Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with
those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Guidance

1.1 Intraoperative blood cell salvage is an efficacious technique for blood replacement and its use is well established in other areas of medicine, but there are theoretical safety concerns when it is used in obstetric practice. Data collection is therefore important and clinicians should report all complications to the Medicines and Healthcare products Regulatory Agency.

1.2 Whenever possible, patients should be fully informed of the potential complications. In addition, use of the Institute's information for the public is recommended.

1.3 This procedure should only be performed by multidisciplinary teams who develop regular experience of intraoperative blood cell salvage.

2 The procedure

2.1 Indications

2.1.1 Blood replacement may be required in obstetric practice during caesarean section, or after vaginal delivery in patients with conditions such as placenta previa or placenta accreta. The usual method of blood transfusion is standard (allogenic) transfusion from a donor.

2.1.2 Intraoperative cell salvage may reduce the incidence of transfusion reactions and transfusion-related infection, compared with allogenic transfusion, and may also be useful when there are difficulties with cross-matching.
2.1.3 Intraoperative blood cell salvage is commonly used in cardiac, orthopaedic and vascular surgery. It has not been routinely adopted in obstetrics because of specific concerns about amniotic fluid embolism and about haemolytic disease in future pregnancies as a result of re-infusing amniotic fluid or fetal red blood cells.

2.2 Outline of the procedure

2.2.1 Intraoperative blood cell salvage is the process whereby blood shed during an operation is collected, filtered and washed to produce autologous red blood cells for transfusion to the patient.

2.2.2 During intraoperative blood cell salvage in caesarean section, blood that is lost during the operation is aspirated from the surgical field using a catheter. The blood is then suctioned into a reservoir in which a filter removes gross debris. The filtered blood is washed and resuspended in saline for transfusion. It may be retransfused either during or after the operation.

2.2.3 The aspirate may include amniotic fluid and blood cells from the fetus. A leukocyte depletion filter is nearly always used in this process to reduce the amount of amniotic fluid contaminants in transfused blood to levels approaching those found in maternal blood.

2.3 Efficacy

2.3.1 In the blood cell salvage arm of a controlled trial, the median volume of re-infused blood was between 250 and 543 ml per woman (n = 139). There was no significant difference in length of hospital stay, or time on ventilatory support between women who received salvaged blood and women in the control group, who received standard transfusions.

2.3.2 In another comparative study of 68 women who had had a caesarean section, the length of hospital stay was significantly shorter with the blood cell salvage procedure – 5.3 days compared with 7.3 days for women who had had the standard transfusion (p < 0.003). For more details, refer to the Sources of evidence.
2.3.3 The Specialist Advisors noted that the efficacy of the procedure may depend on the rate and volume of the blood loss.

2.4 Safety

2.4.1 In the blood cell salvage arm of a controlled trial, there were no instances of clinically apparent amniotic fluid embolism in 139 women. In the blood cell salvage arm of a comparative study of 68 women who had a caesarean section, there were no reported complications from re-infusing salvaged blood. Unused salvaged blood from 15 women was analysed and found to contain fetal haemoglobin at a concentration of 1.8–2.0% in 20% of cases (3/15). These same women were also found to have fetal haemoglobin in maternal blood samples. No complications were reported using salvaged blood treated with a leukocyte depletion filter in a series of four reported cases. For more details, refer to the Sources of evidence.

2.4.2 In a controlled trial there was no significant difference in disseminated intravascular coagulation or rate of infection between women who received salvaged blood and women in the control group, who received standard transfusions.

2.4.3 The Specialist Advisors noted that the theoretical safety concerns include infusion of fetal cells, which could potentially cause haemolytic disease in future pregnancies. Advisors also noted the potential risk of amniotic fluid embolism.

Andrew Dillon
Chief Executive
November 2005

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is
described in the following document.

'Interventional procedure overview of intraoperative blood cell salvage in obstetric procedures', December 2004.

**Information for the public**

NICE has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind.

### 4 Changes since publication

NICE considered the evidence relating to the efficacy and safety of intraoperative blood cell salvage in obstetrics (IPG144) and for intraoperative red blood cell salvage during radical prostatectomy or radical cystectomy (NICE interventional procedure guidance 258) in response to concerns expressed about theoretical risks associated with the procedure. These concerns were the possibility of amniotic fluid embolism and haemolytic disease in future pregnancies when used in obstetrics, and reinfusion of malignant cells when used in radical prostatectomy/cystectomy.

The evidence relating to safety of cell salvage in these procedures was considered adequate and therefore NICE does not intend to review its use in other specific clinical situations unless notified of new indications for intraoperative cell salvage in which there may be new safety concerns.

22 January 2012: minor maintenance.

### 5 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation.
This guidance was developed using the NICE interventional procedure guidance process. It has been incorporated into the NICE pathway on caesarean section, along with other related guidance and products.

We have produced a summary of this guidance for patients and carers. Information about the evidence it is based on is also available.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.