Policy Directive



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Maternity - Prevention, Early Recognition & Management of Postpartum Haemorrhage (PPH)

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Functional Sub group Clinical/ Patient Services - Maternity Clinical/ Patient Services - Nursing and Midwifery Personnel/Workforce - Learning and Development

- **Summary** Area Health Services are required to have procedures for prevention, early recognition and management of postpartum haemorrhage, and to ensure that staff have the knowledge and skills necessary to implement the policy.
- **Replaces Doc. No.** Postpartum Haemorrhage (PPH) Framework for Prevention, Early Recognition & Management [PD2005_264]
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Applies to Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations, Affiliated Health Organisations - Declared, Public Hospitals

- Audience All clinicians in maternity services, operating theatre staff, emergency dept staff
- **Distributed to** Public Health System, Divisions of General Practice, Health Associations Unions, NSW Ambulance Service, Ministry of Health, Private Hospitals and Day Procedure Centres, Tertiary Education Institutes
- Review date 21-Oct-2015
- Policy Manual Patient Matters

File No.

Status Active

Director-General

This Policy Directive may be varied, withdrawn or replaced at any time.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

MATERNITY - PREVENTION, EARLY RECOGNITION AND MANAGEMENT OF POSTPARTUM HAEMORRHAGE (PPH)

PURPOSE

This policy directive provides direction to NSW maternity services regarding the prevention, early recognition and management of postpartum haemorrhage (PPH). PPH remains a major cause of maternal mortality and morbidity and this policy directive should help inform maternity services in the development and implementation of local clinical practice guidelines and protocols.

MANDATORY REQUIREMENTS

All NSW Public Health organisations providing maternity services must have clinical practice guidelines for the management of PPH. All hospitals are required to develop written clinical practice guidelines for the prevention, early recognition and management of PPH. These protocols must include a clear local plan of action for all clinicians to follow with appropriate early involvement of senior consultants in obstetrics, anaesthetics, haematology and intensive care should the clinical scenario warrant such escalation.

Health services and hospitals should comply with the educational program components as outlined in IB2008_002 *Fetal Welfare, Obstetric Emergency, Neonatal Resuscitation Training* (FONT). In particular, maternity emergencies education days must include PPH and maternal collapse/resuscitation in the program content. All clinicians working in maternity units are expected to complete the various components of the FONT program.

Staff in other areas of a hospital may need to respond to a woman with an established PPH. Emergency departments may be first to respond to a PPH in a woman transported to hospital after a birth in the community, (intended or unintended) or a woman who returns to the hospital after discharge from hospital. Theatre/Recovery staff are often involved in the management of women with severe PPH. Staff in these areas, and any other areas where postpartum women may be cared for, must receive appropriate education and training regarding PPH, and this training must be attended every three years. Specific education packages for such staff in such areas must be locally developed and implemented.

Severe PPH (>1500 mls) is considered a significant adverse event and the occurrence must be notified in the IIMS system as per PD2009_003 Maternity Clinical Risk Management Program. Open disclosure regarding the incident must be undertaken as per PD2007_040 Open Disclosure.

IMPLEMENTATION

The Chief Executives of Area Health Services are ultimately responsible for the implementation of this policy directive.

REVISION HISTORY

| Version | Approved by | Amendment notes |
|---------------|-------------------|-------------------------------------|
| November 2002 | Director-General | New Policy |
| (PD2005_264) | | |
| October 2010 | Deputy Director- | Revised policy replacing PD2005_264 |
| (PD2010_064) | General Strategic | |
| | Development | |

ATTACHMENTS

1. Maternity - Prevention, early recognition & management of postpartum haemorrhage (PPH) - Procedures

| Maternity - Prevention, early recognition & management |
|--|
| of postpartum haemorrhage (PPH) |

NSW HEALTH

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1 BACKGROUND

1.1 About this document

PPH remains a major cause of maternal mortality and morbidity in Australia and internationally. PPH is a potentially life-threatening complication of vaginal birth and caesarean section operations. In addition to maternal death PPH can result in anaemia, prolonged hospital stay, delay or failure of breastfeeding, pituitary infarction, need for blood products, haemorrhagic shock and hypotension, coagulopathy, acute tubular necrosis/renal failure, coma, the need for emergency surgical or angiographic intervention, or the need for hysterectomy¹.

A population-based study² of births in NSW between 1994 and 2002 indicated that 5.8 % of women had a PPH in their first pregnancy. The risk of a first PPH in a second or third pregnancy was still 4-5%. The risk of recurrence of PPH in a subsequent pregnancy was up to 15%. Both average blood loss and risk of PPH are greater with caesarean section operations and with the rise in these procedures over the past decade it is important that all clinicians are aware of the prevention, early recognition and treatment of PPH.

This procedure should help inform maternity services in the development and implementation of local clinical practice guidelines and protocols for the prevention, early recognition and management of PPH.

1.2 Key definitions

PPH is defined as blood loss of 500mL or more during and after childbirth.

Severe PPH is defined as blood loss of 1000mL or more OR any amount of blood loss postpartum that causes haemodynamic compromise

A primary PPH occurs within the first 24 hours following birth.

A secondary PPH occurs between 24 hours and 6 weeks postpartum.

Note:

- 1. Generally, the degree of haemodynamic compromise or shock parallels the amount of blood lost, but some women will become compromised with a relatively small blood loss. This may include women with pregnancy-induced hypertension, women with anaemia, and women of small stature.
- 2. Haemodynamic changes of pregnancy may sustain a woman's circulatory status at near normal levels (initially there may even be a small rise in BP) despite large blood loss, until such time as a critical level is reached and there is a sudden and profound change in blood pressure and pulse to indicate shock.
- 3. Manual removal of the placenta at elective or emergency caesarean section is associated with a clinically important and statistically significant increase in maternal blood loss and increased risk of infection^{3,4}.
- 4. The incidence of PPH may be underestimated by up to 50%, due to the clinical difficulty in accurately estimating blood loss⁵.

2 KEY POINTS

| PREVENTION | Active management of the third stage of labour is recommended for all women. Synthetic oxytocin (Syntocinon®) is the current drug of choice for active management of the third stage of labour. All women should be fully informed antenatally of the current evidence regarding benefits and harms of active and physiological management of the third stage of labour. This includes the means available such as oxytocin for prevention of PPH and associated side effects and risks. Every woman should be encouraged to consider and to incorporate prevention and management of primary PPH into her birth plan. This includes women planning birth outside of a traditional birth unit environment, women planning early discharge and women who cannot receive blood products for religious or other reasons⁶. Local policies should be in place for physiological management of third stage for those women who choose physiological management. Antenatal and intrapartum risk factors should be identified and documented together with strategies to mitigate or control the risk of PPH |
|---|--|
| EARLY | Routine observation of all postpartum women for blood loss fundal tone BP and |
| RECOGNITION | Pulse. This is especially important during the first 4 hours post birth. The most important single warning of diminishing blood volume and mild shock is tachycardia, which often precedes a fall in blood pressure. Weakness, sweating and tachycardia may accompany this. See Table 2: <i>Clinical findings in PPH</i> Early discharge programs should include mechanisms for identifying secondary PPH and for monitoring incidence. |
| MANAGEMENT | CALL FOR HELP, commence resuscitation, identify cause of bleeding and give directed therapy according to cause of bleeding (Tone, Tissue, Trauma, Thrombin). See Table 3: Drug therapy for management of PPH, & Table 4: A stepwise approach to management of PPH Delay can lead to further complications requiring comprehensive emergency obstetric and intensive care services. Intractable bleeding requires a multidisciplinary team approach and individualised management, with replacement of blood and clotting factors and ongoing monitoring. Surgery may be required should these measures fail. |
| A CLEAR LOCAL PLAN OF ACTION, WITH | Contact information for key personnel and an agreed communication strategy. Measures to ensure the availability of appropriate equipment and drugs in case of severe PPH. Measures to ensure all staff providing birthing services or those who care for women who have recently birthed are familiar with the principles of prevention, recognition and management of PPH. Measures to ensure all staff are familiar with their local plan of action and are able to act as a team in an emergency situation Measures at hospital level to record the number of women with PPH for reporting to Morbidity and Mortality meetings, to ensure system problems are identified early and rectified quickly. Notification of Severe PPH (>1500 mls). Severe PPH >1500 mls is considered a significant adverse event and the occurrence must be notified in the IIMS system as per PD2009_003 Maternity Clinical Risk Management Program. Open disclosure regarding the incident must be undertaken as per PD2007_040 Open Disclosure. |

2.1 Antenatal and intrapartum risk factors for PPH

| Table T. Antenatal and | intrapartum risk factors for PPH | | | | |
|--|---|---|--|--|--|
| Cause | Aetiology | Clinical Risk Factors | | | |
| Abnormalities of | Atonic uterus | Physiological management of the third stage Prolonged third stage (>30 mins) | | | |
| contraction (Tone) 70% | Over distended uterus | PolyhydramniosMultiple pregnancyMacrosomia | | | |
| | Uterine muscle exhaustion | Rapid or incoordinate labour Prolonged labour (1st or 2nd stage) Labour dystocia High parity Labour augmented with oxytocin | | | |
| | Intra-amniotic infection | Pyrexia Prolonged ruptured membranes (>24 hours) | | | |
| | Drug-induced uterine hypotonia | Magnesium sulphate, nifedipine, salbutamol General anaesthesia | | | |
| | Functional or anatomic distortion of the uterus | Fibroid uterusUterine anomalies | | | |
| Genital tract trauma (Trauma) 20% | Episiotomy or lacerations (cervix, vagina or perineum) | Induced labour Augmented labour Abnormal labour (dystocia) Malposition Precipitous birth Instrumental birth (forceps or vacuum) | | | |
| | Extensions / lacerations at caesarean section | MalpositionDeep engagement | | | |
| | Uterine runture | Previous uterine surgery | | | |
| | Uterine inversion | Strong cord traction in 3rd stage (especially with fundal placenta) Short umbilical cord High parity Uterine relaxation Placenta accreta (especially with fundal placenta) Congenital uterine anomalies or weakness Antepartum use of magnesium sulphate or oxytocin | | | |
| Retained pregnancy tissue (Tissue) 10% | Retained products Abnormal placenta Retained cotyledon or succenturiate lobe | Incomplete placenta at birth Placenta accreta Previous uterine surgery High parity Abnormal placenta on ultrasound | | | |
| Abnormalities of | Retained blood clots | Atonic uterus | | | |
| (Thrombin) 1% | Coagulation disorders acquired during pregnancy Idiopathic thrombocytopenic purpura (ITP) Von Willebrand's disease Haemophilia Thrombocytopenia with pre- eclampsia Disseminated intravascular coagulation (DIC) Pre-eclampsia Retained dead fetus Severe infection Placental abruption Amniotic fluid embolism | Bruising Elevated blood pressure Fetal death Fever Antepartum haemorrhage Sudden collapse | | | |
| | Therapeutic anticoagulation | History of thrombo-embolism | | | |

Table 1: Antenatal and intrapartum risk factors for PPH⁷

Table 1 sets out the main antenatal and intrapartum risk factors for PPH. In some cases, extra precautions may be necessary for birth such as IV access, coagulation studies, crossmatching of blood and anaesthesia backup. It may also be advisable to obtain early advice from a Tertiary Perinatal Centre.

Caesarean section operations carry a greater risk of significant blood loss compared to vaginal birth. Clinicians must ensure all women undergoing a caesarean section operation have had a recent full blood count performed. This may be within the preceding month (routine screen), as part of a pre-operative assessment or in labour. Clinicians must also ensure that all women with identified additional risk factors undergoing caesarean section operations have a current group and hold (or cross-match where clinically indicated) either as part of a pre-operative assessment (in the case of elective procedures) or in labour (in case of emergency procedures). Such additional risk factors include, but are not limited to: grand multiparity, multiple pregnancy, polyhydraminos, macrosomia, uterine abnormalities (e.g. fibroids), intrauterine infection/ sepsis, uterine relaxing agents given (e.g. terbutaline, other tocolytics, magnesium), planned general anaesthetic, placenta praevia, placenta accreta (known or where risk factors identified), pre-eclampsia (including HELLP Syndrome), placental abruption, fetal death in-utero greater than 4 weeks, amniotic fluid embolism, bleeding disorders, drugs (e.g. aspirin / heparin), and caesarean section performed in labour.

NOTE: Since two thirds of cases of PPH cannot be predicted prophylactic therapy and classification of patients according to antenatal and intrapartum risk factors is not a substitute for prevention and for close observation of every woman for PPH post birth.

2.2 Clinical findings in PPH / recognition of the deteriorating obstetric patient

The physiological changes of pregnancy mean that, in women who are not anaemic and otherwise well, postpartum blood loss is generally well tolerated at volumes up to 1000 mls. It is often not until blood loss exceeds 1500 mls that symptoms and signs of shock are apparent. For this reason, severe PPH is defined as blood loss of 1000mL or more OR any amount of blood loss postpartum that causes haemodynamic compromise. Recognition of the deteriorating obstetric patient is vitally important so that appropriate and timely corrective measures may be implemented. Blood loss \geq 1000 mls must be a trigger to clinical review within 30 minutes and a blood loss > 1500 mls must trigger a rapid response as per the Maternity Observation Chart. In women who are already anaemic or unwell for other reasons lesser volumes of blood loss may cause haemodynamic compromise. Non-physiologic alterations in maternal observations should trigger clinical review or a rapid response as per the Maternity Observation Chart. The most important single warning of diminishing blood volume and mild shock is tachycardia, which often precedes a fall in blood pressure. Weakness, sweating and tachycardia may accompany this. Table 2 outlines the clinical findings in PPH associated with varying degrees of blood loss.

| | Degree of Shock | | | | | |
|---------------------|-----------------|---|--|--|--|--|
| | Compensation | Mild Shock | Moderate Shock | Severe Shock | | |
| Blood Loss | 900 mls | 1200-1500 mls | 1800-2000 mls | 2400 mls | | |
| | 15% | 20-25% | 30-35% | 40% | | |
| BP (systolic) | No change | Minor (postural) fall (80-100 mmHg) | Marked fall (70-80 mmHg) | Profound fall (50-70 mmHg) | | |
| Signs & symptoms | Minimal | Weakness, anxiety, <u>+</u> tachycardia, slow capillary refill, <u>+</u> oliguria | Tachycardia, restlessness, cold/clammy skin, pallor, oliguria | Collapse, depressed mental state, air hunger, anuria, circulatory arrest if untreated | | |

Table 2: Clinical findings in PPH⁸

2.3 Prevention of PPH

Healthy, non-anaemic women can be severely affected by major blood loss and maternal morbidity will be even greater in women with moderate or severe anaemia in pregnancy. Antenatal detection and correction of anaemia is therefore an important preventive process.

Active management of third stage of labour is the most effective means of preventing PPH^{9,10}. Compared to *physiological* (*or expectant*) management, active management has been shown to reduce by more than 50% the risk of PPH, low haemoglobin levels postpartum, and the use of blood transfusion. Active management combines administration of a prophylactic oxytocic drug as the anterior shoulder delivers with early cord clamping, cutting, and controlled cord traction with uterine stabilisation.

Physiological or expectant management employs none of the above interventions. The placenta is delivered by maternal effort aided by gravity or nipple stimulation and the cord is clamped when pulsation ceases. All birth attendants should ensure that women who choose physiological management of the third stage are fully informed of the higher risk of PPH due to uterine atony.

In developed countries, two per cent of postnatal women are admitted to hospital with secondary or delayed PPH, half of them undergoing uterine surgical evacuation¹¹. As subacute PPH is easily underestimated, prevention and management of secondary postpartum haemorrhage should be included in routine discharge advice and factored into early discharge decisions and programs.

2.3.1 Prophylactic oxytocic drugs

The risk of PPH can be reduced by 50% with routine administration of oxytocic drugs as part of active third stage management. Routine prophylaxis can result in a 70% reduction in the need for therapeutic oxytocics to treat excessive postpartum bleeding^{6,10}. These significant benefits of routine oxytocic use must be weighed against its potential

disadvantages and the rare but serious morbidity associated with some oxytocics such as ergometrine¹⁰.

In cases of multiple pregnancy, all fetuses must be delivered prior to administration of oxytocic drugs to avoid intrauterine asphyxia.

Oxytocin (Syntocinon®) is the current drug of choice for prevention of PPH^{12,13}. The main advantages are rapid onset of action and the lack of side effects such as elevated blood pressure or tetanic contractions. Oxytocin does not increase the risk of retained placenta or the duration of the third stage of labour and it can be administered after birth of the anterior shoulder. The usual prophylactic dose is 5 -10 units IM or 5 units IV slowly if intravenous access is already established for other reasons (e.g. epidural block or Group B Strep chemoprophylaxis).

Syntometrine® (ergometrine maleate; oxytocin) is associated with a small but statistically significant reduction in the risk of PPH compared to oxytocin where blood loss is less than 1000ml. However, this advantage needs to be weighed against the adverse effects of nausea, vomiting, abdominal pain, headache, dizziness, rash, hypertension, cardiac arrhythmias and chest pain associated with the use of syntometrine¹³. The usual prophylactic dose is 1mL IM following placental expulsion. Each millilitre of Syntometrine contains ergometrine maleate 0.5mg and oxytocin 5 units.

Misoprostol, a prostaglandin E1 analogue, is not currently recommended for routine prevention and control of PPH. In a WHO multicentre double-blind randomised trial comparing misoprostol and oxytocin for prophylaxis of PPH, more women receiving misoprostol had a measured blood loss of 1000 mL or more and more required additional uterotonics. This study found that 10 unit's oxytocin (intravenous or intramuscular) is more effective in the active management of the third stage of labour in hospital settings where active management is the norm¹⁴. A subsequent meta-analysis of prostaglandins for preventing postpartum haemorrhage found neither intramuscular prostaglandins nor misoprostol are preferable to conventional injectable uterotonics as part of the management of the third stage of labour is prostaglanding.

Ergometrine maleate is not recommended for use as first line preventive therapy due to significant adverse effects.

2.3.2 Other components of third stage active management

Studies have yet to identify which elements of third stage management, other than oxytocics, contribute most to the differences in rates of PPH between active and expectant management. Until further evidence is available, active management of the third stage should therefore also include early cord clamping and controlled umbilical cord traction as described below.

Early cord clamping and cutting

Prompt clamping and cutting of the umbilical cord before beginning controlled cord traction should be continued until there is definitive evidence about the timing of cord clamping on the frequency of PPH.

Controlled umbilical cord traction in the presence of oxytocin

This involves palpation of the uterine fundus to confirm uterine contraction followed by gentle cord traction, balanced by upward pressure just above the symphysis pubis. The placenta will deliver spontaneously or may be found at the cervix with gentle digital examination and can then be lifted from the vagina. If neither occurs readily, IV oxytocin may be given.

Retained placenta

Retained placenta is an important cause of PPH. Retained placenta is defined as a placenta that is not expelled within 30 minutes of the baby's birth. Local policies should include measures for management of retained placenta with and without haemorrhage. These include stimulating uterine contraction and ensuring the bladder is empty. If the placenta is not expelled by maternal effort following these measures and no oxytocics have been administered, give oxytocin 10 units IM. Do not give ergometrine as it causes tonic uterine contraction which may delay placental expulsion. Controlled cord traction can be attempted if the placenta is still undelivered 30 minutes after administration of oxytocin, provided the uterus is contracted. If controlled cord traction is unsuccessful, manual removal of the placenta may be necessary, as the incidence of postpartum haemorrhage and other complications begins to rise progressively once the third stage exceeds 30 minutes^{16,17}. This should be carried out in the operating theatre with intravenous access and adequate anaesthesia. It is also important to ascertain haemoglobin, blood group and antibody screen. Cross match may also be advisable¹⁸.

Fundal massage

Following birth of the placenta continued uterine contraction should be confirmed using fundal palpation. Fundal massage may sometimes be necessary to maintain uterine tone.

Checking the placenta and membranes

Check the placenta and membranes for completeness.

Assess for trauma

The lower genital tract should be carefully examined for lacerations and/or signs of haematoma. Following operative birth, visualise the cervix and upper vagina to exclude laceration/haematoma. Haematoma or uterine rupture (e.g. into the broad ligament) should be suspected where signs and symptoms of excessive blood loss are inconsistent with visible blood loss. Classic symptoms of rupture into the supporting ligaments of the uterus, such as shoulder tip pain, should be specifically assessed.

2.4 Management of established PPH

Early recognition of PPH, followed by systematic evaluation and treatment and prompt fluid resuscitation are essential to minimise morbidity and mortality. Treatment consists of general management of excessive bleeding and maternal resuscitation for prolonged bleeding or massive blood loss. The main causes of morbidity and mortality secondary to PPH are delayed and inappropriate correction of hypovolaemia, delay in recognizing coagulation failure and a delay in controlling traumatic bleeding¹⁹. Underestimation of the total blood lost may also be exacerbated if haemorrhage is concealed in the uterine cavity, the abdominal cavity, or retroperitoneally.

Rapid and appropriate fluid replacement to correct hypovolaemia may be lifesaving and can gain time to control bleeding and obtain blood for transfusion should this become necessary. To restore circulating (intravascular) volume, infuse crystalloids (normal saline or Hartman's solution) in a volume at least three times the measured volume lost²⁰. A Cochrane Review of colloid and crystalloid solutions for fluid resuscitation in critically ill patients found no improvement in survival associated with colloids, including albumin or plasma protein fraction, and given their greater expense questioned their continued use outside the context of randomised controlled trials²¹. Research evaluating the use of colloid and crystalloid solutions for fluid resuscitation is continuing.

Blood is the ideal replacement fluid in PPH as it not only replaces lost volume but also the lost oxygen-carrying capacity. This will generally mean giving blood whenever the measured volume lost is greater than about 2 litres or at a lesser threshold if the bleeding is ongoing or there are signs of shock. Decisions to transfuse should take into account current guidelines for appropriate clinical use of blood and blood components²² as well as the benefits and risks for the individual woman.

Appropriate consultation regarding invasive monitoring should be considered in patients with intractable PPH. It is vital to institute measures to identify the source of bleeding in tandem with fluid resuscitation, to monitor coagulation status regularly and to consider early haematology consultation.

2.4.1 Drug therapy for management of PPH

Postpartum haemorrhage can be treated with Syntocinon®, Syntometrine® and ergometrine maleate as per Table 3. Additional drugs are considered below. If the cause is uterine atony and bleeding continues, the choice of an additional agent and route of administration will be determined by the experience of the clinician and the urgency with which administration is required. For example, the intramuscular route would be preferred in settings where there may be a delay in establishing IV access. In the presence of shock where there might be concern about adequate absorption, the IV route would be preferred to the intramuscular route.

Dinoprost (Prostaglandin F2 alpha®) is used to control severe PPH caused by uterine atony that is not responsive to oxytocin, ergometrine or uterine massage²³. Studies have not yet established which preparation, dose, or route of administration is most effective. It should be noted that *dinoprost* is a restricted substance which requires an authority to prescribe/supply. Currently only the following medical practitioners are authorised: specialists with qualifications FRANZCOG or FRCOG, and GP obstetricians in rural locations where no specialist is present.

Prostaglandin F2 alpha® should be used with caution in women with asthma, hypertension, active cardiac, renal or hepatic disease and hypersensitivity. Side effects include nausea, vomiting, diarrhoea, headache, flushing, pyrexia, uterine rupture and cardiac arrest. The usual dose method of use involves the mixing of 5mg prostaglandin F2 alpha® (1mL of a 5mg/mL solution) with 9mL normal saline. The Medical Officer injects 1 mL (0.5 mg) transabdominally into the myometrium on each side of the fundus i.e. 1mg (2mL of prepared solution) into the uterine fundus. This may be repeated at the doctor's discretion if atonia persists, to a maximum dose of 3mg (6mL of prepared solution). Alternatively, a transcervical injection at 9 and 3 o'clock can be given to help contract the uterine arteries.

NOTE: Ensure an IV line, cardiac monitoring, and oxygen therapy are in place before administration of Prostaglandin F2 alpha®. Resuscitation equipment should be available and an anaesthetist on standby.

Misoprostol is a prostaglandin E1 analogue that has an uterotonic action. This action and the fact that the drug is cheap and stable at room temperature have led to many investigations into its efficacy for both the prevention and treatment of postpartum haemorrhage. Given that postpartum haemorrhage is still a major cause of maternal death in developing nations the World Health Organisation has been particularly interested in its clinical usefulness given its properties. The WHO Statement regarding the use of misoprostol for postpartum haemorrhage prevention and treatment, issued through the Department of Reproductive Health and Research, states that the use of misoprostol in addition to other injectable uterotonics is not recommended since it does not add any additional protection²⁴. Systematic reviews of randomized controlled trials show that misoprostol is less effective than oxytocin and other injectable uterotonics and has side-effects such as high temperature and shivering. The conclusion of the most recent systematic review on treatment for primary postpartum haemorrhage states that there is insufficient evidence to show that the addition of misoprostol is superior to the combination of oxytocin and ergometrine alone for the treatment of primary PPH²⁵.

Gemeprost (Cervagem®) is a prostaglandin E analogue that has an uterotonic action. Unlike misoprostol it is more expensive and unstable at room temperature. Case reports from a decade or more ago suggested it may be efficacious in the management of postpartum haemorrhage, however, there are no randomised controlled trials to demonstrate its safety or effectiveness.

NOTE: The treatment of postpartum haemorrhage is not an approved indication for use for dinoprost, misoprostol or gemeprost. Prior to using any drug for an unapproved (off-label) indication, approval should be sought from the local hospital or Area Drug Committee and informed patient consent obtained. In the context of this Policy Directive, this means that any drug approvals required should be sought prior to an emergency - i.e. at the time of developing local hospital policies for prevention, early recognition and management of PPH.

Large multi-centre, double-blind, randomised controlled trials are required to identify the best drug combinations, route, and dose of uterotonics for the treatment of primary PPH. Further work is required to assess the best way of managing women who fail to respond to uterotonic therapy. The use of Prostaglandin E analogues should be restricted to those situations when there is not ready access to routine oxytocic drugs or Prostaglandin F2 alpha®.

Table 3: Drug therapy for management of PPH

| Drug | Dose and Route | Side effects | Contraindications |
|---|--|---|--|
| Syntocinon® (synthetic oxytocin) | IM Syntocinon 10 Units If Syntocinon has been given and the placenta is out, start two IV infusions (16G cannulae) A) 40 units Syntocinon in 1 litre of Hartmanns' Solution at 250 mls/hr B) IV Hartmanns' Solution or 0.9% Sodium Chloride 1 litre NB. Do not administer Syntocinon IV in a dextrose solution - use an isotonic electrolyte solution. | painful contractions nausea, vomiting (water intoxication) transient vasodilatation & hypotension if undiluted IV doses high doses or prolonged administration in electrolyte-free fluids can cause water intoxication | Hypersensitivity to drug |
| Syntometrine® (ergometrine maleate 0.5mg oxytocin 5IU per mL) | IM Syntometrine 1 mL following expulsion of placenta, or when bleeding occurs Repeat dose of 1 mL after no less than two hours if necessary The total dose given in 24 hours should not exceed 3 mL | nausea, vomiting uterine hypertonicity & abdominal pain headache, dizziness skin rashes hypertension bradycardia cardiac arrhythmia chest pain anaphylactoid reactions | any suspicion of retained placenta exclude twin pregnancy hypersensitivity to ergometrine, other ergot alkaloids or any ingredients in the preparation history of hypertension, eclampsia, pre-eclampsia or current diastolic equal to or greater than 90mmHg severe or persistent sepsis heart disease peripheral vascular disease impaired hepatic or renal function |
| Ergometrine maleate | Ergometrine 250 micrograms IM OR Ergometrine 250 micrograms IV. (This should be injected slowly over one minute or diluted to a volume of 5 mL with sodium chloride 0.9% before administration to prevent serious side effects.) Do not add ergometrine to IV flasks containing other drugs. | nausea, vomiting abdominal pain headache dizziness rash peripheral vasoconstriction hypertension cardiac arrhythmias chest pain anaphylactoid reactions | any suspicion of retained placenta exclude twin pregnancy hypersensitivity to ergometrine, other ergot alkaloids or any ingredients in the preparation history of hypertension, eclampsia, pre- eclampsia or current diastolic equal to or greater than 90mmHg severe or persistent sepsis heart disease peripheral vascular disease impaired hepatic or renal function |
| Prostin F₂α® (Dinoprost trometamol) | Mix 5mg prostaglandin F2 alpha (1mL of a 5mg/mL solution) with 9mL normal saline. The Medical Officer injects 1 mL (0.5 mg) transabdominally into the myometrium on each side of the fundus i.e. 1mg (2mL of prepared solution) into the uterine fundus. This may be repeated at the doctor's discretion if atonia persists, to a maximum dose of 3mg (6mL of prepared solution). Alternatively, a transcervical injection at 9 and 3 o'clock can be given to help contract the uterine arteries. NOTE: Ensure an IV line, cardiac monitoring, and oxygen therapy are in place before administration of Prostaglandin F2 alpha®. Resuscitation equipment should be available and an anaesthetist on standby. | nausea, vomiting, diarrhoea, headache, flushing, pyrexia, cardiac arrest relative risks include pelvic infections and uterine rupture | caution in women with asthma, hypertension, active cardiac, renal, pulmonary or hepatic disease hypersensitivity |

2.4.2 Recombinant Human Factor VIIa (rFVIIa)

Recombinant human factor VIIa (NovoSeven®) is a room temperature stable recombinant coagulation factor VIIa (rFVIIa) that is indicated for use in the treatment of bleeding episodes in haemophilia, the prevention of bleeding in surgical interventions or invasive procedures in haemophilia, the treatment of bleeding episodes in congenital Factor VII deficiency, and the prevention of bleeding in surgical interventions or invasive procedures in congenital FVII deficiency. In clinical practice it has been used 'off label' in many specialities including obstetrics. There are case reports of the successful use of NovoSeven® in severe intractable primary postpartum haemorrhage. However, as noted by the manufacturers in the prescribing information, there are no adequate and wellcontrolled studies in obstetric patients. In reports of women without a prior diagnosis of bleeding disorders receiving rFVIIa for uncontrolled post-partum haemorrhage, thrombotic events have been observed. During the postpartum period, patients are at increased risk for thrombotic complications. A consensus statement from the US Consensus Recommendations for the Off-Label Use of Recombinant Human Factor VIIa (NovoSeven®) Therapy²⁶ recommends that its use in cases of postpartum bleeding be limited to rescue in situations where conventional treatment is unsuccessful. Standard treatment includes standard obstetrical management, oxytocic drugs and standard blood component therapy.

The availability of NovoSeven® must be accompanied by strict control over its access and use through robust protocols for management of severe postpartum haemorrhage where conventional therapy is unsuccessful and by access to a haematologist for approval.

NOTE: Prior to using any drug for an unapproved (off-label) indication, approval should be sought from the local hospital or Area drug committee and informed patient consent obtained. In the context of this Policy Directive, this means that any drug approvals required should be sought prior to an emergency - i.e. at the time of developing local hospital policies for prevention, early recognition and management of PPH.

2.4.3 Other measures

Clinicians need to adopt a stepwise approach to the management of postpartum haemorrhage. If initial treatment and subsequent directed therapy is unsuccessful in controlling postpartum bleeding then subsequent escalation requires a multidisciplinary approach (see table 4). There needs to be individualised management according to the clinical scenario with the application of various manoeuvres, both surgical and non-surgical, where applicable. The major principles include appropriate escalation procedures, the achievement of the local control of bleeding source, and attention to haemodynamic status and coagulation.

NOTE: Prevention and early recognition are important to avoid the subsequent morbidity and mortality associated with postpartum haemorrhage.

Table 4: A stepwise approach to the management of postpartum haemorrhage

| Step 1 - Initial assessment and treatment | | | | | | |
|---|---|---|---|--|--|--|
| Early recognition, prom | Early recognition, prompt resuscitation, identify causes of bleeding, baseline laboratory tests | | | | | |
| Resuscitation CALL FOR HELP two large bore IV (16G) oxygen by mask monitor BP, pulse, respiration, urine output, other symptoms (e.g. pain) +/- urinary catheter +/- oxygen saturation | | Assess aetiology & temporarily arrest blood loss to facilitate resuscitation (see* under TONE – Step 2.) • abdominal assessment of uterus (tone, tissue) • explore lower genital tract (trauma) • review history (thrombin) • observe clots | | Laboratory tests FBC coagulation screen group and screen / cross match | | |
| | | Step 2 - Dire | ected therapy | | | |
| Treat cause, massage / c | ompre repa | ess uterus, oxyto hir trauma, revers | ocics for atony, ev se coagulation def | acua ^f ects | te clots or retained tissue, | |
| TONE | | TISSUE | TRAUMA | | THROMBIN | |
| uterine massage* bi-manual compression* oxytocic drugs Prostaglandin F2α® | • man • cure | ual removal titage | correct inversion repair laceration identify rupture haematoma | | reverse anticoagulationreplace factors | |
| | | Step 3 - Intr | actable PPH | | | |
| Multidisciplinary team, compression / packing / angiographic embolisation / fluid and blood components to maintain haemodynamic and coagulation status Individualised management according to situation, medical experience, and the facilities and personnel available. Ongoing monitoring, replacement of blood and coagulation factors. | | | | | | |
| Get help 2nd obstetrician/gynaecologics surgeon experienced in management of massive, intra PPH anaesthetist haematologist or physician OT, lab and ICU staff | al ctable | bi-manual comp +/- pack uterus / adequate replace volume, blood & to definitive surg +/- embolisation | control ression / vagina to allow æment of . clotting factors prior jery | • | BP and coagulation crystalloid solutions blood products +/- rFVIIa | |
| Step 4 - Surgery | | | | | | |
| An experienced gynaecological surgeon to locate the source and stem bleeding / peripartum hysterectomy | | | | | | |
| Examination under anaesthetic Repair lacerations | | An experienced surgeon will car appropriate proc blood supply to | gynaecological ry out the most edure to reduce the uterus | • | Hysterectomy. This may be the safest option for a less experienced surgeon or when vascular ligation fails | |
| Step 5 - Post hysterectomy bleeding | | | | | | |
| Abdomina | al packin | ng | · · | Angi | iographic embolisation | |
| | | | | | | |

3 Training requirements

Area Health Services and hospitals should comply with the educational program components as outlined in IB2008_002 *Fetal Welfare, Obstetric Emergency, Neonatal Resuscitation Training* (FONT). In particular, maternity emergencies education days must include PPH and maternal collapse/resuscitation in the program content. All clinicians working in maternity units are expected to complete the various components of the FONT program.

Staff in other areas of a hospital may need to respond to a woman with an established PPH. Emergency Departments may be first to respond to a PPH in a woman transported to hospital after a birth in the community (intended or unintended) or a woman who returns to the hospital after discharge from hospital. Theatre Recovery staff (post acute care) are often the first to record observations on women post caesarean section operation. Theatre/Recovery staff are often involved in the management of women with severe PPH. Staff in these areas, and any other areas where postpartum women may be cared for, must receive appropriate education and training regarding PPH, and this training must be attended every three years. Specific education packages for such staff in such areas must be locally developed and implemented.

4 **Reporting requirements**

Severe PPH (>1500 mls) is considered a significant adverse event and its occurrence must be notified in the IIMS system as per PD2009_003 *Maternity Clinical Risk Management Program.* Open disclosure regarding the incident must be undertaken as per PD2007_040 *Open Disclosure.*

5 Related policy documents

This policy directive should be read in conjunction with the following:

- PD2007_040 Open Disclosure
- PD2007_061 Incident Management
- PD2007_077 Medication Handling in NSW Public Hospitals
- IB2008_002 Fetal Welfare, Obstetric Emergency, Neonatal Resuscitation Training (FONT)
- PD2008_037 Medicine Evaluation of medicines for use in public hospitals
- PD2009_003 Maternity Clinical Risk Management Program

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7. Attachment 1: Implementation checklist

| Assessed by: | Date of Asses | Date of Assessment: | | |
|--|------------------|---------------------|-----------------|--|
| IMPLEMENTATION REQUIREMENTS | Not commenced | Partial compliance | Full compliance | |
| | | | | |
| Development of local clinical practice guidelines and protocols for the prevention, early recognition and management of PPH. | <u>Notes:</u> | | | |
| 2.Implementation of local maternity | | | | |
| emergencies education including PPH and maternal collapse / resuscitation, in addition to clinicians' mandatory attendance at FONT training every three years | Notes: | | | |
| 3.Implementation of site specific education | | | | |
| packages for staff in other areas where postpartum women may be cared for (e.g. ED, Theatre, Recovery). Theatre/Recovery staff must attend this education every three years | <u>Notes:</u> | | | |
| | | | | |
| 4. Compliance with PD2009_003 <i>Maternity</i> <i>Clinical Risk Management Program</i> and PD2007_040 <i>Open Disclosure</i> . | Notes: | | | |