UK National Screening Committee

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Screening for Screening for vasa praevia in the second trimester of pregnancy

23rd June 2017

Aim

1. To ask the UK National Screening Committee (UK NSC) to make a recommendation, based upon the evidence presented in this document, whether or not screening for vasa praevia (VP) in the second trimester of pregnancy meets the UK NSC criteria to support the introduction of a population screening programme.

   This document provides background on screening for VP.

Current recommendation

2. The 2013 review of screening for VP concluded that universal routine antenatal screening for VP did not meet the UK NSC criteria. Therefore, the Committee did not recommend the introduction of a national screening programme for VP at 18+0 to 20+6 weeks gestation.

   Although the literature included in the 2013 review suggests that VP could be detected by ultrasound, there was insufficient information on the case definition, natural history and epidemiology of the condition to meet the UK NSC criteria. There was also uncertainty on the accuracy and practical application of the test and there was no agreed management pathway for those with confirmed VP and for those with some risk factors in the absence of VP. In this context there was uncertainty about the balance of benefit and harm to be derived from screening all pregnant women with a view to offering caesarean section (CS) to those at risk.

3. A workshop was held in October 2013 to discuss the issues relating to the review. The main outcome was that the RCOG committed to developing guidance in high risk groups. The note of the meeting is attached for information. (**Annex D**)

Review

4. This review was undertaken by Costello Medical Consulting Ltd in accordance with the triennial review process. https://legacyscreening.phe.org.uk/vasapraevia. Expert input was provided by Mr George Attilakos and Professor Basky Thilaganathan.

5. This review focuses on questions relating to uncertainties on the epidemiology and broad risk associations, the test accuracy, and management pathway for VP arising from the previous review. It also focuses on questions relating to velamentous cord insertion (VCI)*. This is because, as discussed at the 2013 workshop, ultrasound detection of VCI at mid-term is included in proposed screening algorithms for VP.

6. The conclusion of this review is to reaffirm the UK NSC recommendation not to screen for VP in the second trimester of pregnancy in the UK. This is because:

   a. there is not enough information about the incidence of VP or VCI in the UK; **Criterion 1 not met**

   b. VP and VCI can be found by ultrasound testing, but there remains insufficient knowledge about the accuracy of the test; **Criterion 4 not met**

   c. CS would normally be recommended for cases of VP identified prenatally. However, there is no high-quality evidence on the optimum management pathway for cases of VP identified prenatally, such as inpatient vs outpatient treatment, or the timing of hospital admission or planned delivery; **Criterion 9 not met**

   d. there are no established management pathways for VCI; **Criterion 10 not met**

7. Consultation

8. A three month consultation was hosted on the UK NSC website. Direct emails were sent to stakeholders of whom 7 organisations were contacted directly. **Annex A**

9. Ten sets of comments to the public consultation were received.

   One set of comments from each of the following stakeholders:

   - The Royal College of Obstetricians and Gynaecologists;
   - The Chelsea and Westminster Hospital NHS Foundation Trust (West Middlesex University Hospital site);
   - Society and College of Radiographers (SCoR);
   - West Middlesex University Hospital;

- a United States based clinician — Kolawole Olayinka (Yinka) Oyelese (MD);
- VASA PRAEVIA raising awareness; and
- two individual members of the public.

Two sets of comments were received from Vasa Praevia Ireland

All comments can be found in **Annex B** below. The responses indicated that the majority of the stakeholders disagree with the suggestion that screening for VP in the second trimester of pregnancy in the UK should not be recommended.

The following themes were reflected across stakeholders' comments.

a. The majority of the stakeholders have noted the importance of the development of a national guideline for those women who are within higher risk groups (e.g. IVF pregnancies). In the absence of screening, this approach would be a significant development.

b. Some stakeholders questioned the reasons for giving separate consideration to VCI compared to other risk factors for VP.

c. Some stakeholders raised the issue of the reported prevalence of VP in the evidence examined. There is a general concern among stakeholders that VP is under-reported because of the lack of awareness of the condition and inaccuracy of how VP cases might be recorded. They suggested that screening for the condition would help to understand the true prevalence of the condition. A number of stakeholders suggested waiting for the completed UK Obstetric Surveillance System (UKOSS) study to report before making a recommendation on screening.

d. Some stakeholders also suggested that the rapid review approach might not be appropriate *'Given the severe outcomes for babies with vasa praevia, should not all data be fully examined, and a full review for vasa praevia be carried out?'*

e. One stakeholder raised concerns about the methodology used by the review and biases in the interpretation of the evidence including the process used to commission the evidence summary.

Recommendation

The Committee is asked to approve the following recommendation:

A systematic population screening programme for vasa praevia in the second trimester of pregnancy is not recommended.

Based on the 20 UK NSC criteria set to recommend a population screening programme, evidence was appraised against the following two criteria:

Criteria		
The Condition		**Met / Not met**
1	The condition should be an important health problem as judged by its frequency and/or severity. The epidemiology, incidence, prevalence and natural history of the condition should be understood, including development from latent to declared disease and/or there should be robust evidence about the association between the risk or disease marker and serious or treatable disease.	Not met ✗
The Test		
4	There should be a simple, safe, precise and validated screening test.	Not met ✗
The Intervention		
9	There should be an effective intervention for patients identified through screening, with evidence that intervention at a pre-symptomatic phase leads to better outcomes for the screened individual compared with usual care. Evidence relating to wider benefits of screening, for example those relating to family members, should be taken into account where available. However, where there is no prospect of benefit for the individual screened then the screening programme should not be further considered.	Not met ✗
10	There should be agreed evidence-based policies covering which individuals should be offered interventions and the appropriate intervention to be offered.	Not met ✗

Annex A

List of individuals/ organisations contacted:

1. Association for Improvements in the Maternity Services
2. British Association of Perinatal Medicine
3. The Harry Cunningham Trust
4. National Childbirth Trust
5. Royal College of Midwives
6. Royal College of Obstetricians and Gynaecologists
7. The Royal Society for Public Health
8. Society and College of Radiographers
9. Vasa Praevia Raising Awareness
10. MBRRACE-UK
11. Alexandra Drought
12. xxxx xxxx
13. Dr Christos Ioannou
14. Elizabeth Daly-Jones
15. xxxx xxxx

UK National Screening Committee

Annex B

The Guidelines Committee and BMFMS have reviewed this document on behalf of the RCOG

Name of Reviewer	Section	Line numbers	Comments
RCOG	General		It is not a 20-week scan. I think the correct term should be "the fetal anomaly scan performed between 18+0 and 20+6 weeks" should be used
RCOG	*General*	*General*	*It should be noted that our guidance is currently being updated and we need to ensure that our recommendations (NSC and RCOG) are consistent.*
RCOG	Plain English Summary	Page 1 3rd para	Description of transvaginal ultrasound as "*an intrusive procedure*" could consideration be given to amending to "*an intrusive but usually painless procedure*" I do not think it should be called intrusive and the word should be removed. I think women should make their own mind up how "intrusive" a procedure is rather than have the description thrown at them. To most women it will not be.
RCOG	Plain English Summary	Page 2 5th bullet point	"*this review did not find any evidence on how many pregnancies are affected by vasa praevia*…" Could it be explained that this is because since the previous review no studies have been reported showing how many cases have occurred in the UK? Question: are there recommendations as to how patient data collection might be improved?

RCOG	Plain English Summary	Page 2 7th bullet point	"*This review did not find any evidence about the best way of treating women with vasa praevia or velamentous cord insertion throughout pregnancy*" This is not a very encouraging comment. Could it be changed to "*This review did not find any <u>new</u> evidence about the best way of treating women with vasa praevia or velamentous cord insertion throughout pregnancy*"

Name:	Alexandra Drought	**Email address:**	xxxx xxxx
Organisation (if appropriate):	xxxx xxxx xxxx xxxx		
Role:	Superintendent Ultrasonographer (SCoR Accredited Consultant Ultrasonographer)		

Do you consent to your name being published on the UK NSC website alongside your response?

YES ☐

Section and / or page number	Text or issue to which comments relate	Comment *Please use a new row for each comment and add extra rows as required.*
Page 4 Recommendations on screening	This review has not found sufficient evidence to support a change in the overall recommendation for VP screening.	It has been 3 years since the vasa praevia UK NSC workshop in 2013, when the RCOG said it would explore the possibility of developing a national statement on the detection and management of vasa praevia in high risk groups. I can see no evidence of this in this latest review of the evidence?
Page 13: Overall incidence	The SLR also identified a large difference in reporting VP incidence between prospective and retrospective studies; the authors suggest that this might be because prospective studies focus more on detecting VP, and retrospective studies may have incomplete data.	There remains an under-reporting of vasa praevia due to the continued general lack of awareness of a large number of medical professionals at all levels. Also, until it is introduced as routine screening (like placenta position is), it will remain under-reported. Furthermore, it is evident that the condition is often inaccurately recorded due to the use of generic terms such as APH or placental abruption on death certificates.

Page 13; Incidence associated with risk factors	63% of VP cases had IVF as a risk factor	The incidence of VP is alarmingly high with IVF (1:202) and this figure will increase as the annual number of IVF pregnancies increases. It is so important that medical professionals delivering IVF services (including maternity and ultrasound services) are made aware of this significant risk. All parents with pregnancies conceived by IVF, should be provided with information allowing them to make informed choices on screening for VP.
Page 16: 2.2.1.1.2. Evidence summary	A study by the UK Obstetric Surveillance System has been completed (12/14-11/15) but has not yet been published.	We still have not received the results of the UKOSS study carried out in 2014/2015. It would be a mistake to say there is insufficient evidence and for the UK NSC to make a decision about screening, without seeing the UKOSS results first.
Page 17: 2.2.1.2.1 Description of the evidence	It is not clear whether these were VP cases that resolved, or false positive results from screening.	We know that 15% of VP cases will resolve by the third trimester, just as we know 90% of low-lying placentas will resolve by 36 weeks. So, cases of low-lying placentas or VP which resolve are not false-positives. **xxxx xxxx** , we do not diagnose vasa praevia until 28 weeks, after which time it is very unlikely they will resolve. We have not had xxxx xxxx false-positive xxxx xxxx in xxxx xxxx using our 28 week rule (and we confirm our VP cases by histology.)
Page 20: 2.2.1.3.2	A particular concern is perinatal mortality, which may occur in over half of VP cases.	We screen for VP in xxxx xxxx as the sonographers find it such a positive aspect of the anomaly scan. Screening for VP presents an opportunity to save a life and to afford parents with sensitive counselling. The RCOG "Saving Babies Lives" and the NHS NSC 'Care Bundles' are trying to reduce the stillbirth rate by 30% by 2020. Screening for VP can help achieve these targets, as currently VP accounts for approximately 150 deaths per annum. xxxx xxxx alone has successfully saved the lives of at least 20 babies since 2012 through the antenatal detection of VP (confirmed at histology)
Page 25: Analysis of evidence relevant to criterion 4	There is no gold standard method for confirming VP antenatally.	With the right training, sonographers are able to identify this condition with 100% sensitivity and specificity, so antenatal ultrasound is the gold-standard test. We have not had any false-positives or false-negatives (confirmed by histology.)

Page 26: 2.2.3.1.	These studies suggest that a prenatal VP diagnosis is associated with better perinatal outcomes that VP diagnoses at birth.	This completely mirrors our experience at the xxxx xxxx We have saved at least 20 babies' lives since we started screening for VP in 2012.
Page 42: 3.1 Review Summary	There is not enough information about the incidence of VP in the UK VP can be found by ultrasound testing, but there is insufficient knowledge about the accuracy of the test.	Until we start screening for the condition, there won't be enough evidence about the incidence. Why don't the NSC and the RCOG go into departments who are routinely screening for VP to see what our figures/evidence shows? (xxxx xxxx.) As VP is a rare condition, it takes time to collect enough figures to then publish a meaningful report with statistical significance.
Page 42: 3.1	There is no high-quality evidence on the optimum management pathway for cases of VP identified prenatally.	Management pathways and surgeries have improved for fetal heart conditions since the introduction of antenatal screening and continue to improve as antenatal detection rates increase. The same would happen if routine screening for VP was introduced and xxxx xxxx already has sound management pathways with our VP patients.

General comments:		Sonographers are being taught how to recognise VP during the routine anomaly scan both clinically and academically within the universities. Screening is coming by stealth, but this is resulting in a two tier service for patients, depending on which Trust or sonographer they access. The RCOG needs to seek the evidence happening on the shop-floor in Trusts right now, rather than just relying on the few published articles in peer-reviewed journals. I believe every pregnant woman should be screened, as this will eliminate a two-tier system and ensure the sonographers have increased familiarity with the condition and can recognise the abnormal from the normal more readily. For every baby that dies from VP, it is a tragedy for the parents and the individual baby, but one that is so easily avoidable.

Name:	Nigel Thomson	**Email address:**	xxxx xxxx
Organisation (if appropriate):	Society and College of Radiographers (SCoR)		
Role:	Professional Officer (Ultrasound)		

Do you consent to your name being published on the UK NSC website alongside your response?

Yes YES☐

Section and / or page number	**Text or issue to which comments relate**	**Comment** *Please use a new row for each comment and add extra rows as required.*
General		The SCoR has many sonographer members who are actively involved with and support the work of the 'Vasa Praevia, Raising Awareness' charity which has previously provided detailed evidence to the NSC. Their evidence supported universal screening. Previous NSC reviews in 2009 and 2013 have not, however, supported universal screening and that is also the conclusion of this 2017 NSC evidence review. Following the previous NSC review in 2013 it was understood by this organisation that although there was not the evidence required to progress universal screening the case for selective screening of those women who are within higher risk groups (e.g. IVF pregnancies) would be investigated and that appropriate advice would be agreed. The SCoR attended a xxxx xxxx xxxx xxxx series of meetings in 2013/2014 along with the RCOG and other interested parties. **No recommendations that we are aware of have since been published. What plans are there for this?**

		SCoR sonographer members have also submitted data to the UKOSS vasa praevia study whose results are awaited. (Surveillance period between 1/12/14 and 30/11/15). This study has not yet reported its results and these may have an affect on any recommendations. There is currently variation between Trusts in implementing the recommendations of the current RCOG Greentop Guideline No: 27 (2011) which pre-dates even the 2013 NSC review. https://www.rcog.org.uk/globalassets/documents/guidelines/gtg_27.pdf The overall position can be confusing for practitioners and students in deciding what they should do and what represents best practice. Vasa praevia is not included as one of the 11 auditable conditions for the FASP18 w to 20w 6d fetal anomaly screening scan but the placenta is evaluated as part of local policy and protocols. At the very least these local policies are likely to include transabdominal assessment of the location of the placenta. Possible instances of vasa praevia will be identified on which the sonographer involved is then obliged to report, often without clear protocols for referral in place. It also means that women will have different levels of examination depending on where they are seen. https://www.gov.uk/government/publications/fetal-anomaly-screening-programme-handbook Appendix 1.
Page 20 2.2 1.3.2	Perinatal mortality	Screening for VP provides an opportunity to save a life as part of NHS England's 'Saving Babies Lives' initiative. https://www.england.nhs.uk/wp-content/uploads/2016/03/saving-babies-lives-car-bundl.pdf
Page 42 3.1	Summary	There are Trusts that are actively screening for VP. Has their experience and data been considered?
Page 13	Overall incidence	VP is likely to be under-reported due to the use of generic terms such as 'APH' and 'placental abruption'. There is also a general lack of awareness of the condition that is evident across all groups of professionals involved with the care of pregnant women.

Name:	Elizabeth Daly-Jones	**Email address:**	xxxx xxxx
Organisation (if appropriate):	xxxx xxxx		
Role:	**Advanced Practitioner in Ultrasound.**		

Do you consent to your name being published on the UK NSC website alongside your response?

Yes ☐ Yes **No** ☐

Section and / or page number	**Text or issue to which comments relate**	**Comment** *Please use a new row for each comment and add extra rows as required.*
Page 20	. VP incidence is likely to be an underestimate	In our own institution we have shown an increased incidence of cases of VP because of a targeted approach to detection of this condition. Unless sonographers are actively looking for this condition (which is within their skill sets) then there will always be an underestimate of the incidence.
Review summary. 3.1. Page 43	There is not enough information about the incidence of VP in the UK	There is still inaccurate coding of these cases and this would contribute to the lack of information available.
Review summary. 3.1. Page 43	It has been suggested that ultrasound detection of VCI should be included in VP screening algorithms. However, this review found that: • Most cases of VCI will not have VP. The reported incidence of VP among pregnancies with VCI is reported to be between 1% and 10%	In a recent audit of our VP cases, in those instances where a VCI was associated with a VP it has been beneficial to see the VCI. Because not only does it raise the alarm bells for the possibility of a VP but where there is one it has enabled tracking of vessels and also their proximity to the internal os to be more accurately undertaken.

Kolawole Olayinka (Yinka) Oyelese, MD

xxxx xxxx

xxxx xxxx

xxxx xxxx

xxxx xxxx

June 3, 2017

Dear Sir/Madam,

SCREENING FOR VASA PREVIA

I am writing regarding the recent review on screening for vasa praevia.

I am a medical doctor (high risk obstetrician) in the United States. I previously trained in the UK, and am well familiar with the healthcare system there as well as the practice of obstetrics and midwifery. My field of specialization includes placental disorders such as placenta previa, placenta accreta and vasa previa. I have authored several research articles on those subjects in leading peer-reviewed journals as well as textbook chapters. I have been a professor for several years. I am asked to review research manuscripts for over 25 leading journals and have assessed, extensively, and on a regular basis, the world literature on vasa previa.

Even more importantly, on almost a daily basis, I am contacted by parents, patients, physicians, midwives and other healthcare professionals from all over the world who have lost babies from vasa previa. I am also often contacted by attorneys acting on their behalves. As such, I have a rare view of vasa previa, both from the clinical viewpoint and from the viewpoint of someone who sees what an avoidable tragedy as a ruptured vasa previa can have on the lives of patients and healthcare providers. I believe to not implement some screening for vasa previa would be a grave mistake that would continue to lead to senseless and avoidable loss of babies.

I am concerned about the recent review on screening for vasa praevia, and feel that both the data and the methods/rationale for screening may have been misinterpreted.

I would like to make the following points:

1. Vasa previa is a condition which carries a high risk of perinatal mortality when undiagnosed prenatally. Our previous study does indicate a mortality rate of 56% when not diagnosed versus < 3% in cases that are diagnosed.[1,2]
2. Vasa previa can be diagnosed with confidence prenatally. [1,2]
3. Perhaps the biggest obstacle to the concept of “screening” for vasa previa is that it is considered to require some new strategy that involves techniques not typically used in prenatal ultrasound. **ALL that is required in “screening” for vasa previa is, when technically possible, routinely identifying umbilical cord insertion into the placenta as part of the anatomy scan.** This is

currently the recommendation of the American Institute of Ultrasound in Medicine in performing a second trimester anatomy scan.[3] The consensus guidelines on fetal imaging from the AIUM, the American College of Obstetricians & Gynecologists (ACOG), National Institutes of Child Health and Human Development (NICHD), American College of Radiology (ACR), and the Society for Maternal Fetal Medicine (SMFM) which recommend **a transvaginal ultrasound with Doppler at 32 weeks in patients with a second trimester low-lying placenta that resolves.**[4] AIUM guidelines also recommend locating the placental cord insertion, whenever technically possible, at the time of the anatomy scan.[3] Based on our experience and thorough evaluation of the literature, if these guidelines are followed, the overwhelming proportion of cases of vasa previa will be diagnosed prenatally.[5]

4. Perhaps the most important goal of prenatal care and obstetric ultrasound is to prevent stillbirth and perinatal morbidity. Prenatal ultrasound has become almost universal in the Western world. Given that vasa previa, when not diagnosed prenatally is associated with a perinatal death rate of at least 56%, while survival after prenatal diagnosis approaches 100%, I find it inconceivable that an argument is still made against screening for vasa previa, especially since estimates of the incidence of vasa previa range from 1 in 500 to 1 in 2000. Vasa previa may be more frequent; Hasegawa and colleagues found an incidence of 1 in 365 pregnancies.[6]

5. Certainly, we routinely screen for much less common conditions, where prenatal diagnosis has little or no impact on survival. To put it in perspective, omphalocele occurs in one in 5400 births, anencephaly 1 in 5000 births, gastroschisis one in 2400 births, spina bifida one in 2858 births, Tetralogy of Fallot one in 3333 births, yet, no-one would think of suggesting that we do not screen for these conditions.

6. Most cases of vasa previa can be diagnosed prenatally by following the United States consensus guidelines for fetal imaging, and that deaths from this condition are almost universally preventable. This is one condition where prenatal diagnosis by ultrasound will almost universally lead to good outcomes and prevent perinatal mortality.

7. In my opinion, this makes a strong case for a 2 tier screen for vasa previa. **It does not require more than what should routinely be done anyway. It would be a tragedy if avoidable deaths continued to occur when they could be prevented.**

I sincerely hope my comments will be taken into consideration in the final determination.

Sincerely,

Yinka Oyelese, MD

xxxx xxxx

REFERENCES:

1. Oyelese KO, Turner M, Lees C, Campbell S. Vasa previa: an avoidable obstetric tragedy. Obstetrical & gynecological survey 1999;54:138-45.
2. Oyelese Y, Catanzarite V, Prefumo F, Lashley S, Schachter M, Tovbin Y, et al. Vasa previa: the impact of prenatal diagnosis on outcomes. Obstetrics & Gynecology 2004;103:937-42.
3. American Institute of Ultrasound in Medicine. AIUM practice guideline for the performance of obstetric ultrasound examinations. J Ultrasound Med 2013;32:1083-1101
4. Reddy UM. Abuhamad AZ. Levine D. Saade GR. Fetal Imaging Workshop Invited Participants. Fetal imaging: Executive summary of a Joint Eunice Kennedy Shriver National Institute of Child Health and Human Development, Society for Maternal-Fetal Medicine, American Institute of Ultrasound in Medicine, American College of Obstetricians and Gynecologists, American College of Radiology, Society for Pediatric Radiology, and Society of Radiologists in Ultrasound Fetal Imaging Workshop. Am J Obstet Gynecol 2014;210:387-397.
5. Atkinson A. Oyelese Y. Vasa previa: Time for routine screening. Fetal and Maternal Medicine Review. 2014.
6. Hasegawa J, Nakamura M, Ichizuka K, Matsuoka R, Sekizawa A, Okai T. Vasa previa is not infrequent. J Matern Fetal Neonatal Med;25:2795-6.

VASA PRAEVIA raising awareness
Response to UK NSC proposed review of screening for VP 2017
(Daren Samat – Trustee)

Thank you for the opportunity to comment on this the third "review" of its kind [the current review]. Since the foundation of our charity we have advocated screening for vasa praevia (VP) as means to reducing or preventing perinatal death and/or other co-morbidity caused by this condition.
We believe this is the shared aim of the Royal College of Obstetricians and Gynaecologists (RCOG) national quality improvement programme Each Baby Counts (EBC)
We comment as follows;

(i) The main aim of antenatal screening is to prevent perinatal death and other adverse perinatal outcomes.
(ii) There is no doubt an antenatal diagnosis of VP, usually by ultrasound, has a marked impact on outcome.
(iii) When the antenatal diagnosis is made by ultrasound the outcome is improved by a factor of 20 and rises to a 97% survival rate, therefore diagnosis by ultrasound is a sine qua non and would achieve the main aim of antenatal screening.
(iv) Antenatal diagnosis is not difficult to achieve.
(v) Antenatal diagnosis of VP, even at its lowest reported incidence, would have a significant impact on the UK stillbirth and neonatal death rate. At its highest reported incidence the impact would be greater still. This is wholly consistent with our aim, the aim of the RCOGs EBC and should be the aim of the UK NSC.
(vi) Following the last review in 2013, all stakeholders including the RCOG, agreed that a persuasive argument for the screening of those in the agreed high risk groups could be made. In 2013 the RCOG were asked by the NSC to look into establishing a program to achieve this. This was not carried forward despite several reminders from VPRA to NSC. We still advocate this view notwithstanding the conclusions in the current review and remain willing to assist in funding and training for such work.
(vii) Therefore the lack of meaningful evidence since the last review may be the fault of the RCOG and the NSC.
(viii) We have previously submitted detailed responses to both prior reviews because it was assumed that ultrasound screening was within the NSC's remit.

(ix) We are concerned at the lack of transparency of the current review process and the independence of the authors. The authors have chosen not to be named preferring to be cited as a limited company. A request to the NSC to identify the authors and their qualifications was surprisingly refused on grounds of exemption pursuant to FOIA, something never before encountered.

(x) Aside from achieving the concession above at (vi), which was not acted upon, none of our prior comments have been acted upon. Publication of both prior reviews did not result in any change to the final published NSC reviews even following comments submitted by stakeholders in the consultation.

(xi) We therefore do not propose to respond to each and every concern we have as many of these have been raised previously and are freely and widely available online (NSC and VPRA website) and are therefore in the possession of the NSC.

(xii) As the authors of the current review will know VP incidence data is due to be published (imminently) by both UKOSS and AMOSS. Such data may well inform the current process in ways that the authors acknowledge the limits the current review. Therefore we pose the question; why not delay this review and complete it in light of such data/evidence from this and any other sources?

(xiii) Based on the disclosure of emails sent to us by NSC, we are concerned to note that there is clear evidence of the private briefing of undisclosed members of RCOG Guidelines committee and of BMFMS by undisclosed UK NSC members of the current draft review in its pre-consultation format prior and to publication/consultation. This is in clear breach of confidentiality rules.

(xiv) When, as stakeholders, we asked for a copy of the pre-consultation document(s) the NSC refused citing exemption of disclosure pursuant to the FOIA notwithstanding the prior circulation to other stakeholders. We accept that confidentiality rules apply, however the circulation of this documentation to others raises the suspicion that some RCOG members have sought to influence the current review prior to publication with the knowledge of the NSC and this also raises doubt as to the independence of the current review.

(xv) Given the conclusion in the current review is that no (new) evidence has been identified to support a change in the previous recommendation we are surprised to note that the author(s) have nonetheless gone on to propose significant changes to the applicability of screening criteria to the known risk factors for VP which led to the previous recommendation.

(xvi) One of the significant changes to the previous recommendation referred to above is the separation of VP and a separate consideration of velamentous cord insertion (VCI). VCI was

hitherto considered a "risk factor" for VP and it remains so in the vast majority of the published literature and at this stage we see no reason to think otherwise.

(xvii) Following a request for a copy the "brief" sent to the authors, the NSC provided us with a "briefing note" purportedly issued to the authors (this note, by its content, was clearly redacted). The note instructed the authors to; "..explore a number of key questions relating to VCI..". It is evident that the NSC directed the authors to consider this rather than leave the authors to an independent review of the literature – perhaps unsurprisingly the authors' focus was on VCI and the conclusions reached were largely based on one published report

(xviii) Despite the hitherto universally accepted risk groups for VP being; multiple pregnancy, IVF and low lying placenta, the current review states that these are (now) outside of the remit of the NSC. If that statement is true, one wonders how this was missed by the author of the last two NSC reviews, the NSC, the RCOG and all the other stakeholders responding to those reviews. One also wonders, if the statement is correct, what the legality is of the NSC exceeding its remit in publishing this document.

(xix) The NSC requested the authors to limit their literature search for VP to; "..go back to 2012..", presumably to ensure no overlap with the past review. The current review has not applied this limit and we suspect that this is to seek to justify the significant changes referred to above despite there being no new evidence.

(xx) There is a plethora of cherry picking of "data" and the conflation of figures to reach questionable conclusions. We do not propose to highlight all but examples of this include;

- Page 8 para 1.1.1 (para 2); "..according to data from the ONS.." – there is no ONS data on the frequency of VP. The review is misleading on this.
- Page 8 para 1.1.1 (para 6) places over reliance on a "postal survey" with an undisclosed inbuilt bias. It results from a case of a ruptured undiagnosed vasa praevia (with prior persistent pv bleeding, undiagnosed VCI and IVF) the infant was delivered at term +1d by emergency c-section at the Wycombe District Hospital in 2005 and resulted in neonatal death at 13 days. The survey reports that the questions were put on the basis of seeking views as to the use of ultrasound to diagnose *asymptomatic* vasa praevia, yet their case was not asymptomatic. The questions were sent with an undisclosed covering letter the contents of which are not disclosed in the report.
- Page 13 para 2 and para 3 – *Overall Incidence* – in calculating the incidence reliance is placed upon Donegan 2014 to demonstrate a VP incidence of 0% from a cohort of 20,074. This is a gross distortion as this study was not reviewing diagnosis of VP but as the authors will know it was reviewing the possible side effects in a vaccine safety trial (of which potential side effects VP was just one).

- Page 16 para 1 – the conclusion that there is no increased risk for twin/multiple pregnancy is surprising. To reach this conclusion, with the exception of the Baulies 2007 study (which clearly shows correlation between twin pregnancy and VP), the authors limited the review of studies to those post 2013. It seeks to distinguish Baulies on the basis of, *inter alia*, an adjustment for IVF cases (despite the obvious link to multiple pregnancies and IVF). We submit that despite the preponderance of earlier pre 2013 literature this is clear attempt to remove multiple pregnancy from the known risk groups without firm or rigorous evidence and no proper consideration of the earlier reports establishing such links. Screening for VP in twin/multiple (and IVF) cases has been shown to be "cost effective" (Cipriano 2010).
- Page 17 para 2.2.1.2.1 – *What percentage of VP cases identified in 2nd trimester resolve by late pregnancy?* The author has mistreated the evidence extrapolated from Swank 2016. The author seeks to suggest that the percentage of "resolved" cases shown in Swank is 27.9% by seeking to include the 15/64 cases where there was no confirmed VP i.e. an unknown – this is wrong and represents a gross distortion of the findings (see also para 2.2.1.2.2).
- Page 17 para 2.2.1.2.1 – Rebarber 2014 – is perhaps an example where the authors seek to make a point by extrapolating a highly selective section of data from the report but without regard to the concluded views of the report. Rebarber, despite suggesting some cases of VP resolve prior to term, actually concludes in favour of screening for VP. Furthermore in this study while some of the fetal vessels were noted to have migrated on later scans there were still aberrant vessels within 2cm of the os (equivalent to low lying placenta) and thus the report suggests that such cases be treated as cases of placenta praevia or low lying placenta cases in any event. NB the same was true of the Bronsteen report where vessels were still seen within 2.5cm of the os. [See below for proposed treatment of such cases and the subsequent diagnosis of VP].

(xxi) The above list is not exhaustive and the point is made that very few of the reports and studies cited in the current review conclude against the effectiveness of screening for VP.

(xxii) With the sea of statistics flowing from the current 150 page "rapid review" – a review which swamps the previous 2 reviews by some considerable distance - we cannot help but feel that the true purpose of what we are looking for has been lost.

(xxiii) The true purpose of screening is set out at paragraph (i) above and overuse of statistics of methodology or criterion for screening are clearly not suited to resolve the undeniable fact that identifying VP will save lives and thus serve the primary purpose of screening to save little lives.

(xxiv) If the current review is correct, that; "..second-trimester ultrasound assessment of placental localisation is recommended within current UK guidelines. Therefore, recommendations for the identification and onward management of associated risks in pregnancies with low-lying placenta is also not within the UK NSC's remit.." then whilst this is outside the scope of the NSC to consider or even report upon, the solution is simple;

- nearly all women with VP will have (or had) low lying placenta in the early stages of pregnancy
- it is already a mandatory requirement to follow up these women at 32 weeks (RCOG GTG 27 and NICE).
- given the clear association of VP to low lying placenta or placenta praevia, simply include a requirement to locate/identify cord insertion in this group to thus confirm or rule out VP.
- this method is supported by Rebarber et al *supra*.
- for good measure one could add a flash of colour Doppler over the cervix to confirm (see also the consensus US guidelines – American Journal of Obstetrics & Gynecology May 2014 p387)
- use of TVS to visualise low lying placenta is already a NICE requirement if on TAS this remains unclear.
- When this is done you will begin to save countless little lives.

Daren Samat
Trustee VPRA
5 June 2017

Name:	xxxx xxxx	**Email address:**	xxxx xxxx
Organisation (if appropriate):			
Role:			

Do you consent to your name being published on the UK NSC website alongside your response?

Yes ☒ **No** ☐

Section and / or page number	**Text or issue to which comments relate**	**Comment** *Please use a new row for each comment and add extra rows as required.*
1	Not enough information to support screening	Screening for vasa praevia does not harm the mother and her baby. Early detection for vasa praevia gives every unborn baby a fighting chance of survival.
1	Early caesareans are risky	In cases like vasa praevia, a baby will die and possibly the mother if a baby is not delivered by caesarean section. The best time to perform a caesarean for vp is 35-36 weeks. With diligent monitoring, a baby will have a better chance of survival if a c section is performed at that time.
		I read the case studies in the 150 page review I am not a professional I am the mother of a beautiful baby xxxx xxxx xxxx xxxx, who's life could have been saved if screening for vasa praevia was offered to all expectant mums. xxxx xxxx was born at 36 weeks and lived for only 34 minutes. I had a terrifying haemorrhage while at work and was rushed to my local maternity hospital by ambulance, after some time a crash c section was performed, this was a terrifying ordeal as I did not know what was happening and didn't know if either of

		us would live. I woke up to my husband crying telling me xxxx xxxx didn't make it. This is the worst thing that has ever happened to us. I later found out that I had a velamentous cord insertion. My experience with VP is that I had an uncomplicated, singleton, pregnancy with no low-lying placenta. Although Vasa Praevia is rare, you should be aware of its devastating effects. Screening can save lives. Please consider the lives of children who will die without early detection. Please do not disregard mothers that do not display the classic risk factors for vasa praevia. Vasa praevia can affect any pregnancy. Yours Sincerely xxxx xxxx

Name:	xxxx xxxx	**Email address:**	xxxx xxxx
Organisation (if appropriate):			
Role:			

Do you consent to your name being published on the UK NSC website alongside your response?

Yes ☐ **No** ☒

Section and / or page number	**Text or issue to which comments relate**	**Comment** *Please use a new row for each comment and add extra rows as required.*
16	A study by the UK Obstetric Surveillance System has been completed (surveillance period December 2014 to November 2015) but has not yet been published.	According to UKOSS, "This study estimated the incidence of vasa praevia in the UK over one year and examined the clinical management of the condition as well as maternal and neonatal outcomes." Much can therefore be learned from this study, and apparent gaps in data and evidence in this review can be filled. Given the suitability of this research to answer many of the questions raised in this study including the incidence of Vasa Praevia in the UK and management of the condition, I strongly feel that the Committee should review the results before drawing conclusions on screening decisions for Vasa Praevia in this review.
42 12	There is not enough evidence about the incidence of VP in the UK And "The 2013 evidence review identified no	The new UKOSS study mentioned on page 16 should give us recent figures for the incidence of VP in the UK, with each risk factor. The have already reported preliminary findings. However, it should be noted that not all cases of vasa praevia which existed during the study period will have been reported,

	publications reporting the epidemiology of VP in the UK population specifically, either in the general population or in pregnancies with specific risk factors".	due to the lack of screening and antenatal diagnosis. My xxxx xxxx would also have been included in the UKOSS study if I had received antenatal diagnosis and if xxxx xxxx had been delivered at exactly 36 weeks or earlier. xxxx xxxx was born just weeks after the end of the study period, on xxxx xxxx at 40+1 weeks by emergency C section following two haemorrhages. The vasa praevia diagnosis was made soon after birth. xxxx xxxx was transferred to the SCBU and received blood transfusions but died at the age of 19 hours. I had a healthy pregnancy with no bleeding, therefore only screening for vasa praevia would have alerted us to its presence. xxxx xxxx was an IVF baby, recognised as being at highest risk, but regrettably despite the evidence available, screening for vasa praevia is not even carried out for high risk pregnancies. We knew nothing about the condition, and xxxx xxxx lost xxxx xxxx life following a desperate struggle. xxxx xxxx was perfectly formed and weighed xxxx xxxx when xxxx xxxx was delivered.
44	Case studies were excluded, and the Royal College of Obstetricians and Gynocologists' Green-top Guidelines (January 2011), nor any other guidelines relating to vasa praevia were referenced in the report.	On the same page the report also states, "Including [case studies] could have provided further information about how to manage VP and VCI after diagnosis" and that "it would be preferable to use published guidelines for management strategies, which take into account the breadth of clinical experience in this area". I believe it is important therefore to include case studies and the RCOG's guidelines in this review, and also published guidelines from other countries including Canada and Australia & New Zealand. The latest guidelines from SOGC and RANZCOG recommend screening women with risk factors and universal screening to locate the cord insertion respectively. These guidelines have been developed using

		evidence based reviews, and not all data used to make these recommendations are from their own countries.
25	The 2013 evidence review identified mainly guidelines, case reports, modelling and decision analysis studies considering the impact of VP management strategies such as: delivery (and the timing of delivery) by CS; the administration of prophylactic steroids to aid lung maturity; early hospitalisation of pregnant women; and in vivo operative fetoscopic laser ablation	The last evidence review included all these sources of information to draw the report's conclusions, so to build upon what is already known about vasa praevia this review should not exclude updates in these areas.
42	The accuracy of ultrasound for detecting VCI is unclear	On page 40 it is stated that "screening for VCI using TAS appears to have good overall accuracy"
42	There are no established management pathways for VCI	The RANZCOG guidelines have a management pathway to deal with cases of VCI which "prompt further evaluation by appropriately trained personnel that may include a transvaginal scan" (RANZCOG, page 7). The guidelines also go so far as to also include further investigation in the presence of "succenturiate lobe or other risk factors associated with vasa praevia".
4	Key gaps in the evidence relating to the epidemiology, the test and the management pathway remain which are unlikely to be resolved without large scale, well designed, prospective studies	The RANZCOG guidelines address this and state, "There are no clinical trials to inform the optimal management in cases of confirmed vasa praevia and because of the severity of the outcome, are not ethically justifiable." (RANZCOG, page 7). Prospective studies to determine the best possible actions to take will never be approved, therefore this review should focus on all the evidence available making conclusions on studies where similar results are achieved. There is overwhelming evidence in several areas; that vasa praevia can be detected (by

		colour Doppler ultrasound); that babies lives are under threat where this condition exists; and that babies can be saved by delivery through early C-section and have a much better prognosis, than they would have by leaving nature take its course.
1	This can lead to heavy bleeding and sometimes the death of the baby	On page 20 it is stated "A particular concern is perinatal mortality, which may occur in over half of VP cases if undiagnosed", and on page 19 it is stated "perinatal mortality among undiagnosed cases of VP is high, but can be reduced to less than 5% through appropriate management of cases if identified prenatally". I feel that the statement on page 1 should be revised in light of the severity of these findings.
1	A diagnosis of vasa praevia during pregnancy allows planning of a caesarean section. This may increase the chance of survival for the baby.	Antenatal diagnosis of vasa praevia with planned caesarean section near to term is reported to lead to survival of up to 97%. A planned caesarean is therefore exceedingly important and hugely increases the chances of survival for vasa praevia babies.
12	Criterion 1 of the UK NSC Screening Criteria states that: The condition should be an important health problem as judged by its frequency and/or severity	The report does not examine the full severity of the condition with regards to the long-term effects on children born without antenatal diagnosis
2	The first two groups are identifiable without screening and recommendations for testing for VP in these groups do not fall within the whole-population remit of the UK National Screening Committee (NSC).	Multiple pregnancy and IVF pregnancies are referred to here. Within which remit do these groups fall? There is a strong case argued in this review to offer screening for IVF pregnancies, but because the NSC does not promote screening for all pregnancies these group are not systematically being screened for vasa praevia.
2	Ultrasound screening for VP in the general pregnant population, as currently proposed, would therefore	Type 2 Vasa Praevia does not usually have an irregular cord insertion, therefore surely it is more important to identify the

	involve identification of both aberrant vessels and the cord insertion site, both as means of identifying the risk of VP at delivery	aberrant vessels as a priority.
1	There is still not enough evidence that screening every pregnancy for vasa praevia would be more helpful than harmful	Pregnant women expect to have screening tests done during pregnancy to pick up any potential problems. They do not expect to reach full term with a healthy baby, only for it to lose its life to a condition which is possible to detect by ultrasound. Screening for vasa praevia would identify which babies are unsuitable for vaginal birth and give every baby the chance of survival it deserves. The harm caused to individuals affected by undiagnosed vasa praevia is immense. xxxx xxxx is no longer alive, and knowing that a simple ultrasound scan could have resulted in xxxx xxxx being saved will continue to affect me for the rest of my life. Vasa praevia babies are often successfully resuscitated at birth and if they do survive they risk severe disabilities which will affect them for the rest of their lives, such as cerebral palsy, and survivors often need organ transplants. This could all be avoided with antenatal diagnosis and careful management. Prior to undergoing a planned C section, every woman with a positive diagnosis for vasa praevia could have multiple scans to reconfirm diagnosis, which should avoid unnecessary surgery. Given the dangers of the condition, I would expect that any pregnant woman would rather know that they had vasa praevia and have to deliver by CS than to not know and subsequently lose their baby.
17	Over 80% of cases had one or more of these risk factors	In the absence of enough evidence to support a national screening program, and with the strong associations to certain risk factors, including placenta praevia or low-lying placenta

		and pregnancies conceived through IVF or other assisted reproductive technologies, should the review not examine the case to be made for screening these high risk groups? Pregnancies in these groups have extra scans in addition to the two standard scans, and as the number of these pregnancies are low it would not require hospitals to provide much additional scanning time.
32	However, other placental and cord variants can result in VP, and VCI can be combined with other risk factors (such as IVF and placenta praevia) that are currently identifiable within existing guidelines and management pathways for pregnant women in the UK.	This statement should be reworded to avoid any inference that the existing guidelines and management pathways, for either IVF or placenta praevia, in any way allow for the identification of VCI or VP.
33	A meta-analysis … is out of the scope of this review	Given the severe outcomes for babies with vasa praevia, should not all data be fully examined, and a full review for vasa praevia be carried out?

Name:	Vasa Praevia Ireland	**Email address:**	xxxx xxxx
Organisation (if appropriate):			
Role:	Trustee		

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Yes x☐ No ☐

Section and / or page numbe	**Text or issue to which comments relate**	**Comment** *Please use a new row for each comment and add extra rows as required.*
Page 1 (summary) 1st paragraph	'birth of a baby can damage blood vessels' &'a diagnosis can allow planning of an elective c- section, this may increase chances of survival	Without an antenatal diagnosis, most certainly labour & birth can cause the death of the baby but same can be said for an ARM without antenatal diagnosis, lack of awareness with no early recognition or rapid response. It has been well and truly documented through expert peer reviewed reports, those who do screen for VP and those fortunate to be afforded an antenatal diagnosis that an elective c-section gifts over 97% of healthy babies the gift of life. Proper care and management can be put in place for mothers and babies. 44% up to 95% survival with diagnosis (Oylesse, 2004)
		TV scan is no more intrusive late in pregnancy as in early pregnancy

Page 1 paragraph 2	This is an intrusive, but usually painless, procedure that involves insertion of a probe into the vagina.	considering how many women access E.P.U services. Given the choice of a TV scan that could potentially save your baby's life or to avoid an unnecessary c-section in comparison to not being afforded one and that your much loved and wanted healthy baby could die or be left with lifelong injuries and not forgetting the risks of injury posed to mother in a crash section, some who require massive blood transfusions & life- saving surgery, care in ICU & NICU & blood transfusions for baby, it is inaccurate of the NSC to think that mothers would refuse a TV scan on the basis of it being intrusive
Page 1 Paragraph 4 Page 2	'Uk screening committee said not enough evidence that screening every pregnancy for VP would be more helpful than harmful'	Screening every pregnancy for any life threatening condition is more helpful than harmful. Is it not unethical to say or do otherwise? A good start would be to screen those with recognized risk factors. USA; Australia & NZ and Canada have made strides in their recommendations for screening for VP and checking placental cord insertion

Paragraph 3 Page 3 Paragraph 3	At least 80% of VP cases are reported to have one or more risk factors and the majority of reports identify the presence of VCI.	Multiple pregnancies have been omitted from the risk factor group. Why? Multiple pregnancies have a high index of up to 40% VCI (a main marker for VP) which raises their risk for VP & Growth discordance. 10% of VP cases affect multiple births. Ref: FM Breathnach & Kent, MD, ESPRIT study noted on references of NSC p.146 no: 48, though an Irish based study gives a very good indication of how prevalent VCI is amongst twin pregnancies (40%) thus demonstrating the need for all twins to have the placental cord insertion check Does this statistic not prove that the placental location must checked in order to diagnosis VP. Vci can easily be looked for using colour doppler at the 20 week scan
Page 42	The accuracy of ultrasound for detecting VCI is unclear	(Nomiyama M , Toyata Y, 1998) proved that cord insertion was visualized by colour doppler imaging in 99.8% of fetuses in their study. The sonographic identification of velamentous cord insertion had a sensitivity of100% , a specificity 99.8% and a positive predictive value of 83% and a negative predicative value of 100%. Ultrasound protocols should now be put in place where prenatal diagnosis can be made https://www.ncbi.nlm.nih.gov/pubmed/9918092

Page 42	Not enough information about the incidence of VP in the uk'.	The UKOSS study should be able to give incidence of VP in the UK. The results must be included in the evidence. As the perinatal statistics do not give a true reflection on the prevalence of VP as it only gives the stats that are recognized to be associated to VP. Some are not accurately recorded and cause of death can be referred to APH/ VCI or something else and if a neonate baby dies from a complication associated to prematurity or secondary complication, then this again could find that VP is not mentioned on the Stats audit. We believe UKOSS have a study completed but results are outstanding, so maybe the NSC would consider waiting on these results before coming to a decision.
Page 42	No high quality evidence on the optimum management pathway for cases of VP identified prenatally	RANZCOG Recommendation 7 & 8 in their guidelines they considered admitting women with prenatal diagnosed to a hospital with appropriate neonatal facilities from around 30 weeks gestation until delivery. The IVPF provide guidelines for mothers to bring to their doctors once diagnosed. These mothers have successful outcomes with safe delivery by planned c section in hospital. As a mother who lost xxxx xxxx due to undiagnosed VP I would like to stress that whatever prenatal anxiety arising from a successful diagnosis of VP, it is nothing compared to the shock and utter devastation experienced losing my completely healthy xxxx xxxx to a condition that can be detected if proper screening for VP was introduced.

	Additional paper 2017	https://www.ncbi.nlm.nih.gov/pubmed/28153653

P.1 summary : 1st paragraph ' birth of a baby can damage blood vessels' & 'a diagnosis can allow planning of an elective c- section, this may increase chances of survival'.

Ans: without an antenatal diagnosis, most certainly labour & birth can cause the death of the baby but same can be said for an ARM without antenatal diagnosis, lack of awareness with no early recognition or rapid response.

It has been well and truly documented through expert peer reviewed reports, those who do screen for VP and those fortunate to be afforded an antenatal diagnosis that an elective c-section gifts over 97% of healthy babies the gift of life.

2nd paragraph: Agree with most part with exception to the last line. TV scan is no more intrusive late in pregnancy as in early pregnancy considering how many women access E.P.U services . Given the choice of a TV scan that could potentially save your baby's life or to avoid an unnecessary c-section in comparison to not being afforded one and that your much loved and wanted healthy baby could die or be left with lifelong injuries and not forgetting the risks of injury posed to much in a crash section, some who require massive blood transfusions & life-saving surgery, care in ICU & NICU & blood transfusions for baby, it is inaccurate of the NSC to think that mothers would refuse a TV scan on the basis of it being intrusive.

3rd paragraph: Multiple pregnancies have been omitted from the risk factor group. Why? Multiple pregnancies have a high index of VCI (a main marker for VP) which raises their risk for VP & Growth discordance. 10% of VP cases affect multiple births. Ref: FM Breathnach & F Malone ESPRIT study noted on references of NSC p.146 no: 48, though an Irish based study gives a very good indication of how prevalent VCI is amongst twin pregnancies (40%) thus demonstrating the need for all twins to have the placental cord insertion checked.

4th paragraph: ' Uk screening committee said not enough evidence that screening every pregnancy for VP would be more helpful than harmful'

Reply: Screening every pregnancy for any life threatening condition is more helpful than harmful. Is it not unethical to say or do otherwise? A good start would be to screen those with recognized risk factors. USA; Australia & NZ and Canada have made strides in their recommendations for screening for VP and checking placental cord insertion.

5th paragraph – bullet points

Why did the NSC not conduct a cohort study since 2008 review if they feel there is not enough evidence? Missed opportunities & time lost. As the perinatal statistics do not give a true reflection on the prevalence of VP as it only gives the stats that are recognized to be associated to VP. Some are not accurately recorded and cause of death can be referred to APH/ VCI or something else and if a neonate baby dies from a complication associated to prematurity or secondary complication, then this again could find that VP is not mentioned on the Stats audit. We believe UKOSS have a study completed but results are outstanding, so maybe the NSC would consider waiting on these results before coming to a decision as this study by UKOSS should have better stats on VP prevalence.

Any baby delivered early can have complications as can a term baby, but this does not outweigh the need for screening & safe delivery of a baby affected by VP who would otherwise be at a greater detrimental risk of harm or death.

There is possibly a small number of false positives as there is possibly a small number missed but this is not a good enough reason to not screen. Only if you have lost a healthy much wanted baby and then to see all the positive outcomes from those who were afforded antenatal screening & a correct care plan that follows the recommendations of the IVPF, do you truly recognize the need for screening and the difference it makes on the outcome. This alone is a testament of the accuracy of the test and to those who perform them and testify to their accuracy with their peer reviewed reports.(Ref: Vasa Praevia, a Preventable Tragedy,British Medical Ultrasound Society 2008; Oyelese & Smulian 2006 Placenta Praevia, Placenta Accreta & Vasa Praevia; Dr Philippe Jeanty, MD.PhD www.fetus.net)

Knowing what we all know about VP, Why would you play Russian roulette with an innocent baby's life? As for unnecessary caesarean sections, if there was a diagnosis or suspicions of VP at the anomaly scan or other scan, this would lead to further evaluation by an MFM specialist to confirm or dismiss before a c- section was needed. If there were still doubts, it is best to err on the side of caution and treat as VP. You will get over surgery whether it was proven to necessary or not at delivery but You never get over the loss of your beautiful precious child..

2nd Last paragraph p.1 ' concern that screening would find pregnancies affected by VCI but no guidance on how to manage them'

We find this comment demonstrates all the more reason that screening for placental cord insertion & guidelines are needed as a matter of urgency on both VCI & VP.

Last paragraph;p.1

This is very disappointing. There has been expert peer reviewed reports in the last 10 years demonstrating that screening works, thus saving precious little lives. How do you differentiate between which baby should live or die? Does this not go against the ethics of the Oath that Doctors swear on to do no harm. Is this not needlessly endangering lives?

Targeted screening has to be implemented at the very least for now, anything less is unacceptable and I say this with a heavy heart knowing that lives will be lost needlessly if the placental cord insertion is not implemented as part of routine antenatal care. Maybe with the UKOSS results on VP prevalence, that on reflection of these the NSC will see things differently?

Page 2: 1st paragraph – Background

It has been well documented without an antenatal diagnosis that in the most part those exposed velamentous cord vessels will indeed rupture or be at risk of compression during labour leading to a high mortality rate (50%-80%) in comparison to 100% survival rate with a pre-natal diagnosis if no other problems exist.

2nd paragraph:Page.2

Surely the NSC would have the remit to produce recommendations for ensuring patient safety & equality of care, and that this can only compliment any current UK guidelines affording all expectant mum's the best possible care & outcomes. The focus of this review is to surely put in place recommendations that would enhance care, protect and preserve life.

3rd paragraph: P.2

If this reviews purpose is to decide whether VP screening is warranted, surely all the risk factors & main markers should be part of the focus of this review.

4th paragraph: P.2

So many countries have adapted to implementations and changes for now checking the placental cord insertion & checking for aberrant vessels. Why the concern about a major departure from current practise in the UK. Any departure and movement that follows in line with the other countries that are working towards preventing needless death & injury is to be welcomed and applauded.

Previous Recommendation:

1st paragraph:P.3

The NSC spoke very strongly for the need for recommending targeted screening in 2013 (Dr Woods).

We see no reference to this here in 2017. We hope this view has not been discarded.

2nd paragraph: P.3

Vasa Praevia has been detectable on ultrasound since as far back as 1987. Modern medicine & technology has moved on in strides in terms of technology; diagnosing and treating not just in obstetrics but neonatal care amongst all walks of the medical field .

With the hi-tec equipment used now and with all the positive diagnosis made by those who do screen for VP, this testifies to both the accuracy and practicality.

As for the concern of no agreed care pathway on diagnosis of VP, surely this demonstrates the need for the NSC to recommend guidelines for an agreed care pathway and screening as a matter of urgency.

Findings and gaps in evidence:

1st paragraph; there is no correct stats on incidence of VP as only deaths associated to VP are recorded and yet some of these are incorrectly attributed to a different condition due to lack of awareness amongst medical community. But for example in Myles textbook for Midwives,12th Edition 1993, makes particular reference to VP on p.49; p.180; p.435 so one has to ask why is there no training on VP in midwifery when it is the textbook or such a lack of awareness in that group as well as Obstetricians ? This needs to be addressed.

Findings & gaps, P.3 continued

VCI is as high as 1-100 in singleton pregnacies and a higher incidence in twins. Again this strongly demonstrates the need for placental cord insertion checking.

Annex C

Comment received from	Comment
Daren Samat	The NSC requested the authors to limit their literature search for VP to; "..go back to 2012..", presumably to ensure no overlap with the past review. The current review has not applied this limit and we suspect that this is to seek to justify the significant changes referred to above despite there being no new evidence.
Daren Samat	Page 8 para 1.1.1 (para 2); "..according to data from the ONS.." – there is no ONS data on the frequency of VP. The review is misleading on this.
Daren Samat	Page 8 para 1.1.1 (para 6) places over reliance on a "postal survey" with an undisclosed inbuilt bias. It results from a case of a ruptured undiagnosed vasa praevia (with prior persistent pv bleeding, undiagnosed VCI and IVF) the infant was delivered at term +1d by emergency c-section at the Wycombe District Hospital in 2005 and resulted in neonatal death at 13 days. The survey reports that the questions were put on the basis of seeking views as to the use of ultrasound to diagnose asymptomatic vasa praevia, yet their case was not asymptomatic. The questions were sent with an undisclosed covering letter the contents of which are not disclosed in the report.
Daren Samat	Page 13 para 2 and para 3 – Overall Incidence – in calculating the incidence reliance is placed upon Donegan 2014 to demonstrate a VP incidence of 0% from a cohort of 20,074. This is a gross distortion as this study was not reviewing diagnosis of VP but as the authors will know it was reviewing the possible side effects in a vaccine safety trial (of which potential side effects VP was just one).
Daren Samat	Page 16 para 1 – the conclusion that there is no increased risk for twin/multiple pregnancy is surprising. To reach this conclusion, with the exception of the Baulies 2007 study (which clearly shows correlation between twin pregnancy and VP), the authors limited the review of studies to those post 2013. It seeks to distinguish Baulies on the basis of, inter alia, an adjustment for IVF cases (despite the obvious link to multiple pregnancies and IVF). We submit that despite the preponderance of earlier pre 2013 literature this is clear attempt to remove multiple pregnancy from the known risk groups without firm or rigorous evidence and no proper consideration of the earlier reports establishing such links. Screening for VP in twin/multiple (and IVF) cases has been shown to be "cost effective" (Cipriano 2010).
xxxx xxxx	Multiple pregnancies have been omitted from the risk factor group. Why? Multiple pregnancies have a high index of up to 40% VCI (a main marker for VP) which raises their risk for VP & Growth discordance. 10% of VP cases affect multiple births. Ref: FM Breathnach & Kent, MD, ESPRIT study noted on references of NSC p.146 no: 48, though an Irish based study gives a very good indication of how prevalent VCI is amongst twin pregnancies (40%) thus demonstrating the need for all twins to have the placental cord insertion check
Daren Samat	Page 17 para 2.2.1.2.1 – What percentage of VP cases identified in 2nd trimester resolve by late pregnancy? The author has mistreated the evidence extrapolated from Swank 2016. The author seeks to suggest that the percentage of "resolved" cases shown in Swank is 27.9% by seeking to include the 15/64 cases where there was no confirmed VP i.e. an unknown – this is wrong and represents a gross distortion of the findings (see also para 2.2.1.2.2).
Daren Samat	Page 17 para 2.2.1.2.1 – Rebarber 2014 – is perhaps an example where the authors seek to make a point by extrapolating a highly selective section of data from the report but without regard to the concluded views of the report. Rebarber, despite suggesting some cases of VP resolve prior to term, actually concludes in favour of screening for VP. Furthermore in this study while some of the fetal vessels were noted to have migrated on later scans there were still aberrant vessels within 2cm of the os (equivalent to low lying placenta) and thus the report suggests that such cases be treated as cases of placenta praevia or low lying placenta cases in any event. NB the same was true of the Bronsteen report where vessels were still seen within 2.5cm of the os. [See below for proposed treatment of such cases and the subsequent diagnosis of VP].
xxxx xxxx	Case studies were excluded, and the Royal College of Obstetricians and Gynocologists' Green-top Guidelines (January 2011), nor any other guidelines relating to vasa praevia were referenced in the report.

Comment received from	Comment
	On the same page the report also states, "Including [case studies] could have provided further information about how to manage VP and VCI after diagnosis" and that "it would be preferable to use published guidelines for management strategies, which take into account the breadth of clinical experience in this area". I believe it is important therefore to include case studies and the RCOG's guidelines in this review, and also published guidelines from other countries including Canada and Australia & New Zealand. The latest guidelines from SOGC and RANZCOG recommend screening women with risk factors and universal screening to locate the cord insertion respectively. These guidelines have been developed using evidence based reviews, and not all data used to make these recommendations are from their own countries.
xxxx xxxx	The 2013 evidence review identified mainly guidelines, case reports, modelling and decision analysis studies considering the impact of VP management strategies such as: delivery (and the timing of delivery) by CS; the administration of prophylactic steroids to aid lung maturity; early hospitalisation of pregnant women; and in vivo operative fetoscopic laser ablation The last evidence review included all these sources of information to draw the report's conclusions, so to build upon what is already known about vasa praevia this review should not exclude updates in these areas.
xxxx xxxx	The accuracy of ultrasound for detecting VCI is unclear On page 40 it is stated that "screening for VCI using TAS appears to have good overall accuracy"
xxxx xxxx	"The accuracy of ultrasound for detecting VCI is unclear" (Nomiyama M , Toyata Y, 1998) proved that cord insertion was visualized by colour doppler imaging in 99.8% of fetuses in their study. The sonographic identification of velamentous cord insertion had a sensitivity of100% , a specificity 99.8% and a positive predictive value of 83% and a negative predicative value of 100%.
xxxx xxxx	There are no established management pathways for VCI The RANZCOG guidelines have a management pathway to deal with cases of VCI which "prompt further evaluation by appropriately trained personnel that may include a transvaginal scan" (RANZCOG, page 7). The guidelines also go so far as to also include further investigation in the presence of "succenturiate lobe or other risk factors associated with vasa praevia".
xxxx xxxx	"This can lead to heavy bleeding and sometimes the death of the baby" On page 20 it is stated "A particular concern is perinatal mortality, which may occur in over half of VP cases if undiagnosed", and on page 19 it is stated "perinatal mortality among undiagnosed cases of VP is high, but can be reduced to less than 5% through appropriate management of cases if identified prenatally". I feel that the statement on page 1 should be revised in light of the severity of these findings.
xxxx xxxx	"However, other placental and cord variants can result in VP, and VCI can be combined with other risk factors (such as IVF and placenta praevia) that are currently identifiable within existing guidelines and management pathways for pregnant women in the UK." This statement should be reworded to avoid any inference that the existing guidelines and management pathways, for either IVF or placenta praevia, in any way allow for the identification of VCI or VP.
xxxx xxxx	'Uk screening committee said not enough evidence that screening every pregnancy for VP would be more helpful than harmful'

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	Screening every pregnancy for any life threatening condition is more helpful than harmful. Is it not unethical to say or do otherwise?
xxxx xxxx	Additional paper 2017 https://www.ncbi.nlm.nih.gov/pubmed/28153653