

How knowledge-sharing can change the standards of fertility care

CREATING THE BEST JOURNEY FOR EVERY CLINIC AND EVERY PATIENT



In the world of fertility, the rapid development of assisted reproductive technologies (ART) has led to pivotal advances in IVF laboratories, improving fertility outcomes and patient safety. It is anticipated that the next leap forward will involve the harnessing of technologies to drive standardization, automation and digitalization of clinics.

As a global leader in delivering innovative solutions in the field of assisted reproductive technology and genomics, CooperSurgical aims to support clinics in embracing and successfully implementing this change process as an essential element of the progression to the fertility care of the future. Through the intelligent and targeted collection of data and utilization of key performance indicators (KPIs) and data metrics, clinics can work towards the standardization of laboratory procedures and provision of individualized treatments based on specific patient needs. As well as helping patients in making better informed decisions, clinics can share their knowledge to drive improvements in fertility care worldwide.

THE POWER OF DATA

Collection of data is not an end in itself, but, in the words of Carla Fiorina (ex-CEO of Hewlett Packard), "the goal is to turn data into information and information into insight." Useful information on the patient journey and on clinic performance is being generated continuously by IVF clinics, but data might be missed or, worse still, collected but not used to drive optimization. Through digitalization, clinics have the opportunity to make the most of this data to produce the metrics needed to improve, optimize and standardize procedures and protocols.

"When we offer support to a clinic, their data not only gives us a clearer understanding of their processes and performance, but also highlights the vital data that might be missing, data that could give insights into how to strengthen the clinical practices," says Inge Errebo, Senior Director of Professional Education and Clinical Support at CooperSurgical. "Data is crucial – if you don't have the data, you don't have any KPIs."

Automation of processes and, importantly, data management is a prerequisite to the collection of complete data sets that then generate metrics or KPIs that facilitate quality improvements. In short, data is turned into insights that might then be shared to the benefit of clinics and patients globally.

DATA COLLECTION DRIVES QUALITY IMPROVEMENTS

For IVF laboratories, data can support standardization, ensuring that all procedures are performed consistently, thereby promoting optimized laboratory performance and positively impacting patient outcomes. Automated data collection makes this process much more manageable, especially in busy centers.

"One of the key benefits of standardization is that it increases consistency of performance and predictability of laboratory outcomes," says Rob Thompson, Director of Digital Innovation at CooperSurgical. "For embryologists carrying out the procedures, this standardization, coupled with adoption of best practices, can give IVF clinics the confidence they are performing optimally and producing the best possible treatment outcomes for their patients."



CooperSurgical developed the RI Witness™ ART Management System, which integrates automated data collection, as a companion to the work done by the embryologists. This type of automation and tracking provides insights to help ensure chain of custody, traceability, efficient workflow management and quality control. RI Witness™ also helps to assess adherence to standard operating procedures and supports standardization.

Automation and data management will have a potentially profound impact on the way laboratories work. "The role of the embryologist is also changing as we move towards more technology and data analysis," says Dr. Marcos Meseguer, Scientific Supervisor and Senior Embryologist at the IVI Valencia, Spain. "I don't think the job of an embryologist is in jeopardy, but the role will continue to shift to include more research and data management."

THE RIGHT KNOWLEDGE GOES A LONG WAY

Though data utilization will help the drive towards standardization and optimization, this is further enhanced when combined with knowledge sharing and high-quality training in technical skills. Through observation and troubleshooting in many different labs, as well as bringing together a wealth of expertise, CooperSurgical seeks to actively support, train and educate professionals in all disciplines to promote the highest standards and best practices.

"We can use education, training and knowledge-sharing to help increase the standards of fertility treatment in the clinic," says Rachel Chin, Clinical Applications Manager at CooperSurgical, "to help strengthen the core practices in each clinic and provide them with a solid foundation for ongoing quality improvement."

THE FUTURE OF FERTILITY CARE IS ALREADY HERE

The fertility industry is changing with advances such as CooperSurgical's RI Witness™ lab management system and the PGTaiSM 2.0 technology platform. For example, PGTaiSM 2.0 harnesses the power of artificial intelligence (AI) and machine learning to improve the interpretation of PGT-A results. Both are examples of the role emerging technologies will continue to play.

Delivering standardization, automation and digitalization to clinics, along with training and knowledge-sharing, are not just for the benefit of one clinic but are part of a larger commitment for the fertility industry to work more closely and more collaboratively. Knowledge shared among lab practitioners, clinicians, nurses and clinic managers has the potential to improve the quality of fertility care for IVF clinics around the world.

Learn how RI Witness™ can help increase overall laboratory efficiency: fertility.coopersurgical.com/equipment/ri-witness/



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Vasa Praevia: Diagnosis and Management

Green-top Guideline No. 27b

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Vasa Praevia: Diagnosis and Management

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This is the fourth edition of this guideline. The first, published in 2001, was entitled *Placenta Praevia: Diagnosis and Management*; the second, published in 2005, was entitled *Placenta Praevia and Placenta Praevia Accreta: Diagnosis and Management*; and the third, published in 2011, was entitled *Placenta Praevia, Placenta Praevia Accreta and Vasa Praevia: Diagnosis and Management*.

The management and diagnosis of placenta praevia and placenta accreta is addressed in Green-top Guideline No. 27a.

Executive summary

Management of women with undiagnosed vasa praevia at delivery

Emergency caesarean delivery and neonatal resuscitation, including the use of blood transfusion if required, are essential in the management of ruptured vasa praevia diagnosed during labour.

B

Placental pathological examination should be performed to confirm the diagnosis of vasa praevia, in particular when stillbirth has occurred or where there has been acute fetal compromise during delivery. [New 2018]

✓

Can vasa praevia be diagnosed antenatally?

The performance of ultrasound in diagnosing vasa praevia at the time of the routine fetal anomaly scan has a high diagnostic accuracy with a low false-positive rate. [New 2018]

B

A combination of both transabdominal and transvaginal colour Doppler imaging (CDI) ultrasonography provides the best diagnostic accuracy for vasa praevia.

D

Should we screen for vasa praevia?

There is insufficient evidence to support universal screening for vasa praevia at the time of the routine midpregnancy fetal anomaly scan in the general population.

D

Although targeted midpregnancy ultrasound screening of pregnancies at higher risk of vasa praevia may reduce perinatal loss, the balance of benefit versus harm remains undetermined and further research in this area is required. [New 2018]

✓

How should women with vasa praevia be managed?

Because of the speed at which fetal exsanguination can occur and the high perinatal mortality rate associated with ruptured vasa praevia, delivery should not be delayed while trying to confirm the diagnosis, particularly if there is evidence that fetal wellbeing is compromised. [New 2018]



In the presence of confirmed vasa praevia in the third trimester, elective caesarean section should ideally be carried out prior to the onset of labour.



A decision for prophylactic hospitalisation from 30–32 weeks of gestation in women with confirmed vasa praevia should be individualised and based on a combination of factors, including multiple pregnancy, antenatal bleeding and threatened premature labour. [New 2018]



In cases of vasa praevia that develop premature rupture of membranes and/or labour at viable gestational ages, a caesarean section should be performed without delay.



To avoid unnecessary anxiety, admissions, prematurity and caesarean section, it is essential to confirm persistence of vasa praevia by ultrasound in the third trimester.



At what gestation should elective delivery occur?

The ultimate management goal of confirmed vasa praevia should be to deliver before rupture of membranes while minimising the impact of iatrogenic prematurity. Based on available data, planned caesarean delivery for a prenatal diagnosis of vasa praevia at 34–36 weeks of gestation is reasonable in asymptomatic women. [New 2018]



Administration of corticosteroids for fetal lung maturity should be recommended from 32 weeks of gestation due to the increased risk of preterm delivery.



1. Purpose and scope

The purpose of this guideline is to describe the diagnostic modalities and review the evidence-based approach to the clinical management of pregnancies complicated by vasa praevia.

2. Introduction and background epidemiology

Vasa praevia occurs when the fetal vessels run through the free placental membranes. Unprotected by placental tissue or Wharton's jelly of the umbilical cord, a vasa praevia is likely to rupture in active labour, or when amniotomy is performed to induce or augment labour, in particular when located near or over the cervix, under the fetal presenting part.^{1,2} Vasa praevia is classified as type I when the vessel is connected to a velamentous umbilical cord, and type II when it connects the placenta with a succenturiate or accessory lobe.

Vasa praevia may be diagnosed during early labour by vaginal examination, detecting the pulsating fetal vessels inside the internal os, or by the presence of dark-red vaginal bleeding and acute fetal compromise after spontaneous or

artificial rupture of the placental membranes. The fetal mortality rate in this situation is at least 60% despite urgent caesarean delivery. However, improved survival rates of over 95% have been reported where the diagnosis has been made antenatally by ultrasound followed by planned caesarean section.³

Vasa praevia is uncommon in the general population with a prevalence ranging between 1 in 1200 and 1 in 5000 pregnancies, although the condition may have been under-reported.^{1–6}

3. Identification and assessment of evidence

This guideline was developed in accordance with standard methodology for producing Royal College of Obstetricians and Gynaecologists (RCOG) Green-top Guidelines. The Cochrane Library (including the Cochrane Database of Systematic Reviews and the Database of Abstracts of Reviews of Effects [DARE]), EMBASE, Trip, MEDLINE and PubMed (electronic databases) were searched for relevant randomised controlled trials (RCT), systematic reviews and meta-analyses. The search was restricted to articles published between May 2009 and July 2016 (the search for the previous guideline was up to May 2009). A top-up literature search was performed in March 2018. The databases were searched using the relevant Medical Subject Headings (MeSH) terms, including all subheadings, and this was combined with a keyword search. Search words included, 'vasa praevia', 'velamentous cord insertion' and 'umbilical cord anomalies'. The search was restricted to humans and the English language. The National Library for Health and the National Guideline Clearinghouse were also searched for relevant guidelines and reviews.

Where possible, recommendations are based on available evidence. In the absence of published evidence, these have been annotated as 'good practice points'. Further information about the assessment of evidence and the grading of recommendations may be found in Appendix I.

4. Management of women with undiagnosed vasa praevia at delivery

Emergency caesarean delivery and neonatal resuscitation, including the use of blood transfusion if required, are essential in the management of ruptured vasa praevia diagnosed during labour.



Placental pathological examination should be performed to confirm the diagnosis of vasa praevia, in particular when stillbirth has occurred or where there has been acute fetal compromise during delivery. [New 2018]



The classic presentation of unexpected vasa praevia in labour is the presence of painless vaginal bleeding (also known as Benckiser's haemorrhage). This occurs mainly when the cervix is effaced and dilated, and the membranes rupture spontaneously or are ruptured artificially.^{2,3} As the total fetal blood volume at term is approximately 80–100 ml/kg, the loss of what may appear as a relatively small amount of blood can have major implications for the fetus and is rapidly fatal.^{3,7–10}

Evidence level 4

A systematic review and meta-analysis of the association among placental implantation abnormalities (including placenta praevia, placenta accreta, vasa praevia, velamentous cord insertion) and preterm delivery in singleton gestations has found a perinatal death rate random effect pooled risk ratio of 4.52 (95% CI 2.77–7.39) for vasa praevia.⁵

Evidence level 2++

5. Can vasa praevia be diagnosed antenatally?

The performance of ultrasound in diagnosing vasa praevia at the time of the routine fetal anomaly scan has a high diagnostic accuracy with a low false-positive rate. [New 2018]

B

A combination of both transabdominal and transvaginal colour Doppler imaging (CDI) ultrasonography provides the best diagnostic accuracy for vasa praevia.

D

The previous version of this guideline concluded that in the absence of vaginal bleeding during the antenatal period, there is no method to diagnose vasa praevia clinically. Vaginal bleeding in pregnancy could be considered as a possible alert symptom for vasa praevia,¹¹ but this is likely to have a very low positive predictive value given the high prevalence of bleeding during pregnancy and low prevalence of vasa praevia.¹² Various tests can differentiate between maternal and fetal blood but are often not timely in a potentially life-threatening clinical situation.

Evidence level 4

The largest study to date on perinatal outcome is based on a cohort of 155 women with vasa praevia that reported a 97% survival rate in cases of prenatal diagnosis compared with only 44% when the diagnosis was made during delivery.¹³

Evidence level 2+

A prospective population-based cohort study using the Australasian Maternity Outcomes Surveillance System (AMOSS) found that there were no perinatal deaths in the 58 cases diagnosed prenatally out of the 63 cases with confirmed vasa praevia at birth.¹⁴

Transvaginal CDI has improved the accuracy of greyscale imaging^{3,15} in diagnosing vasa praevia by demonstrating flow and fetal vascular waveforms on pulsed Doppler through at least one aberrant vessel.^{3,5} Vasa praevia has been defined as a vessel running in the free placental membranes within 2 cm of the cervix.^{16,17} The ultrasound definition of 'within 2 cm from the internal cervical os' was modelled after the existing definitions for low-lying placentas¹⁸ and will vary with gestational age; in particular during the third trimester when the lower segment of the uterus forms. There is limited information regarding the actual safe distance that a vasa praevia needs to be from the internal os to be confident that there is no risk for vessel rupture during labour and delivery. Overall, prenatal diagnosis is most effective around midpregnancy (18–24 weeks of gestation) but needs to be confirmed during the third trimester (30–32 weeks of gestation).^{3,15}

Evidence level 4

A systematic review, including two prospective and six retrospective cohort studies of which six had poor methodology, found prenatal detection rates ranging between 53% (10/19) and 100% for a total of 442 633 women, including 138 cases of vasa praevia.¹⁵ Four out of the eight studies used transvaginal scanning (TVS) for primary assessment, while the remaining four studies used transabdominal ultrasound and only used TVS when vasa praevia was suspected on the transabdominal scan. The results of two prospective studies including a total of 33 795 women reported that TVS CDI performed during the second trimester detects all cases (n = 11) of vasa praevia (sensitivity, 100%) with a specificity of 99.0–99.8%.

Evidence level 2++

A national UK study using the UK obstetric surveillance system of births between December 2014 and December 2015 found that only 25 out of 45 (56%) cases of vasa praevia were diagnosed antenatally.⁶

Evidence level 2+

The Society of Obstetricians and Gynecologists of Canada (SOGC) guideline based on the published literature up to 2009 also indicates that using combined abdominal and transvaginal CDI results in a high diagnostic accuracy with an extremely low false-positive rate.⁷ However, the SOGC guideline¹⁹ update also highlighted that many cases are not diagnosed.

Evidence level 4

6. Should we screen for vasa praevia?

There is insufficient evidence to support universal screening for vasa praevia at the time of the midpregnancy routine fetal anomaly scan in the general population.

D

Although targeted midpregnancy ultrasound assessment of pregnancies at higher risk of vasa praevia has been investigated, the balance of benefit versus harm remains undetermined and further research in this area is required. [New 2018]

✓

The 2017 UK National Screening Committee (UK NSC) external review of the 2013 screening policy concluded that there appears to be little benefit in attempting to identify cases of vasa praevia in the second trimester and that this strategy could be associated with a high false-positive rate.¹² RCTs to investigate whether ultrasound screening for vasa praevia decreases perinatal mortality would be ethically unacceptable in view of the poor neonatal prognosis. The analysis of the literature included in the 2017 UK NSC external review of the 2013 screening policy indicates that up to 80% of vasa praevia cases have one or more identifiable prenatal risk factors.¹² There are no UK data on the epidemiology of velamentous cord insertion and no studies on screening for vasa praevia have reported outcomes (benefits and harms) from identifying velamentous cord insertion in the absence of vasa praevia. Overall, the UK NSC recommendation on screening for vasa praevia is that screening for velamentous cord insertion as a means of identifying vasa praevia should not be implemented. In addition, due to the limited numbers of prospective studies, it is not possible to evaluate the benefits and harms of universal screening over and above a more limited, or targeted, approach to identify vasa praevia in currently identified risk groups, such as women with a low-lying placenta at the midpregnancy routine fetal anatomy ultrasound examination.

Evidence level 4

A 2016 systematic review of the incidence and risk factors of vasa praevia including 13 studies (two prospective cohort studies, 10 retrospective cohort studies and one case-control study) and reporting on 569 410 women found that 83% of the 325 cases reviewed had one or more risk factor, including placenta praevia, bilobed placenta, succenturiate placental lobes, conception by assisted reproductive technology and velamentous cord insertion.²⁰

Evidence level 2++

The 2017 prospective population-based cohort study using the AMOSS found that 55 of the 58 women diagnosed prenatally had at least one risk factor for vasa praevia, with velamentous cord insertion (62%) and low-lying placenta (60%) the most prevalent.¹⁴ These data have also been confirmed by recent retrospective cohort studies.^{17,21,22}

Evidence level 2+

Vasa praevia diagnosed in the second trimester resolves in around 20% of cases before delivery.^{16,23} A follow-up ultrasound examination at 32 weeks of gestation is suggested, particularly in women with a low-lying placenta as, even if it has resolved, it is still associated with a high risk of vasa praevia.⁸ The American Institute of Ultrasound in Medicine has recommended that the placental cord insertion site be documented when technically possible.²⁴ Identification of the placental cord insertion at the routine fetal anomaly scan is easy and accurate,^{3,8} does not add significantly to scan time and requires little additional scanning skills for a trained operator.

A questionnaire survey of obstetricians and gynaecologists in England and Wales with a 55% response rate found that most (80%) respondents felt that a selective screening policy for vasa praevia was not feasible, one-third could not name one risk factor associated with vasa praevia and over one-half had no experience in diagnosing nor managing the condition.²⁵ This survey highlights the need to increase awareness of vasa praevia in healthcare professionals, and also the need to ensure skill validation and quality control across the board.

A decision-analytic model to estimate the lifetime incremental costs and benefits of screening for vasa praevia in all twin pregnancies was found to be cost effective in a study of approximately 132 000 pregnancies.²⁶ Using these data and based on an 80% detection rate, the 2014 UK NSC external review found that the targeted screening of all twins and singleton pregnancies with at least one high-risk factor could reduce the perinatal loss rate by as many as 150 cases per year.¹²

Evidence level 4

7. How should women with vasa praevia be managed?

Because of the speed at which fetal exsanguination can occur and the high perinatal mortality rate associated with ruptured vasa praevia, delivery should not be delayed while trying to confirm the diagnosis, particularly if there is evidence that fetal wellbeing is compromised. [New 2018]



In the presence of confirmed vasa praevia in the third trimester, elective caesarean section should ideally be carried out prior to the onset of labour.



A decision for prophylactic hospitalisation from 30–32 weeks of gestation in women with confirmed vasa praevia should be individualised and based on a combination of factors, including multiple pregnancy, antenatal bleeding and threatened premature labour. [New 2018]



In cases of vasa praevia that develop premature rupture of membranes and/or labour at viable gestational ages, a caesarean section should be performed without delay.



To avoid unnecessary anxiety, admissions, prematurity and caesarean section, it is essential to confirm persistence of vasa praevia by ultrasound in the third trimester.



Delivery by caesarean section of women with confirmed vasa praevia is intuitive and logical, and not based on RCTs.¹²

The objective of the management of vasa praevia diagnosed during the second trimester of pregnancy is to prolong pregnancy safely while avoiding potential complications related to rupture of membranes before or during labour. Two other national societies have existing clinical guidelines on the management of vasa praevia diagnosed during pregnancy,^{7,8,19} but the corresponding recommendations are also based on observational data, decision analyses and expert opinion.

Antenatal hospitalisation in a unit with appropriate neonatal facilities has been proposed from 30–32 weeks of gestation, but the evidence is weak and of low quality.⁸ The purpose of hospitalisation is to allow for closer surveillance for signs of labour and a timelier performance of caesarean delivery before labour and/or before membrane rupture. The 2017 prospective population-based cohort study using the AMOSS found no difference in perinatal outcome when vasa praevia was diagnosed prenatally between women who were hospitalised compared to those with no antenatal hospitalisation.¹⁴ Overall, outpatient care has been associated with excellent outcomes,³ and thus, the benefit of hospitalisation in asymptomatic women remains unproven.

Evidence level 4

Data on the use of TVS cervical length measurements in the management of vasa praevia are limited and the role of cervical cerclage is unknown.¹² Some authors have suggested that outpatient management is possible if there is no evidence of cervical shortening on TVS and there are no symptoms of bleeding or preterm uterine activity.²⁷ Data from the follow-up of women with placenta praevia indicate that the probability of bleeding is higher if the cervix is shorter in length than expected for gestational age.^{28–32}

A 2018 retrospective case–control study of 29 singleton pregnancies with a prenatal diagnosis of vasa praevia in the second trimester found that the rate of cervical length shortening was significantly slower for women with elective compared with emergency caesarean delivery.³³ For each additional millimetre-per-week decrease in cervical length, the odds of emergency caesarean delivery increased by 6.50 (95% CI 1.02–41.20). Similarly, data from a 2017 systematic review on the management of vasa praevia in twins have indicated that TVS cervical length measurements from 26–28 weeks of gestation may be useful to evaluate the individual risk of preterm birth.³⁴

Evidence level 2+

Based on these observations, as well as a lower probability of labour, asymptomatic women with stable cervical length measurements should be the best candidates for outpatient management.

Evidence level 4

8. At what gestation should elective delivery occur?

The ultimate management goal of confirmed vasa praevia should be to deliver before rupture of membranes while minimising the impact of iatrogenic prematurity. Based on available data, planned caesarean delivery for a prenatal diagnosis of vasa praevia at 34–36 weeks of gestation is reasonable in asymptomatic women. [New 2018]

D

Administration of corticosteroids for fetal lung maturity should be recommended from 32 weeks of gestation due to the increased risk of preterm delivery.



Optimal timing of caesarean delivery remains unknown. There is no consensus about the timing of delivery in cases of confirmed vasa praevia and the currently low prevalence of prenatal diagnosis of this condition in the general population precludes any prospective trials to evaluate the ideal timing.^{3,12}

Overall, vasa praevia is associated with an increased risk of preterm birth. The associated complications of prematurity are in many cases the result of iatrogenic preterm birth in an effort to prevent stillbirth. Gestational age at delivery is the only other variable associated with perinatal outcomes in the management of vasa praevia. As for other obstetric situations associated with a higher risk for late preterm delivery, the administration of corticosteroids is recommended.^{7,8,19}

Evidence level 4

In the largest cohort study published so far, fetuses that were diagnosed prenatally had a 97% survival rate for a mean gestational age at delivery of 34.9 (± 2.5) weeks of gestation.¹³

Evidence level 2+

Data from a decision analysis study comparing 11 strategies for delivery timing in a woman with vasa praevia found that delivery between 34 and 36 weeks of gestation balances the risk of premature rupture of membranes, and subsequent fetal haemorrhage and death versus the risks of prematurity.³⁵ The authors found no benefit to expectant management beyond 37 weeks of gestation and that at any given gestational age, incorporating amniocentesis for verification of fetal lung maturity does not improve outcomes.

Evidence level 4

9. Clinical governance

9.1 *Debriefing*

Postnatal follow-up should include debriefing with an explanation of what happened, why it happened and any implications for future pregnancy.

9.2 *Training*

Raising awareness about the clinical risk factors of vasa praevia should be pursued locally, including organising policies or guidelines for flagging up women at risk and arranging for them to see a specialist consultant when suspected.

There should be appropriate training for ultrasound staff in the antenatal diagnosis of vasa praevia.

9.3 *Clinical incident reporting*

There should be written protocols for the identification of and planning further care of women diagnosed with vasa praevia.

10. Recommendations for future research

- National and regional epidemiological data are needed to define a relevant high-risk population and the cost-effectiveness of screening for vasa praevia on service provision.
- Prospective screening studies are needed to evaluate the outcome of velamentous cord insertion in the absence of vasa praevia.
- Prospective multicentre studies on the use of cervical length ultrasound examination are required to evaluate the role of this measurement in the management of vasa praevia.
- Prospective quality data are needed to compare hospitalisation at 30–32 weeks of gestation with outpatient follow-up in the management of vasa praevia.
- RCTs of optimal timing of delivery for vasa praevia are needed.

11. Auditable topics

- Appropriate delivery plan in place if an antenatal diagnosis of vasa praevia is made (100%).

12. Useful links and support groups

- Vasa praevia raising awareness [www.vasapraevia.co.uk/the-experts/].
- The International Vasa Previa Foundation [www.vasaprevia.org].
- Royal College of Obstetricians and Gynaecologists. *Low-lying placenta after 20 weeks (placenta praevia). Information for you*. London: RCOG; 2018 [<https://www.rcog.org.uk/en/patients/patient-leaflets/a-low-lying-placenta-after-20-weeks-placenta-praevia/>].
- UK National Screening Committee. The UK NSC recommendation on Vasa praevia screening in pregnancy. London: UK NSC; 2017 Screening for vasa praevia [legacyscreening.phe.org.uk/vasapraevia/].

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Appendix I: Explanation of guidelines and evidence levels

Clinical guidelines are: ‘systematically developed statements which assist clinicians and patients in making decisions about appropriate treatment for specific conditions’. Each guideline is systematically developed using a standardised methodology. Exact details of this process can be found in Clinical Governance Advice No.1 *Development of RCOG Green-top Guidelines* (available on the RCOG website at <http://www.rcog.org.uk/green-top-development>). These recommendations are not intended to dictate an exclusive course of management or treatment. They must be evaluated with reference to individual patient needs, resources and limitations unique to the institution and variations in local populations. It is hoped that this process of local ownership will help to incorporate these guidelines into routine practice. Attention is drawn to areas of clinical uncertainty where further research may be indicated. The evidence used in this guideline was graded using the scheme below and the recommendations formulated in a similar fashion with a standardised grading scheme.

Classification of evidence levels	Grades of recommendation
<p>I++ High-quality meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a very low risk of bias</p>	<p>A At least one meta-analysis, systematic review or RCT rated as I++, and directly applicable to the target population; or A systematic review of RCTs or a body of evidence consisting principally of studies rated as I+, directly applicable to the target population and demonstrating overall consistency of results</p>
<p>I+ Well-conducted meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a low risk of bias</p>	
<p>I– Meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a high risk of bias</p>	<p>B A body of evidence including studies rated as 2++ directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as I++ or I+</p>
<p>2++ High-quality systematic reviews of case–control or cohort studies or high-quality case–control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal</p>	
<p>2+ Well-conducted case–control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal</p>	<p>C A body of evidence including studies rated as 2+ directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++</p>
<p>2– Case–control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal</p>	
<p>3 Non-analytical studies, e.g. case reports, case series</p>	<p>D Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+</p>
<p>4 Expert opinion</p>	
	<p>Good practice points</p> <p><input checked="" type="checkbox"/> Recommended best practice based on the clinical experience of the guideline development group</p>

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[Correction added on 14 March 2019, after first online publication: SG Vitale has been added to peer reviewers.]

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All RCOG guidance developers are asked to declare any conflicts of interest. A statement summarising any conflicts of interest for this guideline is available from: <https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg27b/>.

The final version is the responsibility of the Guidelines Committee of the RCOG.

The guideline will be considered for update 3 years after publication, with an intermediate assessment of the need to update 2 years after publication.

DISCLAIMER

The Royal College of Obstetricians and Gynaecologists produces guidelines as an educational aid to good clinical practice. They present recognised methods and techniques of clinical practice, based on published evidence, for consideration by obstetricians and gynaecologists and other relevant health professionals. The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the doctor or other attendant in the light of clinical data presented by the patient and the diagnostic and treatment options available.

This means that RCOG Guidelines are unlike protocols or guidelines issued by employers, as they are not intended to be prescriptive directions defining a single course of management. Departure from the local prescriptive protocols or guidelines should be fully documented in the patient's case notes at the time the relevant decision is taken.