

Clinical practice guidelines

Primary postpartum haemorrhage

November 2004

This publication by HAS (French National Authority for Health) contains the clinical practice guidelines produced by the *Collège national des gynécologues et obstetriciens français* in partnership with ANAES (the former French Agency for Accreditation and Evaluation in Healthcare, now part of HAS). These guidelines were validated by the ANAES Scientific Council.



Title	Primary postpartum haemorrhage (PPH)
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Requested by	Collège National des Gynécologues et Obstétriciens Français French National Health Directorate (DGS)
Produced by	Collège National des Gynécologues et Obstétriciens Français ANAES – French National Agency for Accreditation and Evaluation in Healthcare (Guidelines Department)
Assessment method	- Systematic review of the literature (with evidence levels) - Discussion among members of an <i>ad hoc</i> working group - External validation by peer reviewers (see ANAES guide "Recommandations pour la pratique clinique – base méthodologique pour leur réalisation en France – 1999")
Objectives	To issue guidelines that will help reduce maternal deaths in France. PPH was the leading cause of death between 1990 and 2000.
ANAES report manager	Dr. Christine Revel (Department head: Dr. Patrice Dosquet) (Literature search: Gaëlle Fanelli)
Authors of draft report	Working group experts (see Annex 1)
Participants and collaborations (Annex 1)	 - Learned societies - Steering committee (Chair: Dr. G. Lévy, CNGOF) - Working group (Chair: Professor F. Goffinet, CNGOF) - Peer reviewers
Validation by ANAES	ANAES Scientific Council (Referee: N. Nguyen) Validated on November 4, 2004
Related publications on the topic	The full guidelines have been published in French in a special issue of J Gynecol Obstet Biol Reprod 2004;33 (suppl).

I. Introduction

I.1 Background

Postpartum haemorrhage (PPH) was the leading cause of maternal death in France between 1990 and 2000, and the rate of deaths was at least twice as high as in other developed countries.

1.2 Objectives and scope of the guidelines

These clinical guidelines were developed in response to the above situation and deal with the following questions:

- How important a public health problem is PPH?
- What are the risk factors for PPH (antenatal period and labour)?
- What care is recommended for women at risk of PPH (antenatal period and delivery)?
- What care should all pregnant women receive to reduce the risk of onset of PPH or its consequences (antenatal period and delivery)?
- What initial care is recommended in the event of PPH?
- What care is recommended for refractory PPH?
- What invasive methods should be used, and what strategy should be adopted in the event of life-threatening PPH?

These guidelines were produced for standard hospital practice. They do not cover PPH management in conditions that are rare or unusual in France (i.e. home births (rare in France), delivery in a birthing centre (a facility not yet available in France), or delivery in a birthing pool).

II. Assessment method

The guidelines were produced using the method described in Annex 2:

- a critical appraisal of the literature
- discussions within a multidisciplinary working group
- comments by peer reviewers.

They were graded on the basis of the strength of the evidence of the supporting studies (Annex 2). If no grade is given, they are based on agreement among professionals within the working group after taking into account the comments of peer reviewers.

III. Definition of PPH

PPH is defined as blood loss of > 500 ml within 24 hours of delivery. PPH affects about 5% of deliveries and is well tolerated in most cases. However, 500 ml is the blood volume threshold that should trigger active management (agreement among professionals).

IV. Risk factors

The main known risk factors for haemorrhage before or during labour cannot be used to select, with sufficient sensitivity and specificity, those women who need specific preventive measures before the delivery. In most cases of PPH, no risk factors have been clearly

identified. It is therefore not currently possible to recommend a PPH prevention strategy based on identification of risk factors (agreement among professionals).

V. Basic principles that apply to all pregnant women during the antenatal period

- All pregnant women should see an anaesthetist in addition to attending their antenatal checkups. This allows the anaesthetic team to implement the minimum measures needed to manage patients in the event of PPH (agreement among professionals).
- When managing PPH prevention and pregnancy in general, health professionals must inform patients during the pregnancy and at the time of delivery of the benefits and drawbacks of any proposed interventions, so that they can make an informed decision (Clinical Guideline "Information for pregnant women", HAS 2005).
- Blood product supply and distribution in all health care organisations (HCOs) where
 deliveries take place should be arranged so that products can be obtained within 30
 minutes. The procedure to be followed should be established between the maternity
 unit and its transfusion service (agreement among professionals).
- A protocol describing PPH management should be available in each maternity unit. It should be adapted to local conditions of practice, be regularly revised and contain a list of phone numbers for all persons who might be called upon (agreement among professionals).
- The availability of drugs that may be needed in the event of PPH should be checked regularly.
- All maternity units should audit their cases of PPH to check compliance with procedures (agreement among professionals).
- A practitioner with the surgical skills needed to perform haemostasis in the event of severe PPH should be in attendance in all maternity units (agreement among professionals).
- The following documents should be available for all pregnant women admitted to the delivery room (agreement among professionals):
 - results for ABO/RH1(D) blood grouping
 - results for RH and KEL1 phenotype
 - results of an irregular antibody screen performed within the last month.

If these are not available, samples should be drawn and immediately sent to the laboratory. In cases of a very high risk of haemorrhage before the delivery or of elective Caesarean section, results of an irregular antibody screen performed within the last 3 days should be available (agreement among professionals).

- Patients at very high risk of PPH mainly patients with placenta praevia, suspected placenta accreta or severe haemostasis problems can be identified early during the antenatal and anaesthetic consultations, and their management can be planned (agreement among professionals). After diagnosis:
 - the patient should be sent to a centre with appropriate medical and technical facilities (maternal intensive care, blood products available on-site, obstetrician and anaesthetist in attendance 24 hours a day) (agreement among professionals);

- a complete blood count (CBC) should be done to detect anaemia. Iron and folic acid supplementation should be prescribed in cases of anemia. This treatment improves laboratory values (grade A) and could reduce the transfusion requirement in the event of haemorrhage (grade C).
- Elective autologous transfusion is not indicated in women at high risk of PPH. It might be considered in a woman with a rare red cell phenotype or complex alloimmunisation (grade C).

VI. Clinical and pharmacological prevention of PPH during delivery

- Recommended routine measures:
 - Regular monitoring of blood loss, quality of the fundus, heart rate and blood pressure in the delivery room for 2 hours after delivery (agreement among professionals). The data should be recorded in the patient's chart (agreement among professionals).
 - Active management of the third stage of labour, including at the least:
 - as the placenta is separating from the uterus, application of controlled traction on the umbilical cord and counter-traction on the uterus, just above the symphysis pubis,
 - massaging an atonic uterus after the placenta has been expelled (grade A).
 - *Inspection of the placenta for completeness.* Cotyledon or membrane retention is an indication for uterine exploration (agreement among professionals).
 - Slow prophylactic injection (iv or im) of oxytocin (5-10 IU) (grade B) when the anterior shoulder is delivered (active management of the placental stage) or after the placenta has been delivered (grade B).
 - Manual extraction of the placenta if it is not expelled after 30 minutes (grade C).
- Early diagnosis is crucial to the prognosis. The amount of blood loss can be measured by putting a collecting bag underneath the patient as soon as the foetus has been delivered (grade C). However, its efficacy in reducing the risk or severity of PPH has not yet been established.
- Blood losses are greater with Caesarean section than with vaginal delivery. They are particularly difficult to estimate. Active management with appropriate drugs is recommended rather than immediate manual extraction (grade B).
- Misoprostol is not recommended for PPH prophylaxis as it is less effective than oxytocin and has more side-effects (grade A).

VII. Initial management of PPH

- A risk of PPH should be notified immediately to any staff involved (obstetricians, midwives, anaesthetists, nurses). The best management is afforded by a multidisciplinary team working closely together (agreement among professionals).
- Time is important. Staff should record when haemorrhage was first diagnosed, assess
 the amount of blood loss, and start a record of monitoring and management on a
 specific chart (agreement among professionals).

- The cause of bleeding should be investigated without delay (agreement among professionals). The most common causes are uterine atony, retention of the placenta, and cervical or vaginal lacerations.
- Minimum basic care should include:
 - checking that a working venous access is in place;
 - starting monitoring: ECG monitor, non-invasive blood pressure, pulse oximetry;
 - providing volume expansion, initially with crystalloids.
- Anaesthesia appropriate for obstetric procedures should be given as soon as possible under the best safety conditions (agreement among professionals). An irregular antibody screen should be performed if this has not been done within the last 3 days, and the transfusion services should be informed (agreement among professionals).
- If delivery of the placenta has not taken place, manual extraction under anaesthesia should be performed to ensure that the uterus is empty (agreement among professionals). If delivery of the placenta has already taken place, uterine exploration should be performed, even if delivery appears to be complete (agreement among professionals).
- The bladder should be empty and the uterus should be massaged if hypotonic (agreement among professionals).
- Examination of the lower genital tract is recommended if there is any suspicion of cervical or vaginal lacerations, or routinely if general anaesthesia is given for intrauterine procedures (agreement among professionals).
- Uterotonic agents should be given routinely (grade C). Oxytocin is recommended as
 first-line treatment at a dose of 5-10 IU by slow intravenous injection (grade C). This
 should be followed by maintenance therapy by infusion at a rate of 5-10 IU/hour for two
 hours. Prostaglandins are not recommended as first-line treatment for PPH (agreement
 among professionals).
- Any intrauterine procedures should be covered by broad-spectrum antibiotic prophylaxis (grade C).

VIII. Management of worsening PPH

- This section provides guidelines for treating bleeding that persists for more than 15-30 minutes (agreement among professionals). The time before taking further action depends on the amount of bleeding, its haemodynamic impact, and on the measures taken to maintain haemodynamic status (see Fig. 1).
- As for initial care, the best management is by a multidisciplinary team working closely together. Time is yet again crucial to the prognosis (agreement among professionals).
- The obstetrics team should re-investigate any obstetric cause for the bleeding by inspecting the cervix and vagina (if this has not already been done) and by exploring the uterine cavity, if necessary. However, these procedures should not delay the next stage of management.
- Sulprostone should be given by intravenous infusion with a syringe pump within 15-30 min of onset of bleeding (grade C). The intramuscular and intramyometrial routes are contraindicated (grade C). The starting dose should be 100-500 µg/hour. This dose

- should be adjusted to response (persistence of bleeding and uterine tone). The maximum infusion dose is 500 µg/hour (agreement among professionals).
- Intrarectal misoprostol is not recommended in this indication (agreement among professionals).

Management by the anaesthesia and intensive care team

- Initial monitoring (ECG monitor, regular non-invasive BP monitoring, pulse oximetry) should be completed by an indwelling bladder catheter to monitor hourly diuresis (agreement among professionals).
- A second venous access should be inserted and a blood sample drawn for standard tests (CBC and platelets, PT, APTT, fibrinogen). Haemoglobin may be measured on the spot with a portable device (such as the Hemocue[®]). The tests should be repeated as the clinical course changes.
- Basic care may be completed in the event of excessive or prolonged bleeding by:
 - fluid resuscitation and transfusion, ideally performed using a blood warmer with pump (agreement among professionals);
 - inserting a left femoral venous access and an arterial catheter (useful for monitoring haemodynamic values and for repeat blood sampling (agreement among professionals).
- If bleeding is profuse, the transfusion service should be warned immediately to arrange for supplies of blood products to be available (agreement among professionals). If the situation is potentially life-threatening, transfusion should not be delayed to wait for an updated result for an irregular antibody screen (if the previous result is more than 3 days old) (agreement among professionals). Packed red blood cells should be transfused to maintain a haemoglobin level of 7-10 g/dL, for as long as the bleeding persists. If the haemorrhage is accompanied by haemostasis disorders, fresh frozen plasma (15-20 ml/kg) should be given as first-line treatment (agreement among professionals). Transfusion of platelet concentrates is recommended in the event of thrombocytopenia
 - below 50 GL⁻¹ combined with active bleeding during Caesarean section
 - below 30 GL⁻¹ during vaginal delivery (AFSSAPS Guideline, 2003).
- The epidural catheter should be left in position if there are coagulation disorders and should only be withdrawn after laboratory values have returned to normal (grade C).
- In the event of disturbed consciousness and unstable haemodynamic status, orotracheal intubation with mechanical ventilation is required to optimise ventilation and oxygenation and to protect the airways from inhalation of stomach contents (grade C) (see Fig. 2).
- If there is no improvement after 30 min of sulprostone infusion or if the situation worsens, other treatment is required (embolization, surgery) (agreement among professionals) (see next section).

Transfer decision and arrangements

• If the facility is unable to provide appropriate care, the patient should be transferred for the haemostasis procedure (agreement among professionals).

- The decision to transfer the patient and arrangements for ambulance transport are made jointly by the practitioners (requesting department, ambulance service (SAMU-SMUR), receiving unit) (agreement among professionals). Factors to be considered in the choice of receiving unit are its technical facilities, possible admission onsite, and the time factor (agreement among professionals).
- Transportation to another HCO is contraindicated if the patient's haemodynamic status is unstable, in which case surgical haemostasis should be performed on site (agreement among professionals)
- The only treatment that can be given during transport is intensive care; intrauterine procedures cannot be performed (agreement among professionals).
- Monitoring and anaesthesia/intensive care for the patient during embolization should be provided by doctors from the receiving HCO and not by the SMUR team (agreement among professionals).
- As soon as the decision to transfer the patient has been taken, immunology and haematology documents and any necessary information should be sent to the receiving unit so that supply of blood products can be planned. The patient should be transferred with the original documents or copies of them (agreement among professionals).
- For haemorrhage after a delivery outside a maternity unit, and if initial treatment has proven ineffective (ensuring that the bladder is empty, uterine massage, oxytocins followed if necessary by uterine exploration and sulprostone), ambulance transport should be arranged to transfer the patient to an appropriate hospital facility that has been warned of her arrival (agreement among professionals).

IX. Management by invasive methods

Artery embolization

- The decision to perform embolization should be taken jointly by the members of the obstetric, intensive care and intervention radiology teams (agreement among professionals).
- Artery embolization should be performed in an angiography unit equipped with resuscitation equipment and constantly monitored by an anaesthetist and obstetrician (agreement among professionals). The obstetrician should be in attendance in order to perform surgical haemostasis should the procedure fail or in the event of haemorrhagic shock (agreement among professionals).
 - If the patient's haemodynamic status becomes unstable, artery embolization even
 if initially indicated should not be performed, especially if it would take more time
 and/or if the on-site resuscitation resources are not as adequate as immediate
 transfer to the operating theatre (agreement among professionals).
 - On the other hand, if all the necessary conditions are met (stable haemodynamic status, technical facilities nearby, possibility of rapid transfer), artery embolization is recommended for:
 - uterine atony resistant to uterotonic agents, particularly after vaginal delivery;
 - haemorrhage of cervical or uterine origin (placenta praevia);
 - vaginal thrombus;

- cervical or vaginal laceration that has already been sutured or is not accessible (grade C).
- Coagulopathy does not contraindicate artery embolization (agreement among professionals).
- Embolization may also be considered if bleeding persists after arterial ligation (selective or proximal) or hysterectomy (grade C).

Surgery

- When bleeding worsens or fails to respond to medical therapy, the patient should receive general anaesthesia for surgery, even if already under epidural analgesic (agreement among professionals).
- If delivery was by Caesarean section or if embolization is not feasible, the most appropriate first-line surgery is vessel ligation, sometimes combined with uterine packing (grade C). Either ligation of the uterine arteries, possibly with ligation of the round ligaments and the utero-ovarian ligaments, or bilateral ligation of the hypogastric arteries should be performed.
- Uterine artery ligation is easier to perform than the other techniques and has lower morbidity. However, as no data support the superiority of any technique over another, the choice of technique should be based on the surgeon's experience (agreement among professionals).
- A decision to perform hysterectomy for haemostasis is generally taken after failure of embolization or vessel ligation. However, if necessary, it may be performed immediately (agreement among professionals). Ideally, a subtotal hysterectomy should be performed, as it is simpler, faster and as effective as total hysterectomy except for situations such as *placenta praevia accreta*, complex lower segment rupture or severe concomitant cervical laceration (agreement among professionals).
- After embolization or surgery, the patient must be monitored in an appropriate environment such as the resuscitation unit, intensive care or recovery room (agreement among professionals).

Specific case of placenta accreta

Essentially two situations may arise:

- (i) No bleeding: all or part of the placenta may be left in place as this reduces the short-term risk of haemorrhage (grade C). There is currently insufficient evidence to confirm that routine concomitant adjuvant therapy is beneficial (arterial ligation, embolization or methotrexate).
- (ii) Moderate bleeding: arterial ligation may be performed, possibly combined with uterine packing (in the event of Caesarean section) or artery embolization (in the event of vaginal delivery). If this fails or if there is excessive bleeding from the outset, hysterectomy is essential (agreement among professionals).

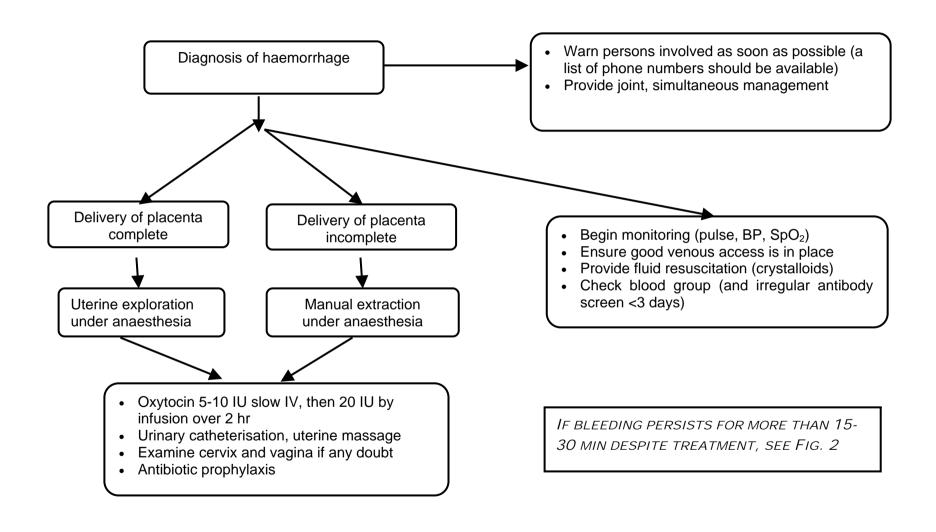


Fig. 1. Initial management of primary postpartum haemorrhage

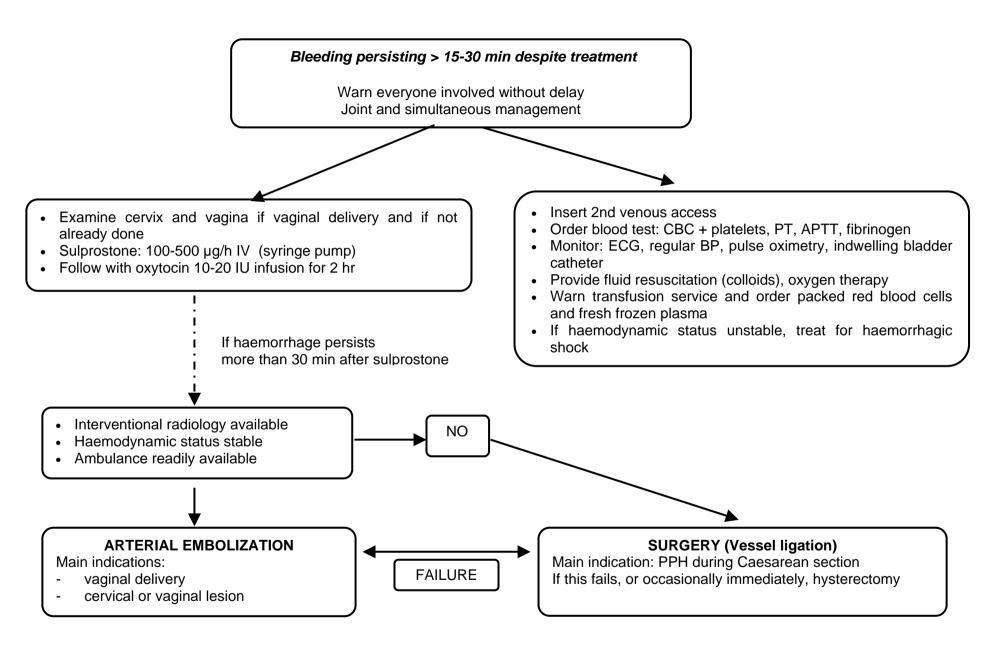


Fig. 2. Management of primary postpartum haemorrhage that persists for more than 15-30 min

Learned societies consulted

Collège National des Sages-Femmes Direction Générale de la Santé Établissement Français du Sang Société Française d'Anesthésie Réanimation Société Française de Médecine Périnatale Société Française de Radiologie

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The method for producing these clinical practice guidelines¹ comprised the following steps:

Defining the scope of the guidelines (Steering Committee): The sponsor (CNGOF) appointed the members of the Steering Committee, and nominated a scientific chair and a coordinator. Professional societies concerned by the topic were contacted to form a working group that would include representatives from these societies and other experts. The Steering Committee drafted specific questions and appointed experts to answer these questions.

Literature search (Documentation Department of ANAES): See below

Drafting the guidelines (Working group). The experts carried out a critical appraisal of the literature and drew up a provisional report which allocated a guideline grading (Table I) for each main recommendation. This report was discussed by the working group and amended in the light of comments from members and peer reviewers (see below).

External validation (Peer reviewers). Peer reviewers were appointed by the Steering Committee. They were either experts in the report topic, practitioners in the private or public sector caring for pregnant women, or user groups. They were consulted by post, primarily with regard to the readability and applicability of the conclusions and guidelines (scores from 1 to 9). Their comments were summarized and submitted to the working group which then drew up definitive conclusions. Peer reviewers were asked to sign the final document.

Validation by the Evaluation Section of the ANAES Scientific Council. A member of the Scientific Council acted as referee and reported to the Council together with the ANAES report manager. The working group finalized the guidelines with due regard to the Council's suggestions.

• Literature search and analysis (general procedure)

The scope of the literature search was defined by the Steering Committee and the project manager. The articles selected were analysed according to the principles of a critical appraisal of the literature, using a checklist, to allocate a level of scientific evidence to each study. Whenever possible, the working group based their guidelines on this review of the literature. Guidelines were graded from A to C as shown in Table 1 depending on the level of the evidence of the supporting studies. If no grading is given, they are based on agreement among professionals.

¹ Full details are given in "Recommandations pour la pratique clinique – base méthodologique pour leur réalisation en France – 1999" (ANAES)

Table 1. Grading of guidelines

Level of published scientific evidence	Grade
Level 1 Randomised controlled trials of high power Meta-analyses of randomised controlled trials Decision analyses based on properly conducted studies	A: Established scientific evidence
Level 2 Randomised controlled trials of low power Properly conducted non-randomised controlled trials Cohort studies	B: Presumption of scientific foundation
Level 3 Case-control studies	C: Low level of evidence
Level 4 Comparative studies with major bias Retrospective studies Case series	