the feet slid in first, leaving the face exposed. The open end of the bag is then closed. The bags used for this purpose only need to be clean – sterile bags are not necessary. All procedures including auscultation are done with the bag on. The bag is removed only after the baby is stabilized inside an incubator in the neonatal unit.
- A hat should be applied without drying, after the baby has been placed inside the plastic bag as the head accounts for 18% of heat loss.
- Resuscitation, when necessary should take place under a preheated radiant warmer in a warm room.
- Stable late preterm infants should be kept ‘skin to skin’ with the mother immediately after birth and allowed to breastfeed.
- In stable preterm infants, clamping of cord must be delayed by at least 60 seconds as this ensures better outcomes. If resuscitation is required, it should take precedence.
Oxygen for resuscitation should be controlled by using an air-oxygen blender where available. The lowest concentration of oxygen possible should be used during stabilization. In the absence of a blender, connect oxygen 5-10L/min to the self-inflating bag without the reservoir to provide an oxygen concentration between 25 to 40%.

Resuscitation for babies <32 weeks gestation should be commenced with 30% oxygen and adjusted according to saturation targets achieved, while ensuring avoidance of hyperoxaemia and hypoxia.

Saturation monitoring probe should be attached to the right hand of the baby preferably by one minute of age, before the monitor is switched on.

If bradycardia of less than 60 beats per minute exists administer 100% Oxygen until heart rate goes above 100.

In newborn resuscitation a T-piece device is currently the best method of providing respiratory support as it can provide a measured peak end expiratory pressure (PEEP) and measured positive inspiratory pressure (PIP) if required. These will avoid alveolar collapse and use of excessive tidal volumes.

In babies breathing spontaneously, start stabilization with CPAP of at least 5–6 cm H2O via a mask if available or via nasal prongs.

Ideally, babies should be transported to the neonatal unit in a transport incubator / ventilator with ongoing respiratory support preferably by CPAP (T-piece and tight mask) or nasal prong oxygen if CPAP is not available.
• Intubation should be reserved for babies who have not responded to positive pressure ventilation via a mask.
• If baby is intubated, make sure the lip level of endotracheal tube (ET) tube is appropriate for the size of the baby and correct positioning of the ET tube should be verified by chest X-ray upon admission to neonatal unit.
• Checking the birth weight at the delivery suite is discouraged as it may make the baby hypothermic.
• Ensure that the baby is shown to the mother before transfer to neonatal unit.
• Assist the mother to express breast milk within the first 6 hours if baby needs admission to neonatal unit. Ensure that the mother is provided continuing assistance to express breast milk 2 to 3 hourly in order to enhance breast milk secretion.
• Assist mother to visit the baby as soon as possible to facilitate kangaroo mother care, establish breastfeeding and increase bonding.
• Continue Kangaroo mother care with breast feeding or with expressed breast milk feeds if baby is < 2kg

2.8. **Postnatal management**
• The mother must be given every opportunity to see and to have contact with her baby.
• Where this is not possible it is the duty of the obstetric team to keep the mother informed about the condition of her baby/babies.
• An interpregnancy interval of <12 months and pregnancy in adolescence are recognized risk factors for preterm birth. Directed contraceptive advice is recommended.
• Appropriate dietary advice must be given for women with a low BMI
• Arrange a postnatal visit for debriefing.
• For management in case the baby dies, refer to the guideline on Death in Utero and Neonatal Death.
2.9. Management of a woman without a uterine abnormality who has had a previous spontaneous preterm birth of a morphologically normal baby before the completion of 34 weeks gestation

- The woman must have a urine culture performed as early as possible in the pregnancy and asymptomatic bacteriuria treated. Eradication of bacteriuria must be confirmed by a repeat culture performed two weeks after completion of treatment.
- At 16 weeks gestation the woman must be recommended weekly intramuscular injections of 17-α hydroxy progesterone caproate 250 mg until 34 weeks gestation. Vaginal micronized progesterone 200 mg daily is an alternative to intramuscular progesterone.
- Assessment with transvaginal ultrasound scans to measure cervical length at 16, 20 and 24 weeks is recommended.
- If at any of these assessments the cervical length is found to be 25 mm or less, cervical cerclage is recommended (e.g. McDonald Suture). Intramuscular or vaginal progesterone as described in 6.2 is recommended to be continued even if a cerclage is inserted.

2.10. Management of a woman without a previous history of a preterm birth with an incidental finding of a short cervix

- If the cervical length by transvaginal ultrasound scan is found to be less than 20 mm at or before 24 weeks gestation, vaginal progesterone (natural micronized progesterone 200 mg daily) from diagnosis until 34 weeks gestation is recommended.
- Cervical cerclage has not been shown to improve outcomes in this category of women.

2.11. Prevention of preterm birth in multiple pregnancy

- Routine administration of progesterone has not been shown to reduce the risk of preterm birth in multiple pregnancy.
- Cervical cerclage in multiple pregnancy may increase the risk of preterm birth.
- Routine admission to hospital, bed rest and tocolytics has not been shown to be of benefit.
- Women with multiple pregnancy with a previous preterm birth should be managed as previously described for similar singleton pregnancies.
2.12. Cervical length measurement: Method of transvaginal sonographic measurement

- Patients should be asked to empty the bladder immediately before the examination.
- Examination should be conducted with the patient in the dorsal or lithotomy position.
- A disposable sheath, preferably a condom should be used to cover the probe. Gel is placed between the transducer and condom, and sterile gel is also used to lubricate the surface of the sheath.
- The ultrasound transducer should be of high resolution: 5 MHz or higher.
- The operator introduces the endovaginal transducer into the anterior vaginal fornix to obtain a sagittal view of the cervix.
- The probe may need to be moved laterally or in other directions in order to optimally image the cervix.
- The image to measure endocervical length should include the internal os, the cervical canal and external os.
- Excessive pressure with the probe may elongate the cervix. To avoid this pitfall, the probe is slowly withdrawn until the image blurs, and is subsequently reapplied with an amount of pressure sufficient to restore the image. This can be avoided by confirming equal cervical widths and density of the anterior and posterior lips of the endocervical canal.
- The endocervical length measurement should not include the lower uterine segment. A useful anatomical landmark is the endocervical glands. The lower uterine segment does not display the hypoechogenic image of the cervical glands. Including the lower uterine segment would result in a falsely longer measurement than the actual endocervical length. The anterior and posterior lips of the cervix should have the same dimensions; unequal dimensions suggest that there is excessive pressure being applied during transvaginal sonography.
- The image used to measure endocervical length should be magnified so that the cervix will occupy at least 75% of the image.
- The cervical length is measured by freezing the screen three separate times. For clinical purposes, the shortest cervical length is reported, provided the image is adequate.
• The duration of the examination should be between 3 and 5 min.
• The presence of funnelling needs to be recorded. A funnel is defined as dilatation of the upper portion of the cervical canal. The width of the funnel must be at least 5 mm. The funnel can only be recognized by confirming that the walls are formed by endocervical mucosa; otherwise, the covering wall of the lower uterine segment can be erroneously considered to be part of a funnel.
• The presence of “dynamic changes” need to be noted. This feature is defined as a prolapse of the membranes through the endocervical canal. The most likely explanation for a dynamic change is a uterine contraction (symptomatic or asymptomatic) in the presence of an excessively compliant cervix.
• If the cervix is curved, the “trace” function can be used to measure the cervix (if not available, cervical length can be determined by adding the sum of two straight sections).
• Observe for the presence of particulate material in the amniotic cavity (“sludge”) in proximity to the cervix and whether such material is free-floating or attached to the cervix. Occasionally, it is possible to gently tap on the anterior uterine wall to determine the effect of pressure on the particulate material.
• A free online course for measuring cervical length is available at: http://www.fetalmedicine.com/fmf/online-education/05-cervical-assessment/
Algorithm for management of preterm labour (PTL)

Suspicious PTL in women presenting with:
- A gestation < 37 weeks AND
- Uterine cramping OR Backache OR vaginal discharge / show

Confirm the diagnosis by detection of:
- Palpable uterine contractions > 1/10 minutes
- Presence of cervical changes on examination:
  - Length < 2cm, Dilatation > 2cm,
  - A change in dilatation in 4 hours ≥ 1cm
- Cervical length at TVS ≤ 20mm
- Fetal fibronectin test – note the high NPV and moderate PPV
(Beware of placental abruption which share some clinical features)

Management

Antepartum
- Confirm GA. Estimate fetal weight by USS
- Establish fetal lie, presentation and engagement
- Assess fetal wellbeing
- Diagnose / exclude PROM
- Check availability of neonatal facilities
- Look for contraindication for prolonging pregnancy

Steroids
- From 24+6 to 34+6 (up to 35+6 in SGA)
- Dexamethasone 8mg IM 12 hourly 3 doses OR
  Betamethasone 12mg IM 24 hourly 2 doses
- Do not give repeat doses routinely. A single rescue dose may be given if initial dose has been < 26 wks.

Tocolytics
- Consider only if time required for steroids to act OR in utero transfer
- Exclude CIs for prolonging pregnancy OR for Nifedipine
- The regimen to use: Nifedipine 20mg PO followed by 10mg every 30 minutes up to 4 doses till contractions cease. Maintenance dose of Nifedipine 20mg PO 8 hourly up to 48 hours.

MgSO4 for neuroprotection (Only if < 32+6)
- Regimen: 4gm IV over 20 minutes and maintenance dose of 1gm/hr till delivery or up to 24 hours

Intrapartum
- Inform the neonatal team.
- A neonatal team member should be present at delivery.
- Continuous fetal monitoring is preferred.
- Cephalic presentation managed similar to high risk labour at term.
- Vacuum extraction is CI if <34+6
- Epidural anaesthesia preferred over pethidine for pain relief.
- CS for any indication should be undertaken by a surgeon competent in preterm CS
- Delayed cord clamping for 2 mins is preferred, if no CIs

Primary and secondary prevention

Previous PTL and normal uterus
- Investigate and treat asymptomatic bacteriuria
- Offer IM / vaginal Progesterone from 16 – 34 wks
- Carry out cervical length measurement at 16, 20 and 24 wks
- Consider cerclage if length <25mm
  Incidental finding of a short cervix with no Hx of PTL
  - If Cx <20mm at ≥24 wks, offer vaginal progesterone.
  - No evidence to support benefit of cervical cerclage
References

1. Roberto Romero1,a,**, Lami Yeo1,2, Jezid Miranda1, Sonia S. Hassan1,2, Agustin Conde-Agudelo1 and Tinnakorn Chaiworapongs1,2 A blueprint for the prevention of preterm birth: vaginal progesterone in women with a short cervix* J. Perinat. Med. 41 (2013) 27–44

Investigation and Management of a Death in Utero
3. Investigation and Management of a Death in Utero

3.1. Preamble
A death in utero is a devastating experience to the mother and her family. Some may never recover from such an experience and affected women are known to have intense, protracted grief reactions and to have depression.

3.2. Definition
Death in utero is defined as the death of a fetus after the completion of the 28th week of gestation. Those with a birth weight of 500 grams or more without signs of life at the time of birth also belong to this group.

3.3. Diagnosis
Absence of fetal cardiac activity on ultrasonography is the recommended method for diagnosing death in utero. Colour Doppler of cardiac activity and umbilical cord will supplement the diagnosis.

In a situation where there is a suspicion of the absence of fetal heard sounds on auscultation or cardiotocography, ultrasound examination to make a definitive diagnosis must be undertaken by without delay.

3.4. Points about breaking the news
Keeping a woman in suspense without a definite diagnosis is very traumatic for her. This situation must be avoided at all costs.

It is important that the woman and her family are given the diagnosis unambiguously. The most experienced practitioner available must be involved in breaking the news.

It is best that that news is broken in a private environment. The presence of a companion will be very helpful. Avoid making any comments that would make the woman feel guilty for the death of her baby.

Address concerns regarding safety of the mother.

Explain investigations to find a cause and plan for delivery. Discuss autopsy. The initial time of breaking the news may not be the best time to discuss this.
Avoid speculation regarding the cause until results of investigations are available, unless there is an obvious cause.

3.5. Care of the mother
Depending on risk factors and available facilities, consider managing the mother in a setting away from other pregnant women and babies.

The mother must be assessed to ensure that there are no immediate risks to her life (e.g. from sepsis or preeclampsia or hemorrhage or uterine rupture or uncontrolled diabetes)

Vital parameters must be monitored regularly.

3.6. Investigations
In a high proportion, the cause of Death in Utero (DIU) will remain unexplained despite investigations. It is likely that the most common cause is undiagnosed late-onset fetal growth restriction.

Nevertheless, it is important that these cases are investigated as best as possible, since finding a cause and even the absence of a detectable cause will have implications for managing future pregnancies and also help in the grieving process of the woman and her family.

This guideline recommends a set of “Core Investigations” in all cases of DIU. These recommendations are based on consensus on their cost effectiveness. In cases where there appears to be an ‘obvious’ clinical aetiology, there could be an underlying and/or associated cause. However, discretion will be needed in cases with lethal fetal anomalies.

The investigations are divided as those that are recommended:
A. at the time of diagnosis
B. immediately following delivery
C. 6 weeks following delivery
3.6.1. **Core investigations to be done at the time of diagnosis of DIU**

a. A comprehensive maternal, family and social history
b. Ultrasound to measure amniotic fluid volume and detect possible fetal anomalies
c. Blood investigations
   i. Full blood count –
   ii. Kleihauer-Betke test (see annex I for method)
   iii. Unexpected antibodies (irrespective of Rhesus status of mother)
   iv. Toxoplasma IgM
   v. Rubella IgM in women who have not been immunized
   vi. VDRL
   vii. HIV screen
   viii. Serum AST/ALT
   ix. Serum TSH
   x. HbA1c (except in mothers who were known to be poorly controlled diabetics)

3.6.2. **Core investigations following birth**

3.6.2.1. **On the baby**

a) External examination (see Annex II for details)
b) Ear swab for culture
c) Blood from the cord or by cardiac puncture for:
   - Microbiological culture
   - Full blood count
   - Blood group and Rhesus
   - Coomb's test
d) If there are skeletal dysmorphic features, an X Ray examination of the baby is recommended.
e) Autopsy, preferably by a Perinatal Pathologist. Where consent for autopsy is not given, placenta and membranes must be sent for histopathological examination.
f) Examination of placenta, cord and membranes (see Annex III for details)
g) Where DIU is managed conservatively beyond three weeks after the death or it is suspected to have occurred prior to three weeks: aPTT and PT
3.6.3. **Six weeks following delivery**
Investigation for thrombophilia should be undertaken six weeks after delivery, where a fetal death is associated with fetal growth restriction, pre-eclampsia, abruptio placentae, maternal thrombosis and/or maternal family history of thrombosis, vasculitis or thrombosis on placental histology or remains unexplained following core investigations. These tests include:

a) Anticardiolipin antibody (IgG&IgM)

b) Lupus anticoagulant

3.6.4. **Selective tests**
These are tests that could be arranged selectively, based on need following discussions with the patient.
At the time of diagnosis

a. Thrombophilia screen
   i. Anticardiolipin antibodies (IgG&IgM)
   ii. Lupus anticoagulant

b. Maternal blood for parvovirus B19 and cytomegalovirus antibodies

c. Serum bile acids

d. Anti Ro/La antibodies where the fetus is hydropic

3.7. **Delivery**
Vaginal delivery is preferred.

Do not hesitate to resort to a cesarean section despite a dead baby, if that would save the mother’s life e.g. placental abruption with active bleeding where delivery is not imminent.

Most women would wish to be delivered early, but there is no contraindication to conservative management.

Women with sepsis, preeclampsia and ruptured membranes and placental abruption are not suitable for conservative management.

Prostaglandins are preferred for induction of labor.

Repeated vaginal examinations and artificial separation of membranes must be avoided.
Artificial rupture of membranes must be avoided unless delivery is imminent or there is a placental abruption.

In case of conservative management, the woman must be monitored with twice weekly full blood counts. Routine use of antibiotics is not recommended in these women.

Women with a scarred uterus will require close monitoring for rupture of the scar during labour.

The woman must be provided support during labor. Allow a companion to be present, wherever possible. Adequate pain relief is very important and may be provided by opioids and epidural. Morphine is preferred to pethidine.

A longer time duration may be allowed for the second stage of labor.

Active management of the third stage of labor is recommended.

3.8. Puerparium

After delivery, the baby may be shown to the mother or the mother allowed to hold the baby, depending on her wishes.

Be cognizant of severe bereavement reactions and possible clinical depression. The mother needs constant support to cope with her loss. She and her family will need reassurance that the death was not due to their fault. Anxiolytics and hypnotics may be required. Suspicion of depressive symptoms warrants referral to a psychiatry team.

Suppress lactation with cabergolin 1 mg as a single dose. Ask the mother not to express milk in case the breasts become engorged. She may need to wear a well fitting brassier. Simple analgesics may be required to alleviate pain in the breasts.

Expedite the investigations, autopsy and administrative requirements. Continue observations of maternal vital parameters. Discharge the mother from hospital as early as is safely possible. She may prefer to be in her own environment at this time of grief. Avoid situations where the mother is required to stay in hospital until completion of investigations (e.g. autopsy), despite her being fit to be discharged.
Documentation must be done thoroughly.

The diagnosis card must include the following minimum information:

- Best estimation of gestational age at the time of death
- Antenatal complications
- Birth weight
- Dysmorphic features
- Placenta & cord
  - Weight
  - Evidence of abruption
  - Cord insertion – central/peripheral
  - Number of vessels
- Preliminary findings of autopsy (if available)
- Whether the placenta was sent for pathological examination
- Investigations

### 3.9. Debriefing

A debriefing, preferably with the Consultant after four to six weeks is recommended. Address their concerns and explain the possible cause for the loss. In a sizeable proportion, despite tests and autopsy, the death may remain unexplained.

The woman may be advised that she may try for her next pregnancy from any time she feels ready, provided correctable problems found in her reports are addressed.

Advise that her next pregnancy needs to be planned. Recommend a suitable family planning method.

### 3.10. Management of the next pregnancy

Early booking is recommended in future pregnancies and dating must be confirmed by ultrasound.

Start low-dose aspirin where appropriate.

It is common for women who have experienced a death in utero to be intensely anxious during future pregnancies. They require constant reassurance.
In women with previous DIU that has been unexplained or due to growth restriction or abrutio placentae, arrange tests to ensure satisfactory placental function. These include mid trimester uterine artery Doppler, growth scans from 28 weeks onwards and middle cerebral artery Doppler in later third trimester. In women with past unexplained stillbirths at or close to term, consider delivery one to two weeks before the time of the previous death, depending on fetal maturity.

3.11. Kleihauer-Betke test

Principle
An acid elution cytochemical method which identifies individual cells containing haemoglobin F. Depends on the fact that HbF containing cells resist acid elution to a greater extent than do normal cells.

Reagents needed
Fixative – 80% ethanol
Elution solution –
Solution A – 7.5g/l haematoxylin in 90% ethanol
Solution B – FeCl3 24g, 2.5 mol/l HCl 20ml in doubly distilled water to 1 litre
For use – Mix well 5 vols of A and 1 vol of B
The pH of the solution should be approximately 1.5
Once prepared, the solution may be kept and used for about 4 weeks.
Counter stain – 1g/l aqueous erythrosine or 2.5g/l aqueous eosin.

Method
EDTA blood can be used.
Prepare fresh air dried films.
Immediately after drying fix the films for 5 min in 80% ethanol (in a Coplin jar).
Rinse the slides rapidly in water and stand them vertically on a blotting paper for 10 min to dry.
Place the slides in a Coplin jar containing elution solution for 20 sec.
Wash the slides thoroughly in water.
Finally place them in counterstain for 2 min.
Rinse in tap water and allow them to dry in the air.
Fetal cells will stain red.
Adult ghost cells will stain pale pink.
Stain controls as follows alongside the test films
Positive control – from a mixture of cord blood and adult blood
Negative control – Normal adult blood

Calculation of volume of F-M haemorrhage using the Kleihauer test

A count of 200 pink staining HbF containing cells in 50 low power fields (i.e. 4 HbF cells in 1 low power field) is equivalent to a FM haemorrhage of 4ml.

References:


2. Management of Stillbirth Green-Top Guideline. Royal College of Obstetricians & Gynaecologists
Management of Anemia in Pregnancy at a Specialist Unit
Management of Aneamia in Pregnancy at a Specialist Unit

4.1. Definition
Anemia is defined as a hemoglobin level of less than 11g/dl, irrespective of the period of gestation. It is subdivided according to severity.

Table 4.1: Classification of Anaemia

<table>
<thead>
<tr>
<th>Severity</th>
<th>Hemoglobin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>10- 10.9 g/dl</td>
</tr>
<tr>
<td>Moderate</td>
<td>7 - 9.9 g/dl</td>
</tr>
<tr>
<td>Severe</td>
<td>&lt; 7 g/dl</td>
</tr>
</tbody>
</table>

4.2. Causes
- The main cause is nutritional iron deficiency. The absorption of iron is less in the first trimester and increases from the second trimester onwards. Anemia is the end-point of iron deficiency and indicates depletion of iron stores in the body. Therefore a non-anemic woman could be deficient in iron. Additionally, there may be multiple nutritional deficiencies (e.g. folate, vitamin B12)
- Hereditary: Thalassemia, haemolytic anaemias (spherocytosis &G6 PD deficiency)
- Haemorrhagic – Helminthiasis, history of bleeding per rectum or heavy menstrual bleeding
- Chronic conditions - TB / Rhumatoid Arthritis / Bone marrow depression, malignancies, chronic renal disease

*Recognized risk factors for anemia include multifetal gestation, teenage pregnancy, high parity, short birth interval

4.3. Screening for Aneamia in Pregnancy
- A full blood count (FBC) is recommended in preference to a single parameter (such as hemoglobin concentration or packed cell volume) at the first antenatal visit and at 28 - 30 weeks if mother is present at a hospital with laboratory facilities.
- For women at high risk for anemia in pregnancy such as multifetal gestations, an additional evaluation at 20-24 weeks is recommended.
4.4. Management of a Woman with Anaemia

Management will depend on
- Severity and presence of symptoms
- Period of gestation
- Previously diagnosed hemoglobinopathies or comorbidities

Women with mild to moderate anemia should be given a two-week therapeutic trial of oral iron (see below for details of oral iron therapy). A rise in hemoglobin level of more than 0.5g/dl is a reliable diagnostic test. This initial step may even be tried in a field setting.

Inquiry should be made about dietary habits and sources of chronic blood loss such as hemorrhoids and appropriate action taken.

Antihelminthic treatment should be offered to women who have not so far taken it.

Women with severe anemia must be referred to a specialist obstetric unit immediately.

The aim of management is to achieve a hemoglobin level >10g/dl by the time of delivery.

Therefore a woman presenting at >38 weeks with a hemoglobin level of 9g/dl or less may require blood transfusion to achieve this.

Intravenous iron therapy may be considered in anemic women with iron deficiency who present between 36 – 38 weeks (refer below for details).

FBC prior to discharge from hospitals recommended in women who have been anemic during pregnancy or those who have had multiple pregnancies or postpartum hemorrhage. Appropriate management and follow up should be arranged for these women.
4.5. **Management of Women who Fail to Respond to a Trial of Therapeutic Iron**

Women who fail to respond satisfactorily should be referred to a specialist obstetric unit to undergo further assessments to establish the underlying cause.

The following investigations are recommended:
- Full blood count
- Blood picture
- Serum ferritin

<table>
<thead>
<tr>
<th></th>
<th>Table 4.2: Indicators of iron deficiency Full blood count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full blood count</td>
<td>Hemoglobin</td>
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<tr>
<td></td>
<td>Hematocrit</td>
</tr>
<tr>
<td></td>
<td>MCV</td>
</tr>
<tr>
<td></td>
<td>MCHC</td>
</tr>
<tr>
<td>Serum ferritin</td>
<td>&lt;20μg /l</td>
</tr>
<tr>
<td>Blood picture</td>
<td>Microcytic hypochromic picture with other feature</td>
</tr>
</tbody>
</table>

Total iron binding capacity, serum iron, transferrin saturation, red cell count and red cell distribution width are not recommended indices in the diagnostic work up.

If the clinical evaluation is significantly different to the laboratory report, consideration must be given to repeating the investigation.

Multiple nutritional deficiencies could coexist (e.g. iron and folate deficiency). A peripheral blood picture would show a polymorphic picture in these situations. A high MCV (>100 fl) is indicative of folate or rarely vitamin B12 deficiency.
4.6. **Antenatal Supplementation**
The current recommendation of periconceptional supplementation of folic acid 1 mg should be continued during the first trimester.

A daily oral supplement of 60 mg of elemental iron and a minimum of 400μg of folate is recommended to be given to all non-anaemic pregnant women.

This is recommended to be started as soon as possible after the gastrointestinal side effects of early pregnancy have decreased (e.g. by 12 weeks of gestation).

It is important that women are advised that the iron supplements be stored in a dry, dark airtight container.

It is also important that they be advised that it should be taken at least one hour before a meal (e.g. 11 am) together with the 50 mg vitamin C tablet.

Tea, coffee and dairy products should not be consumed within an hour before and after the iron supplement.

Women should be advised that the calcium supplement be taken after a meal and not with the iron supplement.

4.7. **Treatment of iron deficiency anemia in pregnancy**

4.7.1. **Oral iron therapy**

- Women with mild anemia should receive 120 mg elemental iron daily with reinforcement of advice regarding compliance and diet.
- The therapeutic dose of oral iron for women with moderate to severe anemia is 120 mg elemental iron per day (taken as two separate doses of 60 mg).
- Therapeutic dose of iron should be continued for a minimum period of three months after the correction of anemia. Thereafter iron supplementation (refer below) should be continued for a minimum period of three months after delivery.
• Advice must be given regarding the correct method of storing and taking iron supplements, referred to above.
• Antihelminthic treatment and dietary advice should be given.
• If a woman develops gastrointestinal side effects to oral iron supplements, it is recommended that the dose be lowered. This is preferable to changing to enteric coated or slow-release formulations.

4.7.2. Intravenous iron therapy

• Intravenous iron therapy should be considered for women with iron deficiency who fails to respond to oral iron therapy, those who are non-compliant and in those with proven mal-absorption.
• Facilities for management of anaphylaxis must be available.
• The dose is calculated based on the hemoglobin deficit and body weight, according to manufacturer’s recommendation.
• The maximum recommended daily and weekly doses must not be exceeded.
• Contraindications include use in first trimester and a previous history of allergic reactions to parenteral iron therapy.
• The routine supplementation dose (60 mg daily) should be continued up to three months postpartum.

4.7.3. Blood transfusion

• Blood transfusion must be considered in women with a hemoglobin level less than 7.0 g/dl at any period of gestation, to achieve a target of 10 g/dl.
• It may also be required in women who have features of cardiac decompensation even at higher levels of hemoglobin.
• Blood should be obtained for investigations including a blood picture before commencement of transfusion.
• Therapeutic oral iron (120 mg per day) should be continued as described above.
4.8. **Additional Precautions during labour in women with a Hb level below 10g/dl**

- Be aware of higher risks of postpartum hemorrhage.
- Delivery should preferably be in a specialist unit where facilities for transfusion are available.
- Ensure intravenous access.
- Ensure availability of compatible blood.
- Avoid prolonged labor.

**REFERENCES**

The following resources were used in developing this guideline:

- WHO Guidelines on iron and folic acid supplementation during pregnancy
Gestational age assessment and determination of chorionicity
5. Gestational age assessment and determination of chorionicity

5.1. Background

- Gestational age assessment by menstrual history is not reliable.
- Ultrasound dating has proven to be more reliable than methods based on last regular menstrual period (LRMP) to predict the date of delivery.
- First trimester ultrasound dating has the potential to reduce the percentage of post term pregnancies by up to 60%.
- Second trimester pregnancy dating is also reliable but to a lesser extent than in first trimester.
- Once the initial dating has been assigned, dating should not be changed in subsequent scans.

5.2. Determining gestational age during first trimester

- Ultrasound scan between 8+0 and 13+6 weeks should be offered to all pregnant women in order to assess the gestational age.
- If the discrepancy between the menstrual and scan dates is more than ± four days, the expected date of confinement re-assigned using the scan date.
- All subsequent fetal biometry measurements should be plotted on the centile charts using the date determined as above.
- Robinson’s CRL formula should be considered as the optimum formula to assess the gestational age.

5.3. Determining gestational age during second trimester when first trimester dating has not been done

- Pregnant women presenting between 14 and 26 weeks should be offered an ultrasound scan to estimate GA using fetal head circumference (HC).
- If the discrepancy between the menstrual and scan dates is more than ± seven days, the expected date of confinement re-assigned using the scan date.
- All subsequent fetal biometry measurements should be plotted on the centile charts using the date determined as above. Chitty’s formula should be considered as the optimum formula for this purpose.
- Composite of other fetal biometry (BPD, FL, AC) or biparietal diameter alone should not be considered.
5.4. **Determining gestational age in late bookers (beyond 26 weeks)**
- It is difficult to date a pregnancy accurately beyond 26 weeks.
- A tentative estimate of gestational age should be assigned using fetal HC during the first scan and repeat HC measurement in 2 weeks should be arranged in order to confirm the GA.

5.5. **Determining gestational age in multiple pregnancies**
- As per singletons, fetal CRL and HC should be considered during first and second trimester respectively.
- Biometry of the larger twin should be considered for dating purpose.

5.6. **Determining chorionicity and assigning nomenclature in multiple pregnancies**
- Chorionicity must be determined during the first trimester by ultrasound using the number of placental masses, the lambda or T-sign.
- Presence of two distinct placental masses or lambda sign confirms dichorionicity and presence of ‘T’ sign confirms monochorionicity.
- Assign nomenclature to fetuses (for example, upper and lower, or left and right) in twin and triplet pregnancies and document this clearly in the woman’s notes to ensure consistency of measurements throughout pregnancy.
5.7. **Algorithm for assessment of gestational age and chorionicity**

**Algorithm for assessment of gestational age and chorionicity**

- **Booking in 1<sup>st</sup> trimester**
  - First trimester is the optimal time for USS dating
  - Should be done between 8<sup>th</sup> to 13<sup>th</sup>
  - Should be done by a competent person
  - Use the Robinson’s CRL formula to estimate EDD
  - If the discrepancy is 4± days from EDD by LRMP, use the USS EDD
  - Do not change the EDD in subsequent scans
  - Plot all subsequent biometry assessments against the estimated GA

- **Booking beyond 1<sup>st</sup> trimester**
  - If between 14<sup>th</sup> to 26<sup>th</sup>
    - Offer USS for dating. The accuracy maybe less than in T1
    - Use the Chitty’s formula with HC for estimation of EDD
    - BPD alone or composite of other fetal biometry (BPI, FL, AC) should not be used.
    - If the discrepancy is 7± days from EDD by LRMP, Use the USS EDD
  - If booking is beyond 26<sup>th</sup>
    - A tentative estimation of EDD using HC should be offered.
    - The accuracy of such an estimation can be low.
    - The scan should be repeated in 2 weeks to confirm the gestational age.

- **In multiple pregnancies**
  - First trimester is preferred for dating and determination of chorionicity.
  - Should be done in the second trimester if the booking is beyond first trimester.
  - CRL with Robinson’s formula should be used in T1.
  - HC with Chitty’s formula should be used in T2.
  - The measurement of the larger twin should be used for GA estimation.
  - If the discrepancy is 4± days from EDD by LRMP, Use the USS EDD

- **The chorionicity should be determined at the dating scan.**
  - Should look for the number of placental masses and Lambda / T-sign.
  - Presence of two placental masses OR lambda sign confirms dichorionicity.
  - Presence of T sign confirms monochorionicity.
  - Assign nomenclature to fetuses and document it clearly in notes. Use terms such as upper, lower, left, right.
Management of Pregnancy in the presence of Uterine Scar
6. Management of Pregnancy in the presence of Uterine Scar

6.1. Introduction
This guideline is to provide recommendations to aid General Practitioners and Obstetricians in the management of Pregnancy in the Presence of Uterine Scar. This treatment could be initiated in a primary care setting or in centres with advanced facilities. The objective of management of pregnancy in the presence of a uterine scar is to make an early identification, appropriate referral, prevent complications and consequently to improve quality of life.

6.2. Scope of the guideline
The most frequent indications for Caesarean Section are previous Caesarean Section or previous uterine scar, dystocia, mal-presentation, and non-reassuring fetal status.

The data available is limited by 3 important factors:
- There are no randomized controlled studies of trial of labour in the presence of a scar versus elective repeat Caesarean Section.
- Adverse maternal or perinatal outcomes are rare and large study populations are necessary to observe a significant difference in maternal and perinatal outcomes.
- The woman's choice to attempt a trial of labour (TOL) in the presence of previous uterine scar is heavily influenced by her health-care provider and local resources, often leading to selection bias in published reports.

A trial of labour is an option and should be considered in women who present for prenatal care with a history of previous uterine scar in the absence of contraindications. In certain situations, trial of labour (TOL) may be detrimental to feto-maternal outcome and should be considered as contraindicated and a Caesarean Section will be advised. But in most cases, successful vaginal birth can be achieved safely for both mother and infant.

Women and their health-care providers will need to discuss the risks and benefits of a trial of labour (TOL) in the presence of previous uterine scar when planning the vaginal birth. The following facts are the current evidence regarding trial of labour versus elective repeat Caesarean Section.
• The success rate of trial of labour after Caesarean ranges between 50% and 85%.

• Predictors of successful trial of labour include a history of previous vaginal delivery and non recurring indications for Caesarean birth, such as malpresentations and gestational hypertension; where success rates are as high as 82%.

However, the decision to allow a vaginal delivery in the presence of uterine scar should be individualized and made by the consultant after deliberating with the patient.

6.3. Diagnosis and assessment
6.3.1. Diagnosis
A pregnant woman with a previous uterine scar attending an antenatal clinic should be identified at the booking/ first attendance at the clinic. All necessary documents, information and details of the previous Caesarean Section, myomectomy and uterine perforations should be looked for and recorded in the present clinic records. Every effort should be made to fill any deficiencies in these required data. At the first visit these women should be seen by the most senior member of the team. In non specialist units these women should be referred to as specialist unit at the earliest opportunity for management and or shared care. (Grade X)

An ultrasound scan should be performed for accurately dating and to check placental localization and exclude abnormal placentation (morbid adherence). (Grade X)

6.3.1.1. Assess facilities and resources
A trial of labour after Caesarean is always associated with a risk of uterine rupture, even if the risk is small.

For this reason, a trial of labour (TOL) in the presence of uterine scar should only be considered in a hospital where provisions for performing an immediate Caesarean Section are available. (Grade X)

• Hospitals which provide a trial of labour (TOL) in the presence of previous uterine scar should have a policy in place to manage such patients so that all resources could be mobilized promptly if an intrapartum emergency occurs.
• Obstetric, anaesthetic, and paediatric teams to attend to such an emergency should be
• Identified and available within the hospital premises. (Grade X)
• Women who live in areas where local hospitals cannot offer an immediate Caesarean Section should be offered the opportunity for early transfer to a facility where this service is available.

The members of the team who could be called urgently in a case of an intrapartum complication (anaesthetic, paediatric, and obstetric services) should be pre-warned when there is a patient with a scarred uterus in labour and their availability confirmed.

6.3.1.2. Assess contraindications to vaginal birth

**Absolute contraindications**

- Previous classical or inverted ‘T’ uterine scar.
- Previous hysterotomy or myomectomy entering the uterine cavity.
- Previous uterine rupture.
- The presence of a contraindication to labour such as placenta praevia, malpresentation.

**Relative contraindications**

- Previous surgery for stress urinary incontinence
- Previous 3rd-4th degree perineal tears

In the absence of contraindications, a woman with one previous Transverse Lower-Segment Caesarean Section should be offered a trial of labour (TOL) with appropriate discussion of maternal and perinatal risks and benefits. (Grade Y)

When the woman requests an elective Cesarean Section in the absence of contraindications for vaginal delivery her wishes should be respected.

6.3.1.3. Assess previous records (Grade X)

- In most cases, this information can be obtained by reviewing the operative records from the previous surgery.
- Searching for the location and type of uterine incision used during the previous surgery is mandatory.
- Other information in this record, such as the indication for the Caesarean Section and the opinion of the previous surgeon, may be helpful.
• The fact that the record has been reviewed and that no contraindications to a trial of labour (TOL) in the presence of previous uterine scar are present, should be documented clearly on the antenatal record.
• If the record is not available, the scar is considered “unknown”.
• Whether the previous Section was elective or emergency Caesarean Section should be documented. Observations in previous lower segment Caesarean Section should be noted.

6.3.1.4. Assess risk of uterine rupture (Grade X)

Risk of uterine rupture
It is an uncommon complication of a scarred uterus but when it occurs is associated with significant maternal and perinatal morbidity and mortality.
Incidence:
• 0.2% to 1.5% in a woman who attempts labour after a transverse lower-uterine segment incision.
• 1% to 1.6% after a vertical incision in the lower uterine segment.
• 4% to 9% with a classical or ‘T’ incision.

For this reason, a trial of labour (TOL) in the presence of last two uterine scars is contraindicated.

The risk of uterine rupture decreases after the first successful vaginal birth in a scarred uterus. The risk of uterine rupture after 0, 1, 2, and 3 vaginal deliveries in a scarred uterus decreases to 1.6%, 0.3%, 0.2%, and 0.35%, respectively.

The relative risk of uterine rupture, maternal morbidity, and perinatal mortality or severe morbidity is increased in those undergoing a trial of labour (TOL) in the presence of previous uterine scar compared to elective Caesarean Section, but the absolute risk remains very low.

In some cases of uterine rupture, perinatal acidosis could not be avoided despite very rapid ‘decision to delivery time’ being recorded.
6.3.2. **Prediction of uterine rupture**
There is evidence that ultrasonographic measurement of the lower uterine segment’s myometrial thickness 36 to 38 weeks’ gestation is a predictor of uterine rupture. If the lower segment thickness was less than 3.5mm the risk of uterine rupture or dehiscence was 11.8%; and if the measurement was greater than 3.5 mm, the risk of uterine rupture was minimal.

6.4. **Management**
6.4.1. **Counselling a patient**
- Compared to a Caesarean Section, there is less blood loss with a successful trial of labour (TOL) in the presence of previous uterine scar and a shorter hospital stay with more rapid recovery and return to full activity.
- Risk of febrile morbidity is low in women who attempt a trial of labour (TOL) in the presence of previous uterine scar and is lowest in those who succeed, compared to elective Caesarean Section. But it is increased in those who attempt a trial of labour (TOL) and ultimately deliver by Caesarean Section.
- Scaring of the uterus is associated with an increased risk of placenta praevia, and abruptio placentae.
- A repeat Caesarean Section has been associated with an increased risk of placenta praevia and placenta accreta in subsequent pregnancies.
- A meta-analysis of published data demonstrated that the overall risk of perinatal death is increased in those attempting a trial of labour (TOL) in the presence of previous uterine scar due to the result of ruptured uterus. However, the risks of perinatal mortality and severe morbidity are directly related to uterine rupture.

6.4.2. **Protocol for intrapartum management (Grade X)**
- The patient should be advised to present to hospital early in labour or where transport is difficult admit before labour.
- Intravenous access should be established and blood should be cross-matched.
- The patient should be kept fasting.
• Labour should be monitored using the partogram and any abnormalities (e.g. tachycardia above 160, bradycardia below 120, loss of base line variation, type1 and type 2 dips) should be notified to the SHO/Registrar/ Consultant who should perform an assessment.

• Continuous fetal heart rate monitoring is mandatory. In the rare instance very close observation of fetal heart with the Doppler/Sonic aid or Pinnard every 15 minutes in first stage and after each contraction in second stage might be a reasonable compromise. (Grade Z)

• There is no contraindication to epidural analgesia. However, lack of pain sensation makes closer observation of uterine contractions and other parameters essential.

6.4.3. Monitoring in labour (TOL) (Grade X)

• Maintaining the national partogram is mandatory to identify lack of progress of labour to avoid uterine rupture.

• Be vigilant for the symptoms and signs of scar rupture, which may include:
  o Suprapubic tenderness and/or
  o changing pattern of abdominal pain. Pain which continues between contractions is ominous,
  o Maternal tachycardia,
  o Vaginal bleeding,
  o Fetal tachycardia or fetal heart decelerations,
  o Cessation of contractions,
  o Appearance of haematurea.

• Continuous electronic fetal monitoring in labour is recommended for all women undergoing a trial of labour (TOL) in the presence of previous uterine scar, as the most reliable first sign of uterine rupture is an abnormal fetal heart tracing which may be sudden in onset.

• Other clinical signs indicating uterine rupture include vaginal bleeding, cessation of contractions, and loss of the presenting part on vaginal examination, disappearance of fetal parts, abdominal pain, haematurea and maternal cardiovascular instability.
6.4.4. Postpartum evaluation
Routine digital exploration of the Caesarean Section scar postpartum is not necessary, except when signs or symptoms suggest uterine rupture.

6.5. Special circumstances

6.5.1. Use of oxytocics
A multicentre randomized controlled trial (RCT) revealed that there is no increase in the risk of uterine rupture, maternal morbidity, or perinatal morbidity or mortality when oxytocin is used to augment the spontaneous labour in a planned trial of labour (TOL) in the presence of previous uterine scar. (Grade Y)

Careful monitoring of the woman for progress of labour is essential. (Grade X)

The use of other agents (e.g.: prostaglandins, Mesoprostol, etc.) to augment labour is not recommended. (Grade X)

6.5.2. Induction of labour
The possibility of uterine rupture with the use of agents to induce labour in women who have a scarred uterus must be stressed and discussed in detail. (Grade X)

There was a trend towards a higher rate of uterine rupture, but this was not statistically significant in (0.7% vs. 0.3%) those who underwent either amniotomy or oxytocin but is significantly increased in those who underwent induction with prostaglandin E2 or mesoprostol.

Medical induction of labour with prostaglandin E2 (dinoprostone) is associated with an increased risk of uterine rupture and should not be used. (Grade X)

6.5.3. Trial of labour in a more than one previous lower segment Caesarean Section
The available data suggest that a trial of labour in women with more than one previous uterine scar may be successful but is associated with a higher risk of uterine rupture. Hence trial of labour is not recommended. (Grade Y)
6.5.4. **Multiple pregnancy**
Evidence is insufficient as studies examined a small number of women. However, greater numbers would be required to detect outcomes such as uterine rupture and maternal and perinatal mortality. Management should be individualized and decision should be taken by the Consultant. (Grade Z)

6.5.5. **Breech presentation**
A large multicentre trial demonstrated that a planned Caesarean birth is associated with better perinatal and neonatal outcomes in breech presentations at term.

Elective Caesarean Section is recommended. (Grade Y)

External cephalic version is contraindicated in a woman with a previous uterine scar. (Grade X)

6.5.6. **Diabetes mellitus**
Diabetes mellitus should not be considered as a contraindication to a trial of labour (TOL) in the presence of previous uterine scar. The likelihood of successful vaginal birth after Caesarean (VBAC) decreases with increasing birth weight and is lowest in those who have never had a successful vaginal birth.

6.5.7. **Inter-delivery interval**
A shorter interval of less than 18 months was associated with a 3-fold increase in the risk of uterine rupture. Women delivering before 24 months of a Caesarean Section should be counselled about an increased risk of uterine rupture in labour.

6.5.8. **Postdates**
Risk of uterine rupture in a trial of labour (TOL) in the presence of previous uterine scar, after 40 weeks was not significantly increased when compared to those who delivered before 40 weeks, whether in spontaneous labour or following induction.

6.5.9. **Unknown scar**
In situations where the scar is unknown, information concerning the circumstances of the previous delivery would help in determining the likelihood of a low transverse incision. If the likelihood of a lower transverse incision is high, trial of labour (TOL) may be offered. (Grade Z)
7. Summary

• To conduct a labour in the presence of a uterine scar, the woman should be delivered in a hospital where facilities for immediate Caesarean delivery are available. The woman and her health-care provider must be aware of the hospital resources and the availability of obstetric, anaesthetic, paediatric and operating-room staff. (Grade X)

• In the absence of contraindications, a woman with one previous transverse lower-segment Caesarean Section should be offered a trial of labour (TOL) with appropriate discussion of maternal and perinatal risks and benefits. (Grade Y)

• The process of informed consent with appropriate documentation should be an important part of the delivery plan in a woman with a previous uterine scar. (Grade X)

• The intention of a woman undergoing a trial of labour (TOL) after uterine scar should be clearly stated and documentation of the details of the previous uterine scar should be clearly marked on the prenatal record. (Grade X)

• Every effort should be made to obtain the previous operative report to determine the type of uterine incision used. In situations where the scar is unknown, information concerning the circumstances of the previous delivery is helpful in determining the location of the scar.

• Women delivering within 24 months of a uterine scar should be counselled about an increased risk of uterine rupture in labour.

• Continuous electronic fetal monitoring of women attempting a trial of labour (TOL) in the presence of previous uterine scar is recommended. (Grade Z)

• Suspected uterine rupture requires urgent attention and expedited laparotomy in order to attempt to decrease maternal and perinatal morbidity and mortality. (Grade X)

• Oxytocin augmentation is not contraindicated in women undergoing labour with a uterine scar but the decision of using oxytocin should be made by the consultant. (Grade X)

• Medical induction of labour with oxytocin is not contraindicated but may be associated with an increased risk of uterine rupture and should be decided by the consultant after appropriate counselling and should be monitored appropriately. (Grade X)
• Medical induction of labour with prostaglandin E2 (dinoprostone) is associated with an increased risk of uterine rupture and should not be used. (Grade X)
• Prostaglandin E1, mesoprostol is associated with a high risk of uterine rupture and should not be used as part of a TOL. (Grade X)
• A foley catheter may be used safely to ripen the cervix. (Grade Y)
• Women with more than one previous scar elective Caesarean Section is recommended. (Grade X)
• Multiple gestation, diabetes mellitus and post datism by itself are not a contraindication to a trial of labour (TOL).
• Suspected or proven fetal macrosomia is a contraindication to a trial of scar.

References

Local papers


Regional papers

International papers

Contributed by:
Dr. Hemantha Perera
Dr. R. Fernandopulle
Dr. R. Pathiraja
Dr. Ajith Fernando
Prof Jayantha Jayawardana
Dr. Madawa Karunaratna
Management of Rhesus Negative Mother
7. Management of Rhesus Negative Mother

7.1. Introduction
The guidelines are to provide recommendations to aid General Practitioners and Obstetricians in the management of Rhesus Negative Mother. This treatment could be initiated in a primary care setting or in centers with advanced facilities The objective of management is to make an early identification of Rh-negative mothers, prevent complications, and consequently to improve quality of life.

7.2. Scope of the guideline
Rhesus (Rh) factor is a protein found on the red blood cells of most people. When a person does not have this factor they are called Rh-negative. When a Rh-negative mother is exposed to Rh-positive red blood cells she may produce antibodies in her blood (isoimmunization). This situation could arise during a pregnancy and in labour. These antibodies could cross to the fetus across the placenta and form complexes with the Rh positive fetal red cells. These affected RBC get destroyed by the reticuloendothelial system of the fetus.

The numerous antigens on the surface of Rh positive red cells have been placed into groups. The Obstetricians are familiar with the Rhesus (Rh) group as it is the most clinically relevant and is still responsible for the largest proportion of hemolytic disease in the newborn. The Rhesus antigen constitutes at least three very similar transmembrane proteins called C, D, E. Although D is the most important antigen other Rh antibodies can provoke antibody formation such as anti E and anti C. However the non-Rh groups such as Kel, MNS and Kidd also have assumed increasing importance since they could produce red cell antibodies as well.

If Rhesus prophylaxis is not given:
- 1% chance of developing antibodies after the delivery of the first baby,
- 7% chance of developing antibodies after the delivery of the second baby,
- 17% chance of developing antibodies after the delivery of the third baby,
- 30% chance of developing antibodies after the delivery of the sixth baby.
Post-delivery immunoprophylaxis using anti-D Immunoglobulin (anti-D Ig) began in Sri Lanka several decades ago. Although the incidence of Rh-negative population has been estimated as 5%, no data is available with regard to Sri Lankan pregnant population.

7.3. Pathogenesis
Angiogenesis in the fetus at about 3 weeks of inutero life and Rh antigen has been identified in the red cell membrane as early as 38 days after conception and it prevails.

After feto-maternal haemorrhage in a Rh-negative mother who is carrying Rh-positive fetus;
• The initial response to D antigen is slow sometimes taking as long as 6 months to develop.
• Re-exposure to the antigen produces a rapid immunological response which usually can be measured in days.

However;
• When the sensitized mother produces IgG anti-D antibodies they cross the placenta and coat D-positive fetal red cells, which are then destroyed in the fetal spleen (haemolysis).
• Mild to moderate haemolysis manifest as increased indirect bilirubin. It appears in the amniotic fluid.
• Severe haemolysis leads to increased red blood cell production by the spleen and liver of the fetus.
• Subsequently, hepatic circulatory obstruction (portal hypertension) with placental oedema, which interferes with placental perfusion and eventually ascites, develops in the fetus.
• Hepatomegaly, increased placental thickness, and polyhydramnios often precede the development of fetal heart failure.
• As liver damage progresses decreased albumin production results in the development of hydropsfetalis.
• ABO incompatibility reduces this risk.
• The reduced risk of Rh sensitisation with ABO incompatibility may result from the rapid clearance of incompatible red cells thus reducing the overall exposure to D antigen.
7.4. Management
Identification of Rh-negative mother pre & post conceptionally and education are important aspects in the management.

7.4.1. Management of post-partum mother (non sensitized)

Management in the delivery room (postpartum)
A. Active management
During the active management feto-maternal transfusion is enhanced. However, considering the poor availability of the Rh negative blood and the potential for post partum haemorrhage active management of the third stage is not discourage.
- Let out cord blood after clamping baby side

Cord blood should be taken for; (Grade X)
  a) 2ml. of blood in a plain bottle for blood group and Rhesus.
  b) 2ml. of blood in an EDTA bottle for fetal Hb.
  c) 2ml. of blood in a plain bottle for serum bilirubin level.
  d) 2 ml. of blood in a plain bottle for direct coomb's test.
  e) 2ml. of blood in an EDTA bottle for reticulocyte count.

B. Test for the size of feto-maternal haemorrhage
Studies have shown that 99.2 — 99.3% of women have a FMH less than 4 ml. at the time of delivery. However, the following clinical circumstances are most likely to be associated with larger feto maternal haemorrhage(FMH).

• Traumatic deliveries including Caesarean Section,
• Manual removal of the placenta,
• Stillbirths and intrauterine deaths,
• Abdominal trauma during the third trimester,
• Twin pregnancies (at delivery),
• Unexplained hydrops fetalis.
International recommendations are as follows:

- Kleihauer acid elusion test which detects fetal haemoglobin (HbF) is the test usually undertaken. (Grade Y)
  In some European countries (exceptions include the UK, France and Ireland), a standard postnatal dose of 1000-1500iu is used with no requirement for a routine Kleihauer test. Unfortunately, this policy does not take account of the fact that up to 0.3% of women have a FMH greater than 15 ml. which will not be adequately covered by 1500iu of anti-D Ig.

- Flow cytometry offers an alternative technique for quantifying the size of FMH.
  It has a number of advantages in that results are more accurate and more reproducible than those from the Kleihauer test and that it detects RhD positive cells, making it particularly helpful in patients with high HbF levels. (Grade Z)

- The resetting technique is a relatively simple serological method, which offers another alternative for quantifying FMH of RhD positive red cells greater than 4 ml.

National recommendations

The recommended policy in Sri Lanka is to obtain an anticoagulant blood sample as soon as possible (within two hours) after the delivery and to undertake the Kleihauer screening test to identify women with a suspected larger FMH who need additional anti-D Ig.

Since this facility is available only in General and Teaching Hospitals, suspected larger FMH should be covered with an additional anti-D Ig dose. (Grade Y)

C. Anti-D Ig preparations available in Sri Lanka (Human Immunoglobulin)
   i. Rhophylac 300 micrograms/2ml. (1500iu) IM/IV
   ii. Rhogam 300 micrograms/2ml. (1500iu) IM/IV
   iii. Rhesogamma micrograms/2ml. (1500iu) IM/IV
   iv. Rhesuman
D. Administration

Intramuscular anti-D Ig is best given to the deltoid muscle.

- Injections to the gluteal region often reach the subcutaneous tissues and hence absorption may be delayed.
- For successful immunoprophylaxis, every effort should be made to give anti-D Ig within 72 hours; best as soon as possible after the sensitizing event. (Grade X).
- If it is not given before 72 hours, it should still be administered as a dose given within 9-10 days, which may provide some protection. (Grade X)
- Women who are already sensitized should not be given anti-D Ig. (Grade X)
- Women who have a weak expression of the RhD blood group (Du) do not form anti-D and do not therefore require prophylaxis.
- It should be noted that anti-D Ig does not protect against the development of other antibodies which can also cause hemolytic disease of the newborn.

**National recommendations:**

Intramuscular anti-D Ig should be given in the upper part of the deltoid muscle as soon as possible within 72 hours. However failure to do so, administering intramuscular anti-D Ig within 9-10 days is advisable. (Grade X)

7.4.2. Management of a mother following early pregnancy complications (Non-sensitized)

Prophylaxis following abortion, ectopic pregnancy, and mole.
National recommendations:

• All RhD negative women require anti-D Ig following abortion; 250 iu before 20 weeks’ gestation and 500 iu after 20 weeks. (Grade X)

• A test for the size of FMH should be performed where available when anti-D Ig is given after 20 weeks. (Grade Z)

**Termination of pregnancy:** Anti-D Ig should be given to all RhD negative women having or suspected of a termination of pregnancy by surgical or medical methods, regardless of gestational age. (Grade X)

**Ectopic pregnancy:** Anti-D Ig 250 iu should be given to all RhD negative women who have an ectopic pregnancy. (Grade X)

**Spontaneous miscarriage:** Anti-D Ig 250 iu should be given to all RhD negative women who have a spontaneous complete or incomplete abortion after 12 weeks of pregnancy. There is evidence that significant FMH only occurs after curettage to remove products of conception but does not occur after complete spontaneous miscarriage. (Grade X)

If surgical evacuation is carried out for incomplete miscarriage Anti-D prophylactic is recommended.

**Threatened miscarriage:** Anti-D Ig 250 iu should be given to all RhD negative women with a threatened miscarriage after 12 weeks of pregnancy. (Grade X)

Where bleeding continues intermittently after 12 weeks’ gestation, anti-D Ig should be given at 6-weekly intervals till the bleeding ceases. Evidence that women are sensitized after uterine bleeding in the first 12 weeks of pregnancy where the fetus is viable and the pregnancy continues is scant 14, though there are very rare examples. However, it may be prudent to administer anti-D Ig where bleeding is heavy or repeated or where there is associated abdominal pain particularly if these events occur as gestation approaches 12 weeks. The period of gestation should be confirmed by ultrasound.
7.4.3. Management of non-sensitized mother antepartum

Anti-D Ig should be given to all non-sensitized RhD negative women after the following potentially sensitizing events during pregnancy:

.antepartum haemorrhage,

External cephalic version of the fetus,

Closed abdominal injury,

Intrauterine death,

Invasive procedures for prenatal diagnosis

(anti-D Ig should be given accordingly. (Grade Y)

National Recommendation;

A dose of 250 iu is recommended for prophylaxis for these sensitizing events up to 20 weeks of pregnancy. (Grade X)

For all events after 20 weeks, a minimum dose of 500 iu anti-D Ig should be given followed by a test to identify FMH where facilities are available. (Grade X)

If found to be greater than 4 ml. red cells, additional anti-D Ig should be given accordingly. (Grade Y)

At or around 28 and 34 weeks to prevent sensitization due to silent FMH routine ante-natal prophylaxis is carried out in developed countries although the incidence of sensitization is 1%.

National Recommendation;

Although advisable to carry out this prophylaxis, to recommend it as a national recommendation is difficult due to financial constraints. (Grade Y)

7.4.4. Management of transfusions of Rhesus (RhD) positive blood components

RhD positive platelet transfusion to RhD negative mother:

If an appropriate product is not available during an emergency, it may be necessary to use RhD positive platelets. In these circumstances, RhD prophylaxis should be given against possible Rh alloimmunisation by red cells contaminating the platelet product. 250 iu (50 mcg) anti-D Ig should be given following every three units of platelets. Patients who have marked thrombocytopenia anti-D Ig should be given subcutaneously to avoid the possibility of haematoma following intramuscular injection.
**Inadvertent transfusion of RhD positive blood:**

**When less than 15 ml.** of RhD positive blood has been transfused accidentally to a Rh-negative woman 500 iu of anti-D Ig should be given.

**When more than 15 ml.** have been transfused, it is preferable to use the larger anti-D Ig IM preparation (2500iu or 5000iu).

The dose should be calculated on the basis that 500 iu of Anti-D Ig will suppress immunization due to transfusion of 4 mls of RhD positive red blood cells.

**When more than 2 units** of Rh positive blood have been transfused, consideration should be given to undertaking an exchange transfusion to reduce the load of RhD positive red blood cells in the circulation.

In this situation, the patient should be counselled regarding the implications of both non-intervention (for future pregnancies) and of the treatment, including any hazards from receiving donated blood, the exchange procedure itself and of larger experts of the National Blood Transfusion Service is recommended. (Grade X)

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 Passive anti-D Ig given in large doses may be detectable for up to 6 months or more and tests for immune anti-D may not be conclusive for 9-12 months.

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7.4.5. **Management of sensitized antenatal mother**

- In Rh-negative mother unexpected antibody (Rh antibody & atypical antibody) levels should be checked at booking visit, 28, 32, and 36 weeks of period of gestation. If positive result is found close follow up is necessary.

- In general the principles used in the management of Rh-negative sensitized patient and the management of the patient with atypical blood antibodies do not differ.

However, the management of the kell-sensitized pregnancy may require more intensive surveillance, since maternal titres and amniotic fluid bilirubin level do not necessarily correlate with disease severity. May need marrow suppression.

- The evaluation of positive antibody screen should include identification of the antibody and its titre. (The ideal would be to check the antibody levels instead of titers). This could be done at Central Blood Transfusion Service Bank, Narahenpita.
Identification of antibodies
All Rh-negative mothers should be referred to a specialist antenatal clinic. (Grade X)
Antibody status of all Rh-negative mothers is better evaluated by the National Blood Transfusion Service.

- A titre of more than 1:4 is considered sensitized.
- The method used should be stated, as the titre will vary according to the method used in the respective laboratory.
- An albumin titre of 1:16 is equal to an indirect antiglobulin test (IAT) titre of 1:32 to 1:128

7.4.6. Already sensitized due to previous event (no prior severely affected pregnancy)

- If the partner is Rh-negative (or negative for the atypical antigen) then, no further test is necessary.
- IAT titres of ≤ 1:32 or less are managed noninvasively with repeat antibody titres every 2-4 weeks.
- IAT titres of ≥ 1:64 – amniocentesis to be done at intervals of 2 to 3 weeks.
- IAT titres of > 1:32 with pregnancies at greater than 27 weeks – ideally are monitored with serial amniocenteses. However, this facility is available in certain centres only. (Grade Z)
- If the father is heterozygous (Dd) or his blood is unavailable then, amniocentesis may be used to determine the fetal Rh (or atypical antigen) status if the IAT titre is > 1:32 or albumin titre > 1:16

Scope for future development

- Fetal DNA testing is available:
  - For RhD, RhE, RhC, RhC and Kell. (Send 5.0 ml. of fluid in a unbreakable sterile plastic conical-bottom centrifuge tube. Do not freeze)
  - For RhE, Rhe, RhC, Kell, and Cellano (k) the parents’ DNA should be tested concurrently (Send 5.0 ml. of blood in a lavender-topped tube on each parent. Do not freeze)
- If the fetus is antigen negative then no further testing is necessary.
- If the fetus is antigen positive then the pregnancy is followed with serial titres and ultrasound as long as titres remain below the “Critical” value.
7.4.7. **First sensitized pregnancy/previously affected pregnancy**
For patients with a previously affected pregnancy, the timing of the initial procedure is determined by past clinical history. It is usually performed at least 4-8 weeks earlier than the prior gestational age at which significant morbidity occurred in previous pregnancy.

In women with extremely high titres (≥ 256), at less than 28 weeks, where the fetus does not demonstrate hydrops, and there is a documented history of fetal death due to hydrops, intravenous immune serum globulin (IVIG) might be offered. The dose is 400mg./kg. per day for 5 days, with repeat infusions every 15 to 21 days. Specific contraindications to intravenous immunoglobulin use include a previous episode of intravenous immunoglobulin-induced anaphylaxis (rare) and selective IgA deficiency.

7.5. **Surveillance**
7.5.1. **Doppler ultrasonography**
Doppler ultrasonography of the middle cerebral artery has also been used to identify fetuses at risk for moderate to severe haemolytic disease. (Grade Y)

**Expected Peak Velocity of Systolic Blood Flow through MCA**
The middle cerebral artery is examined close to its origin in the internal carotid artery. The angle of the ultrasound beam and the direction of the blood flow should be zero degrees. The risk of anaemia is highest in fetuses with a pre-transfusion peak systolic velocity of 2.5 times the median or higher.

7.5.2. **Serial amniocentesis**
Fetuses affected by haemolytic disease secrete abnormally high levels of bilirubin into the amniotic fluid. The amount of bilirubin can be quantitated by spectrophotometrically measuring absorbance at the 450nm wavelength in a specimen of amniotic fluid that has been shielded from light. Alternatively, percutaneous umbilical blood sampling (PUBS) may be used to determine all blood parameters directly.

If amniocentesis is used to monitor the fetus, the results (delta 450) are plotted on a “Liley” curve.
7.5.3. **The Liley curve**
The Liley curve is divided into three zones.

- A result in Zone I indicates mild or no disease. Fetuses in zone I are usually followed with amniocentesis every 3 weeks.
- A result in zone II indicates intermediate disease. Fetuses in low zone II are usually followed by amniocentesis every 1-2 week.
- A result above the middle of zone II may require transfusion or delivery.

Patients with results in zone I or zone II can be allowed to proceed to term, at which point labour should be induced. In most cases, patients in the middle of zone II can progress to 36-38 weeks of gestation. Depending on gestational age, patients in zone III should be delivered or should receive intrauterine fetal transfusion. Serial determination of delta optical density at 450nm and PUBS are the most common methods for the evaluation of fetal states.

7.6. **Intravascular Fetal transfusion**

**Procedure**

- The abdomen is aseptically prepared.
- A 20-guage, 5-inch spinal needle is then guided into the umbilical vein at the placental insertion under ultrasound guidance.
- Fetal blood is aspirated for immediate haematocrit, CBC, blood group and Rh factor.
- Prior to transfusion pancuronium bromide may be administered as an IV bolus.
- Transfusion is performed using group O Rh negative, CMV-negative, washed irradiated packed cells, cross-matched against maternal blood.
- The donor blood is infused at 3-5 ml./ min.
- Fetal blood is aspirated at the conclusion of transfusion to determine final fetal haematocrit.

7.7. **Summary**
The recommended policy of Sri Lanka is to obtain an anticoagulated blood sample as soon as possible (within two hours) after the delivery and to undertake the Kleihauer test to identify women with a suspected larger FMH who need additional anti –D Ig. Since this facility is available only in certain hospitals, suspected larger FMH should be covered with an anti-D Ig mega dose.
Intramuscular anti-D Ig should be given into the deltoid muscle as soon as possible within 72 hours. However in cases of failure it is advisable to administer within 9-10 days.

Some RhD negative women require anti-D Ig following abortion; 250iu before 20 weeks’ gestation and 500iu thereafter. A test for the size of FMH should be performed if available when anti-D Ig is given after 20 weeks.

After suspected termination of pregnancy: Anti-D Ig should be given to all non-sterilized RhD-negative women having a termination of pregnancy, whether by surgical or medical methods, regardless of gestational age.

Ectopic pregnancy: Anti-D Ig 250iu should be given to all non-sensitized RhD-negative women who have an ectopic pregnancy.

Spontaneous miscarriage: Anti-D Ig should be given to all non-sensitized RhD-negative women who have incomplete abortion after 12 weeks of pregnancy.

Threatened miscarriage: Anti-D Ig 250iu should be given to all non-sterilized RhD negative women with a threatened miscarriage after 12 weeks of pregnancy. Where bleeding continues intermittently after 12 weeks gestation, anti-D Ig should be given at 6-weekly intervals. A dose of 250iu is recommended for prophylaxis following sensitizing events up to 20 weeks of pregnancy. For all events after 20 weeks, at least 500iu anti-D Ig should be given followed by a test to identify FMH greater than 4 ml. red cells; additional anti-D Ig should be given as required.

References
2. National Institute for Clinical Excellence (NICE Guidelines) Guidance on the use of routine antenatal anti-D prophylaxis for RhD-negative women N0091 1P 100k May 02 (ABA); www. nice. org.uk


Contributed by
Prof. W. I. Amarasinghe
Dr. Kapila Gunawardana
Dr. Asoka Panadare
Dr. Prasad Rannalu
Dr. Chathura Rathnayaka
Management of Puerperal Sepsis
8. Management of Puerperal Sepsis

8.1. Introduction
This guideline is to provide recommendations to aid General Practitioners and Obstetricians in the management of Puerperal Sepsis. This treatment could be initiated in a primary care setting or in centers with advanced facilities. The objective of management in puerperal sepsis is to make an early diagnosis, treat, prevent complications, and consequently to improve quality of life.

8.2. Scope of the guideline
To prevent maternal deaths and long-term morbidity by early identification and management of puerperal sepsis.

8.2.1. Definition of puerperal sepsis
Puerperal sepsis was defined as infection of the genital tract occurring at any time between the onset of rupture of membranes or labour, and the 42nd day postpartum in which two or more of the following are present:

- Pelvic pain,
- Fever i.e. oral temperature 38.5°C/101.3°F or higher on any occasion,
- Abnormal vaginal discharge, e.g. presence of pus,
- Abnormal smell/foul odour of discharge,
- Delay in the rate of reduction of the size of the uterus (involution) (<2 cm/day during first 8 days).

8.2.2. Definition of puerperal infections
Puerperal infections is a more general term than puerperal sepsis and includes not only infections due to puerperal sepsis, but also all extra-genital infections and incidental infections:

- Infections of the genito-urinary systems related to labour, delivery and the puerperium,
- Infections related to the uterus and its associated structures,
- Infections related to the urinary tract,
- Infections specifically related to the birth process
but not of the genito-urinary systems, e.g. breast abscess, incidental infections, e.g. malaria, respiratory tract infections, It is advisable to consider these possibilities at the time of diagnosis.

8.2.3. Significance
Puerperal infections are an important cause of morbidity and mortality for mothers in developing countries. It is one of the commonest causes of maternal deaths in Sri Lanka.

The infected mother in acute stage, suffers severe pain and is acutely ill very often ending in death.

Often the recovery eventually result in infertility, chronic debilitation and life long suffering.

8.3. Prevention

Antenatal period

- Antenatal care helps to reduce puerperal infections by:
  - Diagnosis and treatment of urinary tract infections.
  - Diagnosis and treatment of anaemia and malnutrition.
  - Diagnosis and treatment of diabetes mellitus.
  - Assessment of risk factors for feto-pelvic disproportion.
  - Diagnosis and treatment of pre-existing sexually transmitted infections e.g. Gonorrhoea, Chlamydia etc.,
  - Diagnosis and treatment of other vaginal infections.
  - Identification and appropriate management of prolonged rupture of membranes (>12 hours) (Grade X)

Refer for specialist care those at risk
  - Previous prolonged labour.
  - History of repeated abortions.

Intrapartum period (Grade X)

- Strict adherence to established antiseptic and sterilization procedures such as, (Grade X)
  - Cleaning hands immediately prior to delivery,
  - Cleaning perineum,
  - Cleaning delivery surface,
  - Sterilized surgical instruments,
Clean cord tie and clean cord care,
Use of a prepacked sterilized delivery kits.

- Institutionalizing all deliveries. (Grade X)
- Restricting vaginal examinations to minimum in premature and prolonged rupture of membranes (PPROM). Refer guideline on Preterm Rupture of Membranes (Grade X)
- Prevention of prolonged labour by maintaining the partogram in all patients who are in labour and intervention at the action line and early maternal transfer when indicated. (Grade X)
- Strict adherence to sterile procedures at every vaginal examination in women in labour.
- Strict adherence to sterile procedures especially when performing an emergency Caesarean Section and/or any other operative procedures such as, removal of retained placenta or retained products of conception. (Grade X)
- Ensuring sterility in the operating room. (Grade X)
- Ensuring sterility in the labour room. (Grade X)
- Encourage-voiding urine during labour there by avoiding unnecessary catheterization.
- Avoid unnecessary episiotomy.
- Use soap, water and effective antiseptics (e.g. chlorhexidine, surgical spirit) to clean hands, wear gloves on both hands for vaginal examination, delivery and handling of infants. (Grade X)
- Use correct methods for sterilization (e.g. 0.5% chlorine solution), proper disinfection techniques (e.g. boiling for 20 minutes) and sterilization (dry, heat or steam) of instruments and equipment. (Grade X)
- Maintain sufficient supply of antibiotics. Consider prophylactic use of antibiotics for invasive procedures, manual removal of placentae, internal version, and third degree perineal tears. (Grade X)

8.4. Management
Components of management:
- Communication & Transport
- Resuscitation
- Monitoring
- Documentation
- Treatment
8.4.1. Communication & Transport

8.4.1A. Non-Specialist Unit

In patients where severe sepsis is diagnosed or suspected initial resuscitative and antibiotic therapy should be commenced as an initial step and such patients should be transferred to a specialist unit without delay. (Grade X)

The specialist unit receiving the patient should be forewarned regarding the condition, the blood group (if available) and medicines given to the patient.

Medical, senior nursing and midwifery staff should be members of the team caring for such patients.

Establish good intravenous access. (Grade X)

Institute intravenous antibiotics (ampicillin, metronidazole, gentamicin, etc.)

8.4.1B. Specialist Unit

- Call Senior Midwifery/Nursing staff
- Alert Obstetrician
- Alert medical staff
- Alert Anaesthesiologist

The services of ward employees should be summoned in appropriate cases. This would facilitate transport and handling of specimens and patients with minimum delay.

8.4.2. Resuscitation

Patients in septic shock or having evidence of severe sepsis, resuscitative procedures should be instituted with out any delay. This is life saving. (Grade X)

8.4.2A. Non-Specialist unit

While preparations are being made in patients who are having severe sepsis to be transferred to a specialist unit the following steps are recommended prior to transfer.

- Establish good intravenous (IV) access (14 G cannula),
- Therapy with intravenous (IV) antibiotics,
- Commence intravenous infusions while waiting,
• Infuse alternatively as rapidly as required the following; Crystalloids e.g. Hartman’s and normal saline solutions (maximum 2 liters), Colloids if available (Hitastarch, Gelatin or Haemacil), (Grade Y)
  • Oxygen by mask at 8 liters/min.
  • Dextrans are hazardous and should not be used in obstetric practice. (Grade X)

8.4.2B. Specialist Unit
  • Good intravenous (IV) access,
  • Blood for cross match,
  • Oxygen via face-mask,
  • Transfusion of blood/ fresh frozen plasma (FFP) depending on need,
  • Intravenous (IV) antibiotics (broad spectrum), discuss with microbiologist.

8.4.3. Monitoring and investigations
8.4.3A. Non Specialist Unit
  • Good Intravenous (IV) access,
  • Blood for; (20 ml)
    • Full blood count (FBC),
    • Bleeding time (BT),
    • Clotting time (CT),
    • Culture and antibiotic sensitivity (if facilities available),
  • Urine full report (UFR),
  • Sterile sample of urine for culture and antibiotic sensitivity,
  • Indwelling catheter for monitoring hourly urine output,
  • Blood pressure (BP) and pulse measurement every 15 minutes.

8.4.3B. Specialist Unit
Intensive care unit (ICU); Care in collaboration with anaesthesiologist is mandatory in severe sepsis/shock. (Grade X)
  • Good intravenous (IV) access,
  • Blood for; (20 ml)
    • Full blood count (FBC),
    • Blood urea (BU),
    • Serum electrolytes (SE),
    • Liver function tests (LFT),
    • Blood for culture and antibiotic sensitivity,
    • Clotting profile.
Perform an abdominal examination and assess uterine size.
Assess uterine haemorrhage and attempt to control it.
Failure to control uterine bleeding is an indication to transfer to a specialist unit.

- Genital swabs
  Perineal, vaginal, high vaginal, endocervical swabs for culture and antibiotic sensitivity,
  - Ultrasound scan (USS) of pelvis,
  - X-ray chest/abdomen (to detect perforations),
  - Regular pulse and blood pressure recording (every 15 mints),
  - Foley catheter to monitor hourly urine output,
  - Central venous pressure (CVP) monitoring (where appropriate and when experienced staff is available),
  - Dedicated intensive care nurse per patient should be arranged whenever possible.

8.4.4. Treatment
8.4.4A. If detected by family health worker (FHW) at home visit:
If the woman is very sick (high fever, altered consciousness, rapid pulse), send her to the closest specialist hospital immediately. (Grade X)

All women with evidence of sepsis including infected episiotomies should be sent to the hospital preferably to the closest specialist unit. (Grade X)
No woman should be managed by the FHW at home. (Grade X)

However, in the exceptional situation where there is a delay in getting to the hospital ampicillin or amoxycillin 3 gms. may be given while awaiting admission.

8.4.4B. Non Specialist Hospital
If managed at non-specialist level, the patient should be reviewed twice a day by the DMO/MO. (Grade X)
Look out for signs of shock, septicaemia, pallor, anaemia, and treat accordingly.
  - Perform an abdominal examination and assess uterine size.
  - Assess uterine haemorrhage and attempt to control it. Failure to control uterine bleeding is an indication to transfer to a specialist unit.
  - Start antibiotics after taking samples for microbiology.
Amoxicillin- clavulinic acid – 1.2 gms. intravenous 8 hourly or 625mg. oral 8 hourly/twice a day,
Or
Ampicillin 500mg. intravenous 6 hourly,
Or
Amoxicillin 500mg. intravenous 8 hourly,
Or
Gentamicin 5mg./kg body weight/day in a single dose or in two divided doses.

- Giving penicillin with gentamicin and metronidazole provides the broadest coverage.
- Give IV fluids: 1 litre of 5% dextrose in saline or normal saline rapidly, followed by 1000 cc every 24 hours.
- Check vital signs and urinary output every 6 hours.
- Reassess every 24 hours: if there is no improvement refer her to a specialist hospital.
- If there is improvement, continue intravenous (IV) antibiotics for 3 days and then follow-up with oral antibiotics.
- At this point, if the woman is much better, send her home on oral antibiotics for 4-7 days, after having checked her haemoglobin level and given her treatment for anaemia if found.
- Even if the women improves initially and subsequently start to bleed, she should be referred to a specialist unit to exclude retained products of conception.
- If the area is malarious, treat her according to the local situation and national policy.
- Inform her to return if she develops fever, vaginal bleeding or abdominal pain.
- If the woman is not better after three days on intravenous antibiotics, refer her to the first referral level.
Special circumstances for transfer to a specialist hospital

- Condition of the patient: If initial assessment indicate moribund state, sepsicaemia, repeated body temperatures above 1010°F, hypotension,
- Tender abdomen / abdominal mass, purulent vaginal discharge,
- Patient not responding to initial treatment and condition getting worse.
- If above-mentioned resuscitative and therapeutic facilities not being available

8.4.4C. Specialist hospital

- Perform a physical examination to rule out pelvic abscesses, pelvic thrombophlebitis, anaemia etc. (Grade X)
- Take vaginal swabs for gram stain and culture and antibiotic sensitivity test and blood for culture and antibiotic sensitivity test. (Grade X)
- Broad-spectrum antibiotic coverage must be initiated immediately after collection of cultures. Group A Streptococcus is exquisitely sensitive to β-lactams. (Grade X)
  - Amoxycillin-clavulinic acid (Amoxyclav) – 1.2 gms. intravenous 8 hourly with or without gentamycin.
  - If response is poor,
    - Imipenem 500 mg. intravenous 8 hourly
    - Or
    - Ticarcillin-clavulinic acid 3.2 gms. intravenous 8 hourly may be used in place of amoxycillinclavulinicacid (Amoxyclav). Depending on culture and ABST results changes may be needed.

Antibiotics taken together are effective against a wide range of bacteria, but may not be capable of clearing up the infection completely, especially if an abscess or blood clot is present.

- Manage complications appropriately, (Grade X)
- Retained placental fragments,
- Presence of blood clots,
- Pelvic abscess;
If the infection is complicated by the presence of an infected focus, it may be necessary to surgically drain the infected site/abscess. Continuing adequate and effective antibiotic therapy in this situation is mandatory. (Grade X)

- **Thrombophlebitis;**
  
  If thrombophlebitis occurs in a superficial vein, self-care steps that include applying heat to the painful area, elevating the affected leg and using a non-steroidal anti-inflammatory drug may be recommended. The condition usually subsides within a week or two. (Grade X)

  In the presence of deep vein thrombosis use of anticoagulants, such as heparin, will prevent clots from growing. After the heparin therapy, use of warfarin (Coumarin) for several months continues to prevent clots from growing. Support stockings—these help prevent recurrent swelling and reduce the chances of complications of deep vein thrombosis.

- **Anaemia;**
  
  If haemoglobin level is <8mg./dl. – blood transfusion is recommended. If haemoglobin level is 8-10 mg./dl. – oral or parenteral haematinics are recommended.

**8.5. Surgical interventions**

- Infected episiotomies can be opened and allowed to drain. Abscesses and blood clots may require surgery.

- When multi-disciplinary approach is indicated the services of a surgeon, haematologist, pathologist and microbiologist may be of paramount importance.

- Clot removal or by-pass. Sometimes, surgery is necessary to remove an acute clot blocking a pelvic vein or an abdominal vein. Procedures such as bypass/stent/filter may be necessary.

- Prompt and aggressive exploration and debridement of necrotic tissue are important.

- Hysterectomy is usually not needed; however, in severe cases involving large bacterial inocula, extensive tissue necrosis, or gangrene, hysterectomy and even removal of adnexal tissue might be indicated.

- Consider other coexisting conditions urinary tract infections (UTI), mastitis, deep vein thrombosis (DVT), respiratory tract infections (RTI), malaria etc.
8.6. General Guidelines

8.6.1. Asepsis and Universal Precautions
Sepsis contributes significantly to maternal and neonatal morbidity and mortality. All possible efforts should be made to minimize sepsis during labour and surgical procedures.

Working in the labour suite, operating theatre exposes the labour room staff to the risk of infection following contamination with infected body fluids. Staff should take necessary precautions to safeguard themselves from such occupational hazards.

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**Recommendation**
All steps in the management of labour and surgical procedures should be carried out under aseptic conditions. Members of the staff should adhere to universal precautions at all times. (Grade X)

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8.6.2. Documentation
Meticulous documentation of all events would improve the quality of patient care and will be useful for future reference. Fetal heart tracings and other relevant reports should be attached to the bed head ticket.

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**Recommendation**
All steps in the management of labour and surgical procedures should be documented in the bed head ticket of the patient. Such records should have the time, the observations, any decisions made and the name of the responsible health care attendant. (Grade X)

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8.6.3. Quality assurance
Quality assurance is an integral part of maintaining a good health care delivery system. Measures taken on this regard would contribute to institutional development as well as improvement in the standard of care in the country. Internal clinical audit, institutional conferences and basic research activities are useful in improving standards of an institution. In-service training in relevant areas and opportunities for continuous medical education should be made available to all grades of staff.

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**Recommendation**
Regular audit cycles of the quality of labour ward practices and operating theatre procedures should be an important aspect of the functions of an obstetric and gynaecological unit. (Grade Y)
References

Further reading


8. Smaill F, Hofmeyer GJ. Antibiotic prophylaxis for Caesarean Section. Cochrane Database of systematic reviews. Issue 1, 2002


Contributed by

Dr. D.Y.K. De Silva
Dr. Athula Fernando
Dr. V.P. Gange
Dr. S.B. Uduwerella
Dr. C. Rathnayake
Dr. Gayan De Silva
Dr. W. Ruwan Pathiraja
Management of Ectopic Pregnancy
9. Management of Ectopic Pregnancy

9.1. Introduction
The aim of this guideline is to provide recommendations to aid General Practitioners and Gynaecologists in the management of Ectopic Pregnancy. This treatment could be initiated in a primary care setting or in centres with advanced facilities. The objective of management in ectopic pregnancy is to make an early diagnosis, treat, prevent complications, and consequently to improve quality of life. This guideline is intended to improve the morbidity and mortality associated with ectopic pregnancy.

9.2. Scope of the guideline

9.2.1. Definition
An ectopic pregnancy is a pregnancy implanted in an abnormal location (outside of the uterus).

9.2.2. Importance of ectopic pregnancy
Ectopic pregnancy is account for maternal deaths. The incidence of ectopic pregnancy is 1.8/1000 (According to the UK data). Most of the ectopic pregnancies are sub clinical/biochemical; therefore true incidence may be higher. The most common site of ectopic implantation is the fallopian tube. Other sites such as the abdomen, ovary, cervix or cornu of the uterus are far less common but are associated with higher mortality. This higher mortality is due to greater detection difficulty and to massive bleeding that can result if rupture occurs at these sites. As a result of septic abortions and pelvic inflammatory disease (PID), the incidence of ectopic pregnancies shows an increased trend over the past decades. (During the past 40 years its incidence has been steadily increasing concomitant with increased STD rates and associated salpingitis. Such abnormalities of the tubes prevent normal transport of the fertilized egg to the uterus). On the other hand increase availability of Gynaecologists and ultrasonography (USS) facility, most of the ectopic pregnancies are diagnosed earlier and appropriate management carried out with reducing maternal mortality and morbidity.
9.3. Aetiology

- The commonest cause of ectopic pregnancy is salpingitis (causes 50% of first time ectopic pregnancies).
- 40% have no known cause. One hypothesis is that there is slowing of transport through the fallopian tube of the fertilized egg. This slow transport could possibly be due to hormonal imbalance (such as due to progesterone releasing IUD, progestin-only oral contraceptives). This could also happen in Artificial Reproductive Technique procedures (ART) or possibly an abnormality of the embryo (e.g. chromosomal).
- Cigarette smoking significantly increases a woman's risk.
- Previous history of ectopic pregnancy increases the risk for another ectopic pregnancy. (Incidence is 7%)
- About 25% of women with an ectopic pregnancy have a history of previous surgery in the abdomen.

9.4. Epidemiology

The occurrence of ectopic pregnancy is reported to be at a rate of about 1-2% of pregnancies and can occur in any sexually active fertile woman. The increase in incidence in the past few decades is thought to be due to two factors:

1. Increased incidence of salpingitis (infection of the fallopian tube, usually due to a sexually transmitted disease (STD), such as Chlamydia or Gonorrhea),
2. Improved ability to detect ectopic pregnancies.

There is a marked increase in ectopic pregnancy rate with increasing age from 6.6 per 1000 pregnancies in women aged 15 to 24, to 21.5 per 1000 pregnancies in women aged 35 to 44. Most ectopic pregnancies occur in women who have had more than one pregnancy. Only 10% to 15% of ectopic pregnancies occur in women who have never been pregnant before.

- Women in whom it is suspected that they are in danger of ectopic pregnancy, with the use of testing and imaging it is now often possible to detect an ectopic pregnancy before symptoms develop. It is important to be aware of the symptoms of ectopic pregnancy because it can occur in any sexually active woman whether or not she is using contraceptives or has undergone tubal sterilization.
9.5. Diagnosis
9.5.1. History
• Symptoms occur as the embryo grows and as bleeding occurs due to leaking of blood through the fimbrial opening of the fallopian tube or from rupture of the tube. Mild bleeding can also occur without causing symptoms.
• The most common symptoms that with which a woman presents to a doctor are abdominal pain (90-100% of women), delayed menses (75-90%) and unexpected bleeding through the vagina (50-80%).
• Before rupture occurs, a vague soreness or spastic (colic) pain in the abdomen may be the only symptom present.
• Abdominal pain can be generalized, or it can be localized on one side or both sides.
• About one quarter of women also have pain in the shoulder because of diaphragmatic irritation from blood in the abdomen.
• During rupture, the pain usually becomes intense.
• Other symptoms also occur though less commonly. Dizziness and fainting occur in about one third of women with symptoms. Pregnancy symptoms also occur in about be an urge to have bowel movement.

9.5.2. Examination
Signs
• The most common finding is tenderness in the abdomen and pelvis.
• Often, a mass is felt on the side of the uterus (adnexial mass).
• In about one third of women, an enlarged uterus is found which is smaller than would be found in a normal pregnancy, except when an interstitial pregnancy is present.
• Tachycardia and hypotension can be found if there has been profuse blood loss.
• However, in most early ectopic pregnancies no abnormal findings can be found.

9.5.2. Investigations
• β-HCG Blood levels
• Transvaginal ultrasonography
9.6. Management
9.6.1. Levels of management

Level 1
General Practitioner (GP), Public Health Midwife (PHM), Medical Officer of Health

• Identification of risk mothers of ectopic pregnancy:
  Past history of;
  - ectopic pregnancy,
  - septic abortion,
  - pelvic inflammatory disease (PID)

Recommendation:
Early referral to level 2 (Grade X)

Level 2
Base Hospital with Obstetrician and Gynaecologist
Ultrasonography (USS) facility,
Laparotomy facility with or without Laparoscopy facility

Level 3

• General Hospital/Teaching Hospital with Obstetrician and Gynaecologist with all level 2 facilities.
Human Chorionic Gonadotrophin (hCG) level measurements available (24 hours)

9.6.2. Management strategies
Expectant management
Ideal at Level 3 (Grade Y)

Not all ectopic pregnancy ends up with maternal morbidity and mortality. There is 89.3 percent self-resolution of the ectopic pregnancies, but there is poor efficacy of this method. Expectant management is an option for;

• When ectopic sac less than 2cm with no identifiable fetal pole and less than 50ml of haemoperitoneum on ultrasonography (USS).
• Clinically stable woman with minimal symptoms and a pregnancy of unknown location.
• Clinically stable asymptomatic woman with an ultrasound diagnosis of ectopic pregnancy and a decreasing serum human chorionic gonadotrophin levels (hCG), initially less than serum 1000 iu/l.

However, one need to realize that selection of patients for expectant management should be done selectively with full compliance of the patient following detailed counselling.

Women managed expectantly should be followed twice weekly with serial hCG measurements and weekly by transvaginal examinations to ensure a rapidly decreasing hCG level (ideally less than 50% of its initial level within seven days) and a reduction in the size of adnexial mass by seven days.

Thereafter weekly hCG and transvaginal ultrasound examinations are advised until serum hCG levels are less than 20 iu/l as there are case reports of tubal rupture at low levels of β-hCG. In addition, women selected for expectant management of pregnancy of unknown origin should be counselled about the importance of compliance with follow-up and should be within easy access to the hospital.

9.6.3. Medical Management

Ideal at level 3 (Grade Y)
Medical therapy should be offered to suitable women, and units should have treatment and follow-up protocols for the use of methotrexate in the treatment of ectopic pregnancy. In stable patients a variety of medical treatment options are as effective as surgery.

If medical therapy is offered, women should be given clear information (preferably written) about the possible need for further treatment and adverse effects following treatment.

Women should be able to return easily for assessment at any time during follow-up.

Medical therapy option may be considered for women with an hCG level below 3000 iu/l.
The presence of cardiac activity in an ectopic pregnancy is associated with a reduced chance of success following medical therapy and should be considered a contraindication to medical therapy. The drug of choice is methotrexate. It can be given intravenous / intramuscular / oral or local injection at the site of the ectopic either laparoscopically, ultra sound guided hysteroscopically. Intramuscular methotrexate given as a single dose calculated from patient's body surface area (50 mg/m²). For most women this will be between 75 mg and 90 mg. Serum hCG levels are checked on days four and seven and a further dose is given if hCG levels have failed to fall by more than 15% between day four and day seven.

However, the success rate is 75%. According to a small randomised controlled trial (RCT) there is no injection. This also gives rise to relatively low drug related side effects. Therefore local injection of methotrexate is preferable to its use systemically. There are no studies to comment on the subsequent fertility rate, as most of the trials are small.

Method of administration needs to be addressed carefully after proper selection of patients. For example there is high failure rate if the ectopic is more than 2cm of fetal pole.

9.6.4. Surgical management

A. Laparotomy

Ideal at level 2 (Grade Y)

Most of the ectopic pregnancies in Sri Lanka are present after rupture and haemo-dynamically unstable. According to randomised controlled trials (RCT) there are controversies of stabilizing the patient and then proceeding with the laparotomy. However, results need to be considered cautiously. Laparotomy is preferred in haemodynamically unstable patients over laparoscopy. According to two randomised controlled trials (RCT), laparotomy patients give subsequent 55% intra-uterine pregnancy (IUP) rate, 16.6% of recurrent ectopic rate and 1.8% persistent tropoblastic activity.

B. Laparoscopy

Ideal at level 3.

This depend on the consultant's preference, and is possible in level 2 as well.
A laparoscopic approach in the surgical management of tubal pregnancy, in the haemo-dynamically stable patient, and is preferable to a laparotomy. This method may be preferable for the ectopic when diagnosed early and unruptured. According to three randomised controlled trials (RCT) laparoscopic method give rise to less blood loss, less hospital stay, low cost and less post-operative analgesic requirements. This study shows higher intra-uterine pregnancy (IUP) (70%) rate, less recurrent ectopic (50%) and higher trophoblastic tissue activity (12._%).

C. Type of surgery
i. Salpingectomy.
According to meta analysis, this method gives rise less recurrent ectopic pregnancy rate (10%) and with no failure of removal of all ectopic tissue. However, there is no difference between laparatomy and laparoscopy except the advantages of laparoscopy.

In the presence of a healthy contralateral tube there is no clear evidence that salpingotomy should be used in preference to salpingectomy.0_12

ii. Salpingotomy.
According to good quality randomised controlled trials (RCT) there is higher rate of recurrent ectopic associated with this method (15%) and higher rate of trophoblastic activity (11%). However trophoblastic activity can be managed medically. There is no significant deference in intrauterine pregnancy (IUP) in both methods.

According to a randomised controlled trial (RCT), that there is no additional benefit of suturing the salpingostomy site, because the intrauterine pregnancy (IUP) rate is similar at 12 month after the surgery with or without suturing.

Randomised controlled trials (RCT) results suggest that there may be a higher subsequent intrauterine pregnancy rate associated with salpingotomy but the magnitude of this benefit may be small. Data from future randomised controlled trial (RCT) examining this question is needed.
The use of conservative surgical techniques exposes women to a small risk of tubal bleeding in the immediate postoperative period and the potential need for further treatment for persistent trophoblastic tissue. Both these risks and the possibility of further ectopic pregnancies in the conserved tube should be discussed if salpingotomy is being considered by the surgeon or requested by the patient.

Laparoscopic salpingotomy should be considered as the primary treatment when managing tubal pregnancy in the presence of contralateral tubal disease and the desire for future fertility.

In women with a damaged or absent contralateral tube, in vitro fertilization is likely to be required if salpingectomy is performed. Because of the requirement for postoperative follow-up and the treatment of persistent trophoblasts, the short-term costs of salpingotomy are greater than salpingectomy. However, if the subsequent need for assisted conception is taken into account, an increase in intrauterine pregnancy rate of only 3% would make salpingotomy more cost effective than salpingectomy. In the presence of contralateral tubal disease the use of more conservative surgery is appropriate.

These women must be made aware of the risk of a further ectopic pregnancy.

**Recommendations. (Grade X)**

- Laparoscopic method is superior to laparotomy method with regard to less cost, shorter hospital stay, less analgesic requirements, higher subsequent intrauterine pregnancy (IUP) and less recurrent ectopic rates. Therefore, laparoscopic method needs to be considered as a first option in unruptured ectopic.
- Laparotomy is best in the case of life saving as well as within inadequate facilities.
- Medical management should be conducted only by well experienced consultants with emergency facilities at hand.
- Expectant management should be carried out only with reliable and compliable patients.
9.7. Special circumstances

9.7.1. Ruptured Ectopic Pregnancy Management
Management of tubal pregnancy in the presence of haemodynamic instability should be by the most expedient method. In most cases this will be laparotomy.

There is no role for medical management in the treatment of tubal pregnancy or suspected tubal pregnancy when a patient shows signs of hypovolaemic shock.

Transvaginal ultrasonography can rapidly confirm the presence of haemoperitoneum, if there is any diagnostic uncertainty.

But expedient resuscitation and surgery should be undertaken. Experienced operators may be able to manage laparoscopically, women with even a large haemoperitoneum safely, but the surgical procedure which prevents further blood loss most quickly should be used. In most centers this will be laparotomy. (Grade X)

9.7.2. Anti-D immunoglobulin
Non-sensitized women who are Rhesus negative with a confirmed or suspected ectopic pregnancy should receive anti-D immunoglobulin. (Grade X)

9.8. Summary
- Single dose methotrexate is best used for those who are asymptomatic, whose β-hCG is < 3000mIU/ml, have tubal size < 3 cm, have no fetal cardiac activity on ultrasonography, and will come in to be followed closely. It cannot be used if there is a heterotopic pregnancy.
- Despite low and declining β-hCG levels, tubal rupture can still occur with methotrexate treatment.
- With severe pelvic pain, monitoring of vital signs and hematocrit can help differentiate between tubal abortion and tubal rupture.
- Most common side effects of methotrexate are;
  § stomatitis,
  § conjunctivitis,
  § mild abdominal pain of short duration.
Rare side effects include dermatitis and pruritis.
Surgery is done only if transvaginal ultrasonography shows an ectopic pregnancy.
Laparoscopic surgery has been found to be superior to laparotomy and can treat most patients.
Persistent ectopic pregnancy refers to the continued growth of trophoblastic tissue after surgery. Special attention should be given to the proximal portion during surgery and the ectopic pregnancy should be flushed out with suction irrigation.
Expectant management is done when ectopic pregnancy is suspected, and transvaginal ultrasonography does not show an ectopic pregnancy. The patient is followed with weekly ultrasonography and weekly β-hCG measurement until the level is < 10 mIU/ml.
All pregnant women who are Rh-negative should receive Rh immunoglobulin.

References

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Contributed by
Dr. A.G.S.K. Ranaraja
Dr. Saradah Hemapriya
Dr. Harsha Attapattu
Dr. R.M.A.K. Rathnayaka