UK National Screening Committee

Evidence map on screening for Vasa Praevia

Date: June 2023

Contents

Aim

This document provides background information on the UK NSC recommendation update on screening for Vasa Praevia (VP) in pregnancy.

Current Recommendation

The UK NSC does not currently recommend screening for VP in pregnancy in the U K. The Committee based this recommendation on the evidence provided by the 2017 UK NSC review carried out by Costello Medical.

The 2017 evidence summary aimed to identify the epidemiology of VP and its outcomes, as well as the performance of transabdominal screening for VP. It also examined screening pathways involving risk factors associated with the condition. Several risk factors have been proposed to be associated with development of VP, which include multiple pregnancy, pregnancies arising from in vitro fertilisation (IVF), low-lying placenta in early pregnancy, succenturiate placental lobes, bilobed or multilobed placentas, and velamentous cord insertion (VCI). The 2017 evidence summary evaluated the systematic detection of VCI as part of a screening strategy for VP.

The review found no UK evidence on the epidemiology of VP. VCI, bilobed or succenturiate (B L/S) placenta, low-lying placenta (LLP) and in IVF were found to have a positive association with VP in the 2017 UK NSC review but there was insufficient evidence to support the role of these in screening of VP.

The review also concluded that there was uncertainty about the accuracy of screening, and that evidence in this area was insufficient to recommend screening.

Following the conclusion of the 2017 evidence summary, the UK NSC also commissioned an exploratory modelling study to estimate the effects of second-trimester, ultrasound-based antenatal detection strategies for VP in a hypothetical cohort of pregnant women. For this project, input was provided by several external stakeholders. A decision-analytic tree model was developed, covering 4 discrete detection pathways/strategies:

- no screening
- screening targeted at women undergoing IVF
- targeted screening in women with LLP
- universal screening women for VCI

The model results suggest that a targeted LLP-based approach could detect a substantial proportion of VP cases, while avoiding overdetection of VCI and requiring minimal changes to current clinical practice. The model concluded that high-quality data is required to explore the clinical and cost-effectiveness of this and other detection strategies further. This is necessary to provide a robust basis for future discussion about routine screening for VP. This exploratory study using decision analytic modelling methods was published in December 2022. Ruban-Fell B, et al. (2022) The impact of ultrasound-based antenatal screening strategies to detect vasa praevia in the United Kingdom: An exploratory study using decision analytic modelling methods.

2023 Evidence Map

As part of the UK NSC evidence review update in 2022 an evidence map on screening for VP in pregnancy was performed by Costello Medical. Evidence maps are rapid evidence products which aim to gauge the volume and type of evidence relating to a specific topic.

The objective of the evidence map was to assess the volume and type of evidence relevant to screening for VP, with a focus on the prevalence of VP and its outcomes in the UK, as well as assessing whether there are any prospective studies reporting the accuracy of transabdominal ultrasound in the second trimester in the UK.

This evidence map addressed the following questions:

1. Is there any UK-based epidemiological data on the prevalence of VP or its outcomes?
2. Are there any prospective studies reporting the accuracy of transabdominal ultrasound in the second trimester in the UK?

The findings of this evidence map provide the basis for discussion to support decision making on whether there is sufficient evidence to justify commissioning a more sustained review of the evidence on VP in the UK.

Summary of findings

Question 1; Of the 399 abstracts reviewed, 1 record was included for this review question. A retrospective study using data from prospective screening of singleton pregnancies for VP, undertaken in aUK Fetal Medicine Unit, between January 2012 and June 2018. This study of 26,830 singleton pregnancies, 22 had suspected VP, with one of these pregnancies later showing no VP, giving an overall incidence of 0.08% (21/26,830; 1 in 1278). To our knowledge this study provides the only estimate of VP incidence in a UK population, which is higher than the estimates from

studies identified in the 2017 UK NSC review on populations considered to be analogous to the UK population, which ranged from 0.02% to 0.04%. However this higher rate may be due to the definition of VP used in the study. Therefore, due to the low volume of studies further evidence review work on the epidemiology of VP in the UK is not currently justifiable.

Question 2; Of the 399 abstracts reviewed, 1 record, reporting on 1 study, was included for this question. A retrospective study that included 2 cohorts of pregnancies complicated by placenta accreta spectrum (PAS) or VP. The study compared the performance of screening for these conditions before and after the introduction of a targeted screening protocol at their centre (Department of Obstetrics and Gynecology, Assaf Harofe Medical Center, Tel Aviv University, Israel). VP was detected with transabdominal ultrasound, but as this was followed by confirmatory transvaginal ultrasound, test accuracy was not reported separately for each step. Therefore, no evidence on the performance of transabdominal ultrasound alone was identified.

Overall, the evidence map concluded that there is insufficient evidence to justify commissioning an evidence summary, and the current UK NSC recommendation on screening in pregnancy for VP should not be changed.

Consultation

A three month consultation was hosted on the UK NSC website. Direct emails were sent to 13 stakeholders. (Annex A)

Twelve comments were received from the following stakeholders (see Annex B for comments):

1. Gill Harrison - Society and College of Radiographers
2. XXXX XX
3. XXX XXXX
4. XXXX XXXX
5. XXXXXXXX X
6. XXXX XXXX
7. XXXX XXXX
8. Katy Sutcliffe - XXXX XXXX XXXX
9. XXX XXX
10. XXXX XXX
11. XXXX XXXX - The Royal College of Midwives
12. XXXX XXXX - British Maternal and Fetal Medicine Society Committee

The majority of stakeholders support the introduction of a population screening programme for VP in pregnancy. All members of the public shared their own personal, professional and / or family experiences to provide examples of when the presence of a screening programme may have improved the pregnancy outcomes. They all spoke of the devastating impact that the condition has had not only on the affected individual but on the broader family. The UK NSC acknowledges this and is grateful for these responses and their contribution to the consultation process.

One stakeholder also provided a detailed response which highlighted papers which might be considered for inclusion in the evidence map, drew attention to the clinical consequences of VP other than increased mortality and criticised the conclusion of the evidence map which was that the next evidence review should take place in three years.

The Society and College of Radiographers supported the conclusion of the evidence map and acknowledged that it would be helpful to have a clear strategy in place to address the evidence gap and consider whether the diagnosis of VCI maybe a helpful tool in a screening population. This response refers to, and aligns well, with the above mentioned modelling exercise. It also aligns well with a recent UK systematic review exploring the clinical impact of VP which concluded that research is needed to 'investigate strategies for incorporating prenatal screening for vasa praevia into routine clinical practice.'

Similarly, the Royal College of Midwives calls for more research being done on this in the UK, to better inform the management and recommendations.

Responses

Although the reviewers are still evaluating the 4 publications suggested for inclusion by one stakeholder, a first evaluation suggests that they do not meet the inclusion criteria of this evidence map. This is because 2 studies were published outside the search dates, and 2 are outside the scope of this evidence map. However, one of these studies, a UK systematic review and meta-analysis, by Zhang et al 2021, looking at the impact of prenatal ultrasound good evidence that early diagnosis improves perinatal outcomes. It suggested that "it is imperative that further research be undertaken to investigate potential strategies to both classify pregnancies at high risk of vasa praevia and identify cases with a confirmed prenatal diagnosis that could benefit from a structure plan for antenatal monitoring and delivery". This is in keeping with the conclusion of the modelling exercise commisioned by the UK NSC (Ruban-Fell B et al (2022)).

Evidence maps provide a way of scanning published literature to look at the volume and type of evidence. These can be used to explore gaps in the evidence identified by the previous UK NSC reviews. The main aim is to inform whether the evidence is sufficient to commission more sustained evidence review work on the topic under consideration. Although, the conclusion of the 2023 VP evidence map is that at present, there is insufficient published literature to justify further evidence review work on screening for VP, it is clear from the public consultation that in the UK, there is growing interest in screening to prevent adverse outcomes from VP and interest in exploring different strategies that might achieve this. The Committee has experienced similar situations in the past, where although there was no evidence to justify a further review work, the lack of evidence identified by the evidence map stimulated some research activity in the area. For example, when the annual call for topics received a proposal to examine evidence for the introduction of a screening programme for breech presentation in the third trimester of pregnancy the result was an HTA call expressions of interest in this area.

Conclusion

Options for screening for VP remain under-explored in the UK and there remains very limited evidence on which to base recommendations. A targeted approach which builds on current practice, such as the detection of low-lying placenta at mid-term, may provide a starting point from which a wider antenatal detection strategy could be considered.

It is recommended that screening should not be undertaken outside of high quality research settings. The UK NSC Secretariat will seek opportunities to stimulate research as capacity allows.

Annex A: List of Organisations Contacted

1. Faculty of Public Health
2. HSIB Maternity Investigation Programme
3. National Childbirth Trust
4. NHS ANNB Screening Programmes
5. Royal College of General Practitioners
6. Royal College of Midwives
7. Royal College of Obstetricians and Gynaecologists
8. Royal College of Physicians
9. Royal College of Physicians and Surgeons of Glasgow
10. Royal College of Physicians of Edinburgh
11. Society and College of Radiographers
12. The Harry Cunningham Trust
13. Vasa Praevia Raising Awareness

Annex B: Consultation Responses

Name: Gill Harrison

Email: XXXX XXXX

Organisation: Society and College of Radiographers

Role: Professional Officer for Ultrasound

Publish submitter's name: True

Publish Organisation name: True

Condition: Vasa praevia

The Society of Radiographers Ultrasound Advisory Group provided the following feedback:

Based on the 2023 evidence map, it does show that there is still insufficient empirical evidence to recommend population screening. It is encouraging to see publication of the Ruban-Fell et al (2022) study, which does begin to address some of the long-standing questions and provide a good foundation for future research to build on.

It would be helpful to have a clear strategy in place to address the evidence gap and consider whether the diagnosis of VCI maybe a helpful tool in a screening population.

Name: XXXX

Email: XXXX XXXX

Notify: True

Condition: Vasa praevia

Affected Comment:

Our granddaughter XXXX was born on XXXX stillborn due to undiagnosed Vasa Previa. A simple scan would have saved the trauma that my daughter son in law and all the family had to face. This wasn't a multiple or IVF pregnancy. XXXX lost the majority of her blood and died before birth when our daughters waters broke. The crash team worked tirelessly on XXXX bringing her back to life where she then spent 11 days in NICU. We can only pray for the best long term outcome. Our daughter also had a team working with her and this is a day we still struggle to get over.

Evidence Comment:

It is not acceptable in the UK that a ticking time bomb is waiting to take the next babies life. The trauma is indescribable. Other countries including Ireland offer this, how on earth do we not. It is a mistake of the highest level. Babies are dying, this cannot continue.

Discussion comment:

Change the UK law now

Recommendation comment:

It 100% should be recommended. Why, simply to give these babies a chance of life rather than a death sentence that can be prevented by simple screening.

Alternatives comment:

Without screening this fatal condition could be missed. With it an a caesarian section the baby will survive and the trauma prevented.

Other comments:

This can affect anyone, I promise you if anyone reading these comments thinks this won’t happen to them or their family, think again. Our daughter was deemed low risk and this was her third pregnancy and her first daughter, it happened. Another thing to note she had bleeding 5 days before delivery, she was told on the phone this was normal, bleeding may be common but it is not normal. Please ensure all staff don’t dismiss bleeding as normal, it’s a known sign of Vasa Previa. We now know this. Thanks in advance for listening to those who have been affected by Vasa Previa. The majority of families today are grieving, we are blessed but certainly not secured of a healthy granddaughter due to starvation of oxygen for one. Make screening in Uk law.

On behalf of the Royal College of Midwives kindly accept my comments for the consultation on screening for Vasa previa.

On review of the Evidence Map version 1.1.

To address the question in this evidence map 'Is there is sufficient evidence to justify commissioning a more sustained review of the evidence on VP in 2022?'

As mentioned in the document, only one study was identified during the search.

In addition, as stated in the document:

'This 2023 evidence map found that at present, there is insufficient published literature to justify further work on screening for VP.'

We agree with the decision to reconsider the evidence for screening in the future.

And as mentioned in the document, this can then lead to recommendations for management of women who have risk factors for VP.

Although there is a low incidence of VP (0.46 per 100 pregnancies), this is an important area of work which will change the management of VP and improve outcomes for women and our midwives in managing such cases.

We look forward to more evidence/research being presented on this in the UK, to better inform the management and recommendations.

Thank you for accepting our comments at this time.

We look forward to hearing the next steps about this and our continued work in this area.

Kind regards

XXXX XXXX
XXXX XXXX
Royal College of Midwives

Name of Reviewer	Section	Line numbers	Comments
British Maternal and Fetal Medicine Society Committee	1	Page 8 Page 9	The 1 UK based study (Zhang et al 2020) is actually a large study of 26,830 pregnancies. There is unlikely to be further studies of this size reported in the UK over the next 3 years. It would be valuable to let this data speak rather than close down opportunities to improve clinical practice by the summary quote Re Question 1 ''at present, there is a very low volume of evidence on the epidemiology of VP or its outcomes in the UK to justify further work on this question'' Don't understand the relevance of Question 2. 'The evidence of the performance of transabdominal ultrasound to diagnose VP' should be replaced by 'The evidence of the performance of transabdominal ultrasound followed by confirmatory transvaginal ultrasound to diagnose VP'. This seems to be the subtext of the Costello medical document itself! The UK screening committee should consider changing this question. Again dismissing Q2 as its stands by 'lack of evidence' seems wrong. The evidence map (including the Zhang 2020 reference) and the Ruban-Fell et al 2022 analytical model for UK VP screening (PLoS ONE 17(12):e0279229 are useful resources for promoting a pragmatic pathway in the UK based on at the very least 'good practice'. The UK screening committee should therefore be cognisant of the language which they use within their document and summary. **From clinical experience a quote of 'there is no evidence for..' can be a strong barrier to improving care pathways.** The care pathway for improving the detection of VP, reducing perinatal loss from VP can be advanced with the references above and working largely within and developing the resource of the routine mid trimester FAS programme and the RCOG placenta praevia and accreta diagnosis and management document (GTG 27a 2018).
	Document		In addition there is no mention the UKOSS study on Vasa Previa (2015). The same group did an extended modelling based study in 2021 - but this seems to have been overlooked. Ruban-Fell B, Attilakos G, Haskins-Coulter T, Hyde C, Kusel J, Mackie A, et al. (2022) The impact of ultrasound-based antenatal screening strategies to detect vasa praevia in the United Kingdom: An exploratory study using decision analytic modelling

			methods. PLoS ONE 17(12): e0279229. https://doi.org/10.1371/journal.pone.0279229 It is unlikely that a large number of studies will be conducted, any time soon, in the UK to report on the epidemiology of a condition with a likely prevalence of 0.04-0.08%. Therefore, any future evidence map is likely to be futile, as well.
			If there is not enough evidence maybe need to plan forward with a modelling approach that has been mentioned
	Evidence Map	Pages 5-6	Why is previously gathered evidence not merged with the new evidence map – surely this will increase the numbers? The numbers of cases or studies are not stated hence I do not have a feel for if this is worthwhile or not

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Name: XXXX XXXX

Email: XXXX XXXX

Notify: True

Condition: Vasa praevia

Affected Comment:

I was diagnosed with Vasa Previa during my first pregnancy in 2020, at 28 weeks. I had a lot of complications during my pregnancy, including bleeding from 24 weeks, with no cause identified, as Vasa Previa was not routinely checked for, due to the current guidelines. There were many times I thought I would loose my baby due to the bleeding, and with no cause given, my anxiety was high and I was on edge for my whole pregnancy, scared to go to the toilet and see blood. Almost three years later, I have panic attacks when starting my period, as I associate seeing blood in my underwear with the fear I felt during my pregnancy.

I paid for a private scan at 28 weeks pregnant as the NHS refused to even scan me for the condition, despite having almost all the warning signs. I was laughed at by the NHS and told I wouldn't have the condition 'as it's so rare'. I was diagnosed with Vasa Previa at this scan, and admitted at 30 weeks for monitoring. At 30+4 weeks my waters broke during my admission, causing heavy bleeding and my son was born by emergency c-section. If I hadn't of paid for that private scan and hadn't advocated for my baby, I highly doubt I would have been admitted, and like many women with undiagnosed Vasa Previa, would have experienced a still birth.

My son had a very difficult NICU stay and suffered greatly due to blood loss and a traumatic birth. He suffered from a brain bleed and necrotising enterocolitis from his stomach being starved from blood after going into shock at delivery. He received countless blood transfusions during his stay. He is now 2 years old and has multiple on-going issues from being premature.

I myself suffered with post-natal depression, birth trauma and PTSD from the whole experience. Due to the lack of care and advice I received during my pregnancy, and going also undiagnosed with the condition for most my pregnancy, I feel I detached myself from forming a bond with my baby, as a coping mechanism of the possibility of

loosing my baby. I cannot remember my sons first 18 months very well and was in despair for most of them.

I completely have lost trust in medical professionals, and felt as if I was medically gas light, knowing something was wrong with my pregnancy, and being palmed off by my consultant. Due to this experience, my partner and I have decided we will not ever be mentally able to go through with another pregnancy, therefore will not have another child.

I now see pregnancy as something to be afraid of, and fear for any family members or friends that have been pregnant since. I struggle to be around babies as they remind me of all the time I lost with my son, resulting in me giving up my 10 year profession of working as a nursery nurse.

Evidence Comment:

The Vasa Previa foundation has conducted research that 10% of still births could be prevented, if Vasa Previa was scanned for during pregnancy.

There is also evidence that if the condition is diagnosed during pregnancy and properly managed, the risks to the baby are significantly reduced.

Discussion comment:

Many women with Vasa Previa do not display any signs, and therefore go on to have a normal pregnancy, only to display issues in delivery, often when it’s too late for the baby to be saved.

All I can ask when considering this review, is to put yourself in the position of a women with Vasa Previa, or their partner. If something was wrong, would you want to know? If you had a condition that could be fatal for your unborn child, would you want it to be picked up and managed properly? How would you feel if you lost your child, when it could have been easily prevented by something as simple as a scan?

Many women do not know this condition even exists, until they are bitterly sweet diagnosed with it. This condition does not receive the recognition it deserves. Perfectly healthy babies are loosing their lives due to this condition, it is going

undiagnosed and destroying families. This is not something that should be happening in a developed country like the United Kingdom.

Recommendation comment:

I believe every pregnant women should be educated on the condition and be given the choice if they would like to be scanned for it. I am aware that some hospital trusts do this, however it should be a standard practice at ALL NHS hospitals. Hospitals already have the equipment to diagnose this condition, so I feel it should be offered at every woman's 20 week scan. The condition is fatal if it is not diagnosed, so why would it not be scanned for? Every woman should have a choice, as they do with having screening for Down syndrome antenatally. Why is Vasa Previa any different?

For my family and I, if I was diagnosed with this condition at my 20 week scan, it would have saved so much heart ache and ongoing trauma. I could have been offered advice and support throughout my pregnancy. I would have known what was wrong, what to do in an emergency, what to look out for.

Alternatives comment:

I don't believe there are any alternatives. The condition can only be diagnosed by a scan. Not all women display signs, so this isn't indicative enough to go off. I displayed many of the 'warning signs' and still wasn't diagnosed by the NHS.

Name: XXXX XXXX
Email: XXXX XXXX
Notify: True
Condition: Vasa praevia

Affected Comment:

I had vasa previa and a velementous cord insertion when I was last pregnant. It is extremely important for women to get screened for this condition. There's only a 50/50 chance of infant survival (perhaps even less in recent literature) if it goes undetected. It is an incredibly preventable death. The mother just needs to be screened and taken

care of properly, be on bed/hospital rest, etc. Every country should do the screening to protect these babies and the welfare of their mothers.

Evidence Comment:

I'm not sure

Discussion comment:

This is an extremely important and high risk condition that every woman who is pregnant needs to be screened for and taken seriously.

Recommendation comment:

As per my original comment, babies have far lower survival rates when this condition goes undetected. I believe it's a 50/50 survival rate vs a 98% survival rate if it is detected and the proper precautions are in place. That is extremely significant.

Alternatives comment:

They need to stay up to date and well educated and informed on this condition. It's important for women to have the ability to go on hospital rest because if their water breaks the babies could bleed out in 15 minutes.

Other comments:

None other than mandatory screening, bed rest and hospitalization, and a c-section for these mothers. It's very important that the mothers receive c-sections with this condition.

Name: XXXX XXXX
Email: XXXX XXXX
Notify: True
Condition: Vasa praevia

Affected Comment:

I currently have an anterior assessory lobe and a posterior placenta previa. If my placenta moves even slightly back I will be at risk at vasa previa and the blood vessels are very close to the cervix now as the anterior lobe is only 6.9mm away from the cervix. I had my last scan at 20weeks and they want to wait until 32 weeks to scan me again. I feel if me and my baby aren't getting the right care.If I bleed noone for sure can state where it is coming from until I have a scan at the hospital and depending when that is that could be too late.

Evidence Comment:

I should have a few more scans to check the placenta movement as at any point this could create vasa previa.

Discussion comment:

I think anyone at risk of vasa previa whether it be from an extra lobe or placenta previa should have more scans to stay aware of what is happening inside.

Recommendation comment:

Definitely should. The earlier the diagnosis the better the outcome and life's saved.

Alternatives comment:

More ultra sounds and monitoring. Support for those going through it, as it causes alot of anxiety and mental health issues.

Name: XXXX XXXX
Email: XXXX XXXX
Notify: True
Condition: Vasa praevia

Affected Comment:

My daughter was born four months ago. She suffered a HIE grade 2 event at birth. This was as a result of VP. I also had a I also had a VCI. During pregnancy I had

placenta previa, and then a low-lying placenta, which moved upwards towards the end of my pregnancy.

Evidence Comment:

From my point of view, the evidence seems thin on the ground. There seems to be a little evidence from the UK. The evidence gathered seems to be relatively inconclusive.

There seems to be not enough evidence being gathered for review. As VP is so rare and currently not screened for, could the cases of mothers who have VP detected during labour be used as evidence?

Recommendation comment:

I think that VP should be screened for. Although rare, the danger VP poses to both mother and baby is very serious. Had my VCI/VP been detected during my pregnancy, my daughter could have been delivered safely.

Alternatives comment:

Even if VP is not routinely scanned for in the second trimester, perhaps other markers should be scanned for. Medical professionals were aware of my placenta previa and subsequent low-lying placenta – this seems to be an indication of other abnormalities such as VCI/VP. As well as tracking the location of the placenta in scans following the 20 week scan, perhaps mothers should be offered a scan which looks to detect any further abnormalities.

Name: Katy Sutcliffe
Email: XXXX XXXX
Organisation: XXXX XXXX
Role: XXXX XXXX
Publish submitter's name: True
Publish Organisation name: False

Condition: Vasa praevia

As a junior obstetric registrar, cared for a woman who had an diagnosed vasa praevia, which ruptured in labour and despite an emergency c-section her baby died. This tragic case has had a huge impact on me personally and professionally. There was a coroner's inquiry which took place over 3 years after the incident and was deeply upsetting for the family and all staff involved. The coroner concluded that the care in the case had been reasonable and appropriate. Ultimately, it has been a huge influence in my decision not to practice obstetrics as a consultant and delayed my decision to start a family myself (I did not feel I could attend coroner's court pregnant when this woman was grieving the loss of her own child).

I'm sure you will hear from families in this consultation, as obviously they have had the greatest loss but wanted the voice of a healthcare professional as a second victim to be heard too.

This could have been avoided if the vasa praevia was diagnosed antenatally and the woman had an elective c-section. Her child would be starting school this year.

Name: XXXX
Email: XXXX XXXX
Notify: True
Condition: Vasa praevia

Affected Comment:

My daughter had vasa praevia and could have had a stillborn baby as well as potentially losing her own life. The NHS (XXXX XXXX) missed the condition as they didn't do a simple trans vaginal scan at her 20 week pregnancy. Luckily we had arranged private consultations where they picked up the condition and we transferred to a specialist fetal medicine unit (at XXXX XXXX XXXX) for the remainder of her care. If a trans vaginal scan was routinely performed at the same time as the standard 20 week scan, then many lives could be saved. The time and cost involved would be minimal.

Recommendation comment:

Screening should be recommended as many lives would be saved if the condition is picked up.

Alternatives comment:

I cannot think of any other way. Trans vaginal screening at 20 weeks is the only way to pick up the condition. If detected, then regular trans vaginal scans would be needed to monitor the condition in case early delivery by caesarean section is needed.

Name: XXXX XXXX
Email: XXXX XXXX
Notify: True
Condition: Vasa praevia

Affected Comment:

I am a British citizen who gave birth to a healthy daughter in Australia in 2015 thanks to vasa previa screening. The condition was flagged at a routine ultrasound due to the use of colour Doppler and checking of foetal vs maternal blood vessels crossing the cervix. Please test for this condition in the uk. To know my daughter likely wouldn't have made it had I given birth in my home country is heartbreaking. It is a simple, quick test that can be done as part of a routine pregnancy ultrasound.

Evidence Comment: No

Discussion comment: No

Recommendation comment:

Yes recommend screening for vasa previa. It is the safest way to prevent foetal complications.

Alternatives comment:

Screening is effective. Other options such as monitoring blood loss during pregnancy are not fail safe – I was asymptomatic but had a clear case of vasa previa as confirmed by the state of the placenta and membranes on delivery.

Other comments:

Please screen for vasa previa

Name: XXXX XXXX

Email: XXXX XXXX

Organisation:

Role: XXXX XXXX

Publish submitter's name: False

Publish Organisation name: False

Condition: Vasa praevia

Dear Sirs

Re: Vasa Praevia Antenatal Screening Programme

1. On 5th December 2022 (as part of the NSC's annual 'call for topics') we lodged with the NSC submissions in relation to the need for urgent review of the NSC's 'not screened for' position on Vasa Praevia. Within those submissions we set out in full, our families own personal experience, and the details of the trauma sustained by our daughter. I thus refer the NSC to my 5th December 2022 correspondence.

2. In the hours and days after her birth via emergency c-section we were given the diagnosis of Vasa Praevia (VP). We asked the question *'could / should this have been detected on scan'*. We then learnt that, yes, this condition is readily detectible antenatally, and can easily be looked for at the routine antenatal anomaly scans, but isn't looked for. The despair, disbelief, anger and frustration we felt upon learning this, learning that our daughter's trauma could have been entirely avoided, through very simply screening during antenatal scans, can not be overstated. The stark reality is that many other families are, to this day, having similar or indeed much worse experiences than our own, as a result of the ongoing absence of screening for VP.

3. We consider that it is important that the NSC fully consider the human impact of its decision making, and ask that the NSC read our letter of 5th December 2022 in conjunction with this response. We very much hope that the NSC has reached out to other families who have been given a VP diagnosis antenatally, and that the NSC has been proactive in ensuring that all such families are aware of this consultation and have been given opportunity, should they feel able and want to contribute, to lodge individual submissions. It is important that the NSC considers that impact, and hears directly from families.

4. I would ask the NSC panel members to consider how they would feel if they, their partner, their child, had been the victim of this. I would invite those taking decisions on this issue at this juncture to try, in so far as is possible, to fully contemplate the extensive and often life long repercussions of the 'no screening' policy. It is important to recognise the ripple effect of trauma, pain and anguish which accompanies any traumatic birth, and which devastates families when a baby is lost or sustains life limiting birth injury. These babies, these families, are not just statistics.

5. I note that the UK NSC screening recommendation re Vasa Previa are currently based on the last UK NSC review of this condition that occurred in August 2017 (nearly 6 years ago). At

that time, it was noted that there was a gap in available evidence to recommend a screening programme, the 2017 review concluding that:-

> *'this review has not found sufficient evidence to support a change in the overall recommendation for VP screening. 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 other reasons given for not screening for Vasa Previa were as broken down further as follows:-

> *'Screening for vasa praevia during pregnancy is not recommended because:*
> *(a) it is not known how many babies are affected by it in the UK*
> *(b) it is not known how accurate screening tests are at detecting it*
> *(c) screening may mean some women are offered an early caesarean when they do not need one*
> *(d) some women may be reassured by false tests and still have a problem during delivery'*

6. As previously emphasised, none of those points remain valid today, and have not been valid for several years. The NSC/NHS itself has now had almost 6 years to complete the required studies and data collation it was said was necessary back in 2017. Within our earlier submissions we have already made reference the breadth of relevant national and international research readily available (via internet searches) which has been available for several years; and now entirely undermines the basis upon which the NSC, in 2017, decided not to screen for this condition.

7. In relation to the difference that screening can make, we have referred to the article *'Perinatal outcome of pregnancies with prenatal diagnosis of vasa previa: systematic review and meta-analysis (W. Zhang,S. Geris,N. Al-Emara,G. Ramadan,A. Sotiriadis,R. Akolekar) First published: 31 July 2020'* as can be found at https://obgyn.onlinelibrary.wiley.com/doi/10.1002/uog.22166; which states as follows regarding the drastically different outcome for mother / baby if Vasa Previa is diagnosed antenatally:-

> *'.. the risk of perinatal death was 25-fold higher when a diagnosis of vasa previa was not made antenatally, compared with when it was (odds ratio (OR), 25.39 (95% CI, 7.93–81.31); P < 0.0001). Similarly, the risk of hypoxic morbidity was increased 50-fold in cases with vasa previa without a prenatal diagnosis compared with those with a prenatal diagnosis (36/61 vs 5/224; OR, 50.09 (95% CI, 17.33–144.79)). The intact perinatal survival rate in cases of vasa previa without a prenatal diagnosis was significantly lower than in those with a prenatal diagnosis (28.1% (95% CI, 14.1–44.7%) vs 96.7% (95% CI, 93.6–98.8%)) (IRD, 73.4% (95% CI, 53.9–92.7%); Z = –7.4066, P < 0.001).*
>
> ***Conclusions***
>
> *Prenatal diagnosis of vasa previa is associated with a high rate of perinatal survival, whereas lack of an antenatal diagnosis significantly increases the risk of perinatal death and hypoxic morbidity. Further research should be undertaken to investigate strategies for incorporating prenatal screening for vasa previa into routine clinical practice'*

8. The 2019 article by Dr Yinka Oyelese on this subject provided fuller analysis and relevant evidential references. *See* *https://doi.org/10.1016/j.ajog.2019.08.034*. The below quote from that article particularly resonates, and I would ask that the NSC has the below at the forefront of its mind now:-

> '*There is perhaps no other condition in which prenatal diagnosis makes such a profound difference between survival and death for the fetus and/or neonate. Ultrasound is now universally used, and while it will detect countless conditions, very few, if any, of these conditions allow for a clear simple intervention to save fetal lives, as does the prenatal diagnosis of vasa previa. Given that ultrasound is so accurate in the prenatal diagnosis of vasa previa and that there is an effective intervention to prevent perinatal death, it is time that there is a more universal approach of screening and diagnosis of this condition. There are those who argue that a randomized controlled trial must be conducted before instituting such a policy. Unfortunately, given the relative rarity of this condition, a randomized trial will not be possible, and even if it were, in my opinion, it would be ethically unacceptable to allow babies to die a preventable death when there is clearly evidence of the accuracy of diagnosis and the effectiveness of the intervention in preventing perinatal death'.*

9. It must be asked, given the compelling evidence available by 2020 (pulled together so effectively in the above reports) why did the NSC not review it's screening policy at that juncture? Why has it taken more than 5 years since the 2017 NSC review for the NSC itself to commission studies that were deemed necessary back in 2017? That delay has already had catastrophic consequences for so many families.

10. I suspect much of the UK population would share the view that it is '*ethically unacceptable to allow babies to die a preventable death when there is clearly evidence of the accuracy of diagnosis and the effectiveness of the intervention in preventing perinatal death'.* The reality however is that most of the UK population do not know that this condition exists, and in turn, are denied the opportunity of opting into screening for it (whether that be state funded or privately funded). That must change.

11. Astonishingly there is, again, suggestion in the latest NSC consultation 'evidence map' material (released in March 2023) that that the implementation of screening should, once again, be delayed for another three years allowing more time for more research. This is, in my respectful submission, simply unacceptable and unconscionable. Changes in practise and policies are needed now. Action is needed now. The UK and our NHS is falling so far behind the practises of other countries and now must have regard to the international data available and the greater success other nations have in preventing death and harm from this condition.

12. The simple fact is that NHS maternity care is not utilising readily available technology, to maximise safety and save lives. The technology does now exist, and is available in all hospitals, to screen for VP and features of it. We know that colour doplers are particularly effective and capable of detecting VP and the warning signs for it, yet sonographers are not routinely using the technology which is, literally, in their hands, to do this.

13. I note in Canada that guidance recommends that:-

'The position of the placental cord insertion should be clearly documented during the routine second trimester sonographic examination, with use of transvaginal sonography as needed, to screen for marginal and velamentous cord insertion as well as assessing the proximity of these variants to the cervical os'.

That practise alone seen as being effective in identifying antenatally most women at risk of vasa previa. Such imaging practices deemed unlikely to miss this diagnosis. (see *Jain V, Gagnon R, Guideline No. 439: Diagnosis and Management of Vasa Previa Journal of Obstetrics and Gynaecology Canada (2023), doi: https://doi.org/10.1016/j.jogc.2023.05.009*. I would encourage the NSC to consider in full the approach taken by Canada and review this document in it's entirety.

14. Whilst the UK continues to have such a poor maternity safety record, yet further delay, drift, contemplation and inaction is not the solution. The evidence re the clear merit in screening for VP was evident in 2017, the evidence was overwhelming by 2020, and the picture is even clearer now, thanks also to the latest joint expert paper entitled *'The case for screening for vasa previa: time to implement a life-saving strategy'* prepared *by Y. OYELESE, and London based experts C. C. LEES and E. JAUNIAUX. (see Ultrasound Obstet Gynecol 2023; 61: 7–11, Published online in January 2023* *https://obgyn.onlinelibrary.wiley.com/doi/10.1002/uog.26085*.
That recent article meticulously references a total of 50 other earlier publications, all of which can be accessed through the above link. I would encourage the NSC to fully consider not only the above reports, but also, in turn each of those 50 referenced publications also.

15. In my view, as a mother, as a patient, and a child protection professional, is that the evidence collated, considered, and analysed by Doctors Oyelese, Lees and Jauniaux, is extensive and compelling. It makes abundantly clear that there is much research, and much data already available, which very clearly evidences a long standing ability to screen effectively for VP utilising modern sonography technology. The following statistics quoted therein (from a broad evidential base) are striking:-

    - *Epidemiological data from different countries indicate that the prevalence of VP could be as high as 1 in 1200*
    - *A prospective study of 26 830 pregnancies in the UK identified 21 cases of VP confirmed at birth, corresponding to a rate of 1 in 1278 pregnancies*
    - *The authors estimated that, if no cases of VP had been diagnosed antenatally, 50% would have resulted in stillbirth, and that antenatal screening for* ***VP would prevent around 10% of stillbirths from all causes****.*
    - *There are around 700 000 births per year in the UK, with a rate of one case of VP per 1278 pregnancies approximately 550 pregnancies present with VP annually. As the perinatal mortality of undiagnosed VP is around 56%* ***over 300 perinatal deaths from VP could be prevented every year in the UK.***

16. It must also be emphasised that stillbirth rates associated to VP are only one part of the picture. Of those babies who survive birth many will have short lives, or suffer life limiting brain damage with Hypoxic-Ischemic Encephalopathy (HIE) commonly associated with VP cases. Many babies will undergo the trauma of resuscitation, blood transfusion, and require intensive care, often including 'Therapeutic Cooling' to try to minimise further brain damage occurring as a result of the reduced blood volume and oxygen supply caused by VP. We

know than only a minority of those babies will escape brain damage and the associated health conditions; thereafter requiring life long medical and social care intervention and support in education. The human and financial costs of that should also be acknowledged.

17. It should also be highlighted that almost all cases of VP undiagnosed prior to labour will have the severe adverse outcomes which fall under the HSIB Maternity Investigation Programme criteria, and should have been notified to HSIB. Whilst there may well be some underreporting, HSIB should still be well placed to assist this consultation with further insight into the occurrence rate of suspected VP, correlating risk factors, and statistics regarding the health consequences of it. During this NSC consultation period I have lodged with HSIB a FOI request for relevant data (see Exhibit 2). That request for data was first made back in November 2022, with more precise questions put to HSIB on 5th April 2023, and was copied to the NSC at that time. Regrettably, at the time of drafting on 3rd June (the final day of this consultation), a response from HSIB is still awaited and now weeks overdue. It can however be confidently estimated, given the known occurrence rate of VP, and the known adverse consequences of if, is that up to 250 babies each year suffer varying degrees of HIE as a result of the condition, in addition to the estimated 300 deaths.

18. I note that further recent literature of relevance and assistance now includes the recently published NSC funded report entitled *'The Impact of ultrasound-based antenatal screening strategies to detect vasa praevia in the United Kingdom: An exploratory study using decision analytic modelling methods' prepared by Benjamin Ruban-Fell, George Attilakon, John Marshall and multiple professional colleagues.*
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0279229 .

    I very much welcome the fact that a study has been commissioned, particularly in light of the fact that the 2015 UKOSS research was never completed / published, and UKOSS have confirmed they have done no further studies over recent years. I note the discussion / analysis therein re how targeted screening (of different forms, with different approaches) will save many, but not all of those lives. We must ask ourselves, are any avoidable deaths tolerable? Should we not be implementing universal screening to catch all cases of VP until such time as 'targeted screening' is 100% effective? If any mother is to be denied the option of screening on the NHS shouldn't they at least been advised of the condition and made aware of the option to fund that screening privately if they so wish?

19. I find the content and recommendations set out in the Costello Medical 'evidence map' (dated January 2023) astounding. There is an erroneous statement by Costello Medical that '*there is insufficient published literature to justify further work on screening for VP'; which appears* nonsensical when you consider the abundance of publications there are on this issue internationally and when you cross reference to the other recent articles / reports referred to above. Perhaps Costello Medical has not seen / considered those before producing the 'evidence map'. It is very clear that there is current, and has long since been, an abundance of literature and research to evidence the massive benefits to be derived from screening for VP, to evidence the catastrophic consequences of not screening, and to evidence the success of screening in preventing entirely avoidable deaths. There is now also much data to allow some comparison of the respective effectiveness of the different targeted screening approaches. Costello Medical, astonishingly, appear to be recommending that there be no screening programme at all, and the matter not revisited again for a further 3 years. The Costello 'evidence map' concluding with the following sentence.

'On the basis of this evidence map, the volume and type of evidence related to screening for VP is currently insufficient to justify an update review at this stage and so should be reconsidered in 3 years' time'.

We know that circa 1000 infant lives will be lost, and the lives of their parents, siblings and wider family members, will, needlessly devastated, and that 100's of children will suffer brain damage (needlessly) over the next three years if the recommendation of Costello Medical were to be followed. That can not be right.

20. The clear way forward is for screening to be immediately introduced without further delay, and for all expectant mother's to be told about this condition and thereby empowered to make their own decisions re whether they do or do not want to engage in screening. Any of the screening options put forward would be far far better than the current 'not screened for' position. The only valid question appears to be if / how targeted screening only can hereafter be made more effective and catch the maximum number of cases, comparable to the universal screening option. None of the eminent experts, only the Costello Medical report, suggests that 'no screening' is an appropriate way forward. Yes, more research and evidence collation can and should be undertaken to perfect and improve screening over future years, but screening must be introduced forthwith, informed by the abundance of evidence already available.

21. Other sources of data (if more were needed), which might assist with fuller understanding of VP, and how to effectively identify it antenatally, would include records from the histology labs assigned the task of placental analysis. We note that Greentop Guildline 27b already requires as follows in relation to cases of suspected Vasa Previa, that

    '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'.

    It is unclear to me what research or statistical analysis is undertaken in those regional labs, from the placental analysis done in them. Or indeed if there is any cross referencing to retrospective analysis of antenatal scan images that are held by the treating trust. A FOI request was lodged with our local regional lab at XXXX during the course of this consultation. It is evident from the FOI response answers that the lab hasn't yet collated statistical data, but evidently this could be done if needed. (see Exhibit 3). Better collation of data may have may be of assistance in better understanding the correlating presentations and risk factors of VP in the longer term, in turn inform a more effective programme of targeted screening. In the meantime universal screening is the clear immediate way forward to save lives and prevent harm. Further research can run alongside effective screening in the interim.

22. There is evidently no confidence, yet, that target screening alone will in fact be fully effective or would still result in unacceptable harm and death. **There is however confidence that universal screening would be highly effective. My own clear view, looking at the statistics, is that the introduction of universal screening is essential and required urgent roll out. It should be offered on a universal basis to all women who wish to opt in to it. Screening should not be denied to any pregnant mother unless and until a programme of targeted screening is shown to be fully effective**. 1000's of children have been lost and harmed over recent years as a result of the 'no screening policy'. Every day that goes by those numbers increase. More avoidable harm, more avoidable loss.

23. I would encourage the NSC to fully reflect upon the entirety of the recent Y Oyelese, C.C. Lees and E. Jauniaux report; and I specifically highlight the following text / points from that report which strike me as being compelling:-

    - '*Significant health resources are dedicated to prenatal screening programs with the intention of detecting severe abnormalities, preventing stillbirths and improving perinatal outcomes. Many conditions that are screened for routinely are much rarer than VP. For example, spina bifida, anencephaly, omphalocele and encephalocele occur in approximately 1 in 1724, 2008, 3846 and 7299 births, respectively; the corresponding screening value for these conditions has apparently never been challenged. Furthermore, for most of these conditions, prenatal diagnosis has little impact on survival rates and long-term outcome'.*
    - *'Only the UK RCOG recommends against screening for VP under any Circumstances'*
    - *'Routine screening vs targeted screening for VP - Routine identification of the placental cord insertion at the mid-trimester transabdominal anomaly scan, as is recommended by the USA guidelines together with a CDI sweep of the region over the cervix, is a highly effective approach for universal VP screening. In the absence of this, targeted screening is better than no screening at all' .*
    - *'…, given the high mortality associated with VP if undiagnosed prenatally, the high accuracy of ultrasound screening for VP and the almost universal survival of prenatally diagnosed fetuses delivered by CS, there is a strong case for introducing widespread VP screening. A qualitative survey of women with VP found that those diagnosed at delivery would have wanted to receive an antenatal diagnosis with ultrasound, and felt it was a failure of the medical system when this was not achieved'*
    - *'Screening for VP reduces adverse perinatal outcomes, including stillbirth and neonatal death, as well as long-term neurodevelopmental impairment from VP and the corresponding devastating psychosocial trauma for parents. There are no other conditions in which prenatal diagnosis makes such a profound difference between survival and death. It is time to implement widespread screening for VP'.*

24. Within my 5th December 2022 submissions to the NSC (during the 'annual call for topics') I reflected upon the UK's failure to meet (or even come close to) stated national targets, and it is appropriate to again reflect upon that now:-

25. In 2015 the government set out an ambition to reduce the rates of stillbirths, neonatal deaths, maternal deaths and brain injuries in babies that occur during or soon after birth by 50% by 2030, and this target was then brough forward to 2025 in the 'Long Term Plan'. I note that to deliver on this ambition, and the earlier vision set out in Better Births report of February 2016, NHS England established the national Maternity Transformation Programme launched in July 2016. I note that Each Baby Counts was the RCOG's national quality improvement programme to reduce the number of babies who die or are left severely disabled as a result of incidents occurring during term labour.

26. We are not on track to meet that target, as is show by the ONS date and the table below

Year	Stillbirth mortality rate, per 1000 births	Neonatal mortality rate (of babies born at 24 weeks or over) per 1000 births
2015	4.4	1.6
2016	4.3	1.6
2017	4.1	1.6
2018	4.0	1.5
2019	3.8	1.4
2020	3.8	1.3
2021	4.1	1.4

https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/bulletins/childhoodinfantandperinatalmortalityinenglandandwales/2021#:~:text=The%20neonatal%20mortality%20rate%20ambition,live%20births%20(Figure%202).

These figures could have been significantly improved with a VP screening programme.

27. I note that the ONS's reports and response to FOI request (XXXX XXXX) provided us with the following data re still-births

    2021 - 2,597 babies
    2020 - 2,371 babies
    2019 - 2,522 babies
    2018 - 2,689 babies
    2017 - 2,873 babies.

    https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/livebirths/bulletins/birthsummarytablesenglandandwales/2021

    https://www.ons.gov.uk/aboutus/transparencyandgovernance/freedomofinformationfoi/stillbirthandmiscarriagedatafrom2015to2022

    Those statistics are horrifying, and clearly illustrate the current failures to meet maternity targets. We now known that all of those figures could have been 10% lower had there been a screening programme in recent years.

28. We know that HIE brain damage often causing life long disability is the alternate consequence of VP not being diagnosed prior to labour. We know that screening will significantly reduce those figures also. In turn also providing cost savings for the NHS re the immediate and lifelong care and support those children and their families will require; and more fundamentally and importantly, affording those children normal and healthy lives. Perpetuating the NSC 2017 'not screened for' decision will do nothing to reduce the above figures, it will lead to further loss, and further immeasurable and unconscionable pain and suffering. That can not be right. That can not be an acceptable way forward.

29. NHS maternity services have been heavily criticised in the Ockenden and Kirkham reports, and much work needs to be done to improve services, and for targets to be achieved and that steps should be being taken to save lives wherever possible, following up on all identified categories of avoidable deaths / avoidable harm, including VP. The need for rapid and significant improvements in our NHS maternity services is well established, and indeed recent publications by the CQC has again highlighted that progress has been much too slow and much still needs to be done. The concept of 'each baby counts' is universally supported, and few would tolerate any policy by the NHS that sacrifices the lives and health of neonates and expectant mothers; as does the current policy on Vasa Previa screening.

30. Introducing proper screening from Vasa Previa in the NHS, is clearly an area that would have the immediate impact of reducing neonatal death and significant harm to hundred's of babies each year. It can not be appropriate for the NHS to tolerate these entirely avoidable deaths / entirely avoidable instances of birth trauma, and severe brain injury. It must be acknowledged that the care needed by brain damaged infants, and the practical and psychological support needed by families who have / continue to suffer as a result of the lack of screening in itself is massively costly to the NHS and the long term costs of this harm to the NHS and other public services that have to 'pick up the pieces' of such loss and trauma need to be properly acknowledged and considered.

31. More fundamentally, I would assert that any decision not to screen and accept neonatal deaths / harm from this condition is morally wrong, as is withholding from parents knowledge of the existence of this condition denying them the opportunity to seek a privately funded scan if not offered on the NHS.

32. **Any decision by the NSC to simply accept the occurrence of entirely avoidable neonatal deaths / harm, would in my respectful submission, be in direct contravention to the core principles of the 'Maternity Transformation' and 'Each Baby Counts' programme, and is only contributing the lack of success in meeting stated maternity national targets.** It must now be acknowledged that many infant lives are being lost as a result of the absence of any effective screening within the NHS and this is unacceptable when this is now well established as a 'avoidable obstetric tragedy'.

33. The implementation NOW of universal screening is a very immediate way to make a massive improvement in our maternity outcomes nationally. Immediate reductions in still births, neonatal deaths and harm would be seen under any of the screening options. Universal screening can be fully effective in preventing all death and harm from VP. The associated strain on NICU, paediatric, and postnatal services and a variety of wider mental health and social care services would in turn reduce over time. More fundamentally, the devastation caused from the negative outcomes of VP can be eliminated. That has to be desirable. That has to be pursued without further delay.

Yours faithfully

XXXX XXXX
XXXX

Enc:

Exhibit 1 (Earlier 5/12/22 referral to NSC, to be read in conjunction with this response) – see email of 5/12/22

Exhibit 2 (5/4/23 FOI request to HSIB) – previously copied to NSC

Exhibit 3 XXXX response.

Exhibit 1

XXXX XXXX
XXXX XXXX
XXXX
XXXX
XXXX
XXXX

5th December 2022

BY EMAIL - screeninginformation@dhsc.gov.uk

National Screening Council

Referral re Maternity Care - Proposed National Screening for Vasa Previa

- name of topic - **Referral re Maternity Care - Proposed Antenatal National Screening for Vasa Previa**
- type of screening proposed - expectant mothers population (antenatal care)
- your name – XXXX XXXX
- your organisation, if any – n/a
- your email address – XXXX XXXX
- summary of your proposal and why the topic is within the remit of the UK NSC (up to 200 words) & a summary of the condition, the test and the treatment (up to 500 words)

I understand that NSC is responsible for determining the nature and scope of maternity screening in the UK.

I write in order to request that there be a formal review of UK screening programme for Vasa Previa in the UK which has not been considered since 2017.

Vasa Previa is a rare but serious condition where exposed blood vessels from the umbilical cord lie across the cervical during pregnancy or unprotected. Vasa previa can occur on its own with placental abnormalities, such as a velamentous cord insertion. A velamentous umbilical cord is characterized by membranous umbilical vessels at the placental insertion site; the remainder of the cord is usually normal. Membranous vessels can arise as aberrant branches of a marginally inserted umbilical cord or they can connect lobes of a bilobed placenta or the placenta and a succenturiate lobe. Because Wharton's jelly does not surround and thereby protect the vessels, they are prone to compression and rupture, especially when they are located in the membranes covering the cervical os (ie, vasa previa). These complications increase the chances of perinatal

mortality and morbidity. If a case is undiagnosed and the baby is born naturally, the blood vessels can rupture, which could lead to fetal exsanguination (complete blood loss), often within 10 minutes, thus fatal for baby. Or if baby is delivered rapidly (by emergency c-section) before exsanguination, and in receipt of prompt transfusions, often the baby is often left with severe brain damage from the period of depleted blood supply / oxygen.

Ultrasound screening for VP during the second trimester is now known to be a very effective means of identifying vasa previa antenatally, and can be done at the routine mid-pregnancy scan, without need for additional appointments.

I write to the NSC at this stage as a mother who, in XXXX 2021, following the birth of her daughter, was told that there had been significant life threatening blood loss to her baby daughter as a result of Vasa Previa. I had never head of Vasa Previa. I received the Vasa Previa diagnosis, post labour, as my child was fighting for her life, and being subjected to 'therapeutic colling'. As a Child Protection professional I was astounded, in the hours that followed, to learn that the emergency had been preventable, and Vasa Previa is capable of being diagnoses on scan, yet there is no programme screening for this condition in the UK.

There is clear evidence to show that the NHS's decision not to screen for Vasa Previa is costing lives, being fatal in most cases for the infant, where not diagnosed antenatally. In those cases where the baby is 'saved' by emergency c-section, the baby has still encountered a lack of blood and oxygen, and remain at massive risk of life limiting brain damage.

Conversely, it is now well established that in cases where there is early detection antenatally, and a suitably tailored care plan for early / planned c-section, there is in the vast majority of cases a positive outcome with no harm to baby. It is also the case that the technology exists, and is present in all hospitals, to undertake the relevant screening during routine mid-pregnancy antenatal scans.

- <u>any evidence showing benefit from screening, ideally from a randomised controlled trial (RCT) – Please see below</u>
- <u>up to 10 references to support your application – Please see below</u>

I note that the UK NSC screening recommendation re Vasa Previa are currently based on the last UK NSC review of this condition that occurred in August 2017 (over 5 years ago). At that time, it was note that there was a gap in available evidence to recommend a screening programme, the report noting 'this review has not found sufficient evidence to support a change in the overall recommendation for VP screening. 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 other reasons given for not screening for Vasa Previa were as broken down further as follows:-

'Screening women for vasa praevia during pregnancy is not recommended because:

(a) it is not known how many babies are affected by it in the UK
(b) it is not known how accurate screening tests are at detecting it
(c) screening may mean some women are offered an early caesarean when they do not need one
(d) some women may be reassured by false tests and still have a problem during delivery'

None of those points remain valid today, and the NHS itself has now had 5 years to complete the required studies and data collation it was said was necessary back in 2017. I am unclear whether the NHS has in fact completed the 'large scale, well designed, prospective studies' it was said was necessary? In any event, it appears that there are now, from other sources, relevant data and studies that can be utilised as part of a now overdue review. I note that the NSC website stated that *'Next review estimated to be completed: 2021 to 2022'.* As the review is now overdue and I would invite the NSC to undertake this urgently.

Within the submissions below I highlight examples of the abundance of data and research now available re the rates of Vasa Previa, the increase instances of it amidst the increased in IVF conception, and the drastically different outcomes that present when there is antenatal diagnosis. I shall also highlight our own example of how the trauma and harm caused by not being screened, in illustrating that this far outways any anxiety that might be caused by adding this condition to conditions routinely looked for at antenatal screening.

Further, we already known from the Ockenden and Kirkham reports that the pursuance of 'natural births' should not be prioritises over safe births, and thus point (c) above is clearly not currently a valid point and every patient had the right to make informed choices about whether they do / do not wish to opt for a caesarean section armed with the best available data re their own health / risk factors, and that of their unborn baby.

It is clearly imperative that there be an urgent and thorough review of this NHS policy not to screen for Vasa Previa. **Without screening the NHS will continue to see entirely avoidable neonatal deaths, and the occurrence of severe brain damage to infants, devastating the lives of hundreds of families.**

It is well established that our NHS is failing mothers and newborns, on several levels, and I would submit that denying mother's screening for Vasa Previa, and also denying mother's any information about the existence of this condition and any risk factors they may have, is inappropriate and contributing to unacceptable death rates and unacceptable rates of brain damage to neonates.

It is relevant to highlight the wider policy targets that the NHS is faced with. I note that in 2015 the government set out an ambition to reduce the rates of stillbirths, neonatal deaths, maternal deaths and brain injuries in babies that occur during or soon after birth by 50% by 2030, and this target was then

brough forward to 2025 in the 'Long Term Plan'. I note that to deliver on this ambition, and the earlier vision set out in Better Births report of February 2016, NHS England established the national Maternity Transformation Programme launched in July 2016. I note that Each Baby Counts was the RCOG's national quality improvement programme to reduce the number of babies who die or are left severely disabled as a result of incidents occurring during term labour. I note that the NHS maternity services have been heavily criticised in the Ockenden and Kirkham reports, and much work needs to be done to improve services, and for targets to be achieved and that steps should be being taken to save lives wherever possible, following up on all identified categories of avoidable deaths / avoidable harm, including Vasa Previa.

The need for rapid and significant improvements in our NHS maternity services is well established, and indeed recent publications by the CQC has again highlighted that progress has been much too slow and much still needs to be done. The concept of 'each baby counts' is universally supported, and few would tolerate any policy by the NHS that sacrifices the lives and health of neonates and expectant mothers; as does the current policy on Vasa Previa screening.

It is to be noted that many expectant mothers are not aware of the existence of Vasa Previa, or aware that this is a known condition that jeopardises the lives of mother and baby, and is often fatal for baby, that the NHS has chosen not to screen for. It is, in my view, entirely inappropriate that parents are not advised of this condition and in turn able to make informed choices about whether they wish to pay privately for screening for the condition if it is not being offered by their NHS trust.

I would argue that introducing proper screening from Vasa Previa in the NHS, is clearly an area that would have the immediate impact of reducing neonatal death and harm to hundred's of neonates. It can not be appropriate for the NHS to tolerate these entirely avoidable deaths / entirely avoidable instances of birth trauma, and severe brain injury. It must be acknowledged that the care needed by brain damaged infants, and the practical and psychological support needed by families who have / continue to suffer as a result of the lack of screening in itself is massively costly to the NHS and the long term costs of this harm to the NHS and other public services that have to 'pick up the pieces' of such loss and trauma need to be properly acknowledged and considered. More fundamentally, I would assert that any decision not to screen and accept neonatal deaths / harm from this condition is morally wrong, as is withholding from parents the existence of this condition denying them the opportunity to seek a privately funded scan. **Any decision by the NSC to simply accept the occurrence of entirely avoidable neonatal deaths / harm, would in my respectful submission, be in direct contravention to the core principles of the 'Maternity Transformation' and 'Each Baby Counts' programme, and is only contributing the lack of success in meeting stated maternity national targets.** It must now be acknowledged that many infant lives are being lost as a result of the absence of any effective screening within the NHS and this is unacceptable when this is now well established as a 'avoidable obstetric tragedy'.

The points made back in 2017 NSC report that '*(a) It is not known how many babies are affected by it in the UK, and (b) it is not known how accurate screening tests are at detecting it are no longer accurate.* It is clear that technology and the pool of available data and research has moved on significantly since the 2017 report. Whilst back in 2017 / 2018 it was not felt there was sufficient data and evidence available to warrant a screening programme, that is simply no longer the case.

As early as 2018 the RCOG noted as follows re numbers:

> ***'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'. (*Vasa Praevia: Diagnosis and Management (Green-top Guideline 27b)Green-top Guideline No. 27b**)

It appears that there was also a UKOSS study but I have been unable to obtain the results of that, which may now in any event be outdated. See https://www.npeu.ox.ac.uk/ukoss/completed-surveillance/vp

Much more data is now available and shows that the rate of occurrence is at the higher end of the scale estimated by the RCOG back in 2018 and likely to be increasing as the average age of parenthood increases, and more babies are being born through IVF.

I include below some data from more recent published research for ease of reference:-

> **Published report - '*Vasa previa and associated risk factors: a systematic review and meta-analysis (Sureka Pavalagantharajah, Linda A Villani, Rohan D'Souza)' (found at https://pubmed.ncbi.nlm.nih.gov/33345868/), published April 2020*,** which notes the rates of occurrence to be at 0.46 cases per 1000 deliveries:-
>
> *'**Results:** We included 21 studies that reported 428 pregnancies with vasa previa of 1,027,918 deliveries (0.46 cases of vasa previa per 1000 deliveries). These studies fared well on risk of bias assessment using the Study Quality Assessment Tool for Case Series Studies of the National Heart, Lung, and Blood Institute. The prevalence and 95% confidence intervals of known risk factors for vasa previa included a low-lying placenta (61.5%, 53.0%-70.0%), velamentous cord insertion (52.2%, 39.6%-64.7%), bilobed or succenturiate lobed placenta (33.3%, 20.9%-45.7%), use of in vitro fertilization (26.4%, 16.0%-36.8%), and multiple gestation (8.92%, 5.33%-12.5%).*
> ***Conclusion:** Vasa previa affects 0.46 cases per 1000 pregnancies. Given the high prevalence of prenatally detectable risk factors in affected pregnancies, the cost-effectiveness of screening strategies for vasa previa either in isolation, using a risk factor-based approach, or universally, in tandem with cervical-length screening using transvaginal ultrasound, should be revisited.'*

That figure of a rate of occurrence at 0.46 cases per 1000 is consistent with a variety of other research and data sources that can be readily now accessed online.

Amidst a birth rate in the UK of circa 625,000 per year, it follows that there will be between 300 and 400 cases each year of Vasa Previa in the UK, threatening the lives of mother and baby, and substantial devastating loss and harm is arising for many of those families in the absence of screening.

No doubt the NHS now has its own data source and hopefully has done the study it identified as being needed in 2017. I note that HSIB are amongst the body's which will now have collated each year since 2018, data in relation to cases of confirmed or suspected Vasa Previa. In recent weeks I have asked HSIB for their support and provision of relevant information, which has not yet been forthcoming. However, no doubt, the NSC could liaise with HSIB, re this, and also with the individual Trusts, the RCOG, and CQC, and HM Coroners, in relation to the statistics they may be able to provide re:-

- the occurrence rates of confirmed or suspected Vasa Pevia cases (which external research puts at 0.46 per 1000 deliveries and circ 1 per 200 in cases of IVF, with other known risk factors which increase the rate).
- The known or estimated rates of infant death, and rates of therapeutic cooling and brain damage arising out of these cases
- accurate understanding of the psychological harm caused to families and cost to the NHS of services needed re the same

- accurate understanding of the physical demands and costs incurred on the NHS as a result of the subsequent medical interventions needed in those cases, such as therapeutic colling, extended periods in neonatal or paediatric intensive care, and treatment and care for long term care for brain damaged children.

In relation to the difference that screening can make, I would direct the NSC to Further research entitled **'Perinatal outcome of pregnancies with prenatal diagnosis of vasa previa: systematic review and meta-analysis (W. Zhang,S. Geris,N. Al-Emara,G. Ramadan,A. Sotiriadis,R. Akolekar) First published: 31 July 2020' can be found at https://obgyn.onlinelibrary.wiley.com/doi/10.1002/uog.22166;** which states as follows regarding the drastically different outcome for mother / baby if Vasa Previa is diagnosed antenatally:-

> *'.. the risk of perinatal death was 25-fold higher when a diagnosis of vasa previa was not made antenatally, compared with when it was (odds ratio (OR), 25.39 (95% CI, 7.93–81.31); P < 0.0001). Similarly, the risk of hypoxic morbidity was increased 50-fold in cases with vasa previa without a prenatal diagnosis compared with those with a prenatal diagnosis (36/61 vs 5/224; OR, 50.09 (95% CI, 17.33–144.79)). The intact perinatal survival rate in cases of vasa previa without a prenatal diagnosis was significantly lower than in those with a prenatal diagnosis (28.1% (95% CI, 14.1–44.7%) vs 96.7% (95% CI, 93.6–98.8%)) (IRD, 73.4% (95% CI, 53.9–92.7%); Z = –7.4066, P < 0.001).*
>
> ***Conclusions***
>
> *Prenatal diagnosis of vasa previa is associated with a high rate of perinatal survival, whereas lack of an antenatal diagnosis significantly increases the risk of perinatal death and hypoxic morbidity. Further research should be undertaken to investigate strategies for incorporating prenatal screening for vasa previa into routine clinical practice. © 2021 The Authors. Ultrasound in Obstetrics & Gynecology published by John Wiley & Sons Ltd on behalf of International Society of Ultrasound in Obstetrics and Gynecology'*

There is an abundance of wider research and publication now available. For eg see link via https://www.sciencedirect.com/topics/medicine-and-dentistry/vasa-previa, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4870668/

I feel it is also important, in lodging this referral for review of the screening programme, to not only refer the NSC to the data now available, but also to give the NSC insight into the harm caused in our case, as a case example. I feel it is important that those who will make the decision as to whether or not screening is introduced to be aware of the and despair families feel when told their baby is the victim of an entirely preventable emergency. The despair, anger and frustration we felt at being told in XXXX 2021 that it could all have been avoided by screening can not be overstated and I would ask the panel to consider how they would feel if they, their partner, their child, had been the victim of this. Please also read the below, conscious of the fact that may other families are, to this day, having similar or indeed much worse experiences as a result of the ongoing absence of screening for Vasa Previa:-

Below is a brief summary of our case:-

> In my case, an APH the circa 10 hours before the birth was not acted upon by medical staff, and further significant bleeding then occurred immediately upon artificial rupture of membranes at 12:19pm the following day, which the treating team suspected was Vasa

Previa and therefore progressed to an emergency category c-section with transfer to theatre commencing at 12:27. There is a sense all consuming fear and dispair that engulfs a parent as the flood of blood is observed and the babys heart rate jumps and then drops amidst the loss of blood supply. That fear and the sense of helplessness is something that will always be prevalent in my memories and haunt me forever and it is distressing to know that other women continue to go through this in our NHS.

My daughter was born 22 minutes later at 12:41, floppy, unresponsive, not breathing, and requiring resuscitation and blood transfusion with severe brain trauma suspected. Blood transfusion was administered 29 minutes after birth (some 51 minutes after the foetal blood loss at ARM amidst a lack of available blood supply). Significant maternal blood loss also then followed measured at 3.6l. Maternal blood transfusion was effected, whilst my daughter also received transfusion and was simultaneously being ventilates, and 'cooled'.

As I awoke from the General Anaesthetic, still groggy, I was told that my daughter has suffered blood loss as a result of Vasa Previa and that 'therapeutic cooling' (therapeutic hypothermia with intracorporeal temperature monitoring for hypoxic perinatal brain injury) had been commenced alongside lifesaving resuscitation and blood transfusion, and she was now being treated and ventilated elsewhere in the hospital and I was unable to see her at that time. I was told that she would be transferred to an alternate hospital, without me, to undergo further therapeutic cooling for 72 hours starting that evening. As I began to process this information, I asked the question 'could / should this have been detected on scan'. I recall the sense of raw dismay and despair and anger as I subsequently learnt from discussions and basic research that yes, this condition is readily detectible antenatally, and could be looked for at the routine antenatal scans that all women have, but is not looked for. I had a total of 7 scans during my pregnancy as a high risk patient. How is it that the opportunity to look for this condition was not taken on any of those 7 occasions. The technology does now exist, and is readily available in all hospitals, to screen for Vasa Previa and features of it. Colour doplers are particularly effective and capable of detecting vasa previa and the warning signs for it, yet sonographers are not routinely using the technology which is, literally, in their hands, to do this.

My daughter was taken from XXXX XXXX to XXXX and as she left with the transportation team we were petrified we would not see her again, and prohibited from going with her (amidst covid restrictions and my own poor postoperative condition). Her father only being allowed to follow in the early hours of the following morning and myself 8 hours later.

Over subsequent days that followed, my daughter underwent the trauma of her intrusive and painful treatment, and lay being 'therapeutically cooled' in an incubator, metal probes in her head monitoring her for seizures, tubes through her stomach, with fluids and morphine being administered, probes measuring temperature, and our entirely family petrified that we would lose her or that she has suffered catastrophic / life changing brain injuries. We spent those days looking for any sign that she was responsive, able to see, able to hear. Those initial days and hours were harrowing, and the trauma of the same have had a long lasting impact that continues to this day. She was denied any physical contact over that period and clearly in distress and being medicated with morphine to try to manage the same.

Nothing I can draft her can fully and accurately convey the degree of this trauma and the anguish and raw anxiety created by these circumstances, as parents have to wait to see

and go through stages of fearing whether their baby will ever wake up, ever be able to breath on their own, move independently, communicate. Parents watching the C-fab monitors and trying to interpret what is shown, and what condition their baby is in, what pain they are in, what prognosis they have.

Whilst we were being told at the time (and for months later) that the HIE event had been caused by Vasa Previa, and learnt more about the condition, our anxiety, fear and trauma was only exasperated by the knowledge that it could all, very easily, have been prevented and safe delivery effected if only there had been proper scanning and screening for this condition. I recall the intense sense of anger at the NHS, but also at myself, for not researching more during pregnancy, not knowing about the existence of this condition, not myself booking a private screening for this condition. I am trying her, but can never fully convey, the impact of that combination of anger and guilty that I felt of those days, entangled with apprehension and fear. Anger also that there appears to be no national standards requiring hospitals to have established procedures in place to expedite deliveries in suspected Vasa Previa case, and to have emergency blood immediately available in the theatres, despite it being known that failure to deliver in under 10 minutes will likely be catastrophic for baby.

We were immensely grateful for the care and compassion shown by the very professional staff on the neonatal ward at XXXX (being the regional specialist centre), and the time and care they took in explaining to us both the positives and persisting risks that would ensue, including risks of severe disability or cerebral palsy. For the avoidance of doubt, we know that the colling process was necessary once brain injury had been sustained, to help minimise any further harm. The reality is however that the absence of screening for vasa previa subjects many babies and families to the above, when it could easily be avoided.

Such trauma, and the ongoing uncertainties and anxieties, leads to long lasting psychological trauma upon families left with uncertain futures and need for close monitoring of the infant over subsequent months and years as the brain continues to develop. It is only in recent months that we have become reassured that our daughter has no significant physical difficulties arising from her trauma, and we shall continue to monitor for any cognitive / development / neurological difficulties for years to come.

All these months on, we do not have clear answers re whether Vasa Previa was definitely the cause, whether there was an accompanying placental abruption, as has now also been proffered as a potential cause. We know that placental pathology analysis showed marginal cord insertion (a risk factor for Vasa Previa) and placental damage, and know that our daughter survived against all the odds and its very rare for a baby who loses blood supply at the rupture of membranes to then survive (especially when emergency blood wasn't available for 51 minutes thereafter). We will never know whether specific screening for Vasa Previa / associated placental abnormalities such as marginal cord insertion would have prevented the emergency and trauma in our particular case; but what is clear is that a screening programme will, each year, make 100's of pregnancies safer and save lives and save time and time again the kind of trauma we describe above.

In concluding my referral to the NSC, I have chosen to describe these events to the NSC, in an attempt try to convey the reality of the situation faced by parents whose baby survives birth but then needs treatment for the HIE event. In not screening for this condition the NHS is subjecting parents and neonates to this trauma; and in many cases far worse trauma in the entirely avoidable

loss of a baby. The trauma many families experience is far far greater than our own, and there are many 100's of families in the UK who have lost a baby or are now caring for a severely brain damaged child, as a result of the lack of Vasa Previa screening.

Statistically there will be more than 300 cases of Vasa Previa in the UK each year, many of them fatal, many of them resulting in significant brain damage, without proper antenatal screening. That can not be appropriate and can not be allowed to continue to occur, when the ability to detect Vasa Previa antenatally is literally in the hands of the sonographer and the screening can be done as part of existing antenatal scan appointments with ever improving colour dopler technology. I would urge the NSC to fully consider the true and long lasting impact on families of lack of screening, and refer back to the 'every baby counts' principles, not just whether it is financially beneficial to the NHS to screen for this condition. Every day that goes by without that screening will lead to ongoing risk, and the ongoing occurrence of entirely preventable death and harm.

Yours faithfully

XXXX XXXX

Exhibit 2

XXXX XXXX
XXXX XXXX
XXXX
XXXX
XXXX
XXXX

XXXX XXXX
XXXX XXXX

HSIB Governance Team & Freedom of Information Team

Premier House, Second Floor
Caversham Road
Reading
Berkshire
RG1 7EB

Via email - foi@hsib.org.uk

cc: governance@hsib.org.uk

5th April 2023

Dear Sirs

FREEDOM OF INFORMATION REQUEST

Outstanding request for Statistical Data re Vasa Previa cases

As you know I was diagnosed with Vasa Previa (postnatally) following the birth of my daughter in XXXX 2021. My daughter required therapeutic hypothermia treatment with intracorporeal temperature monitoring for hypoxic perinatal brain injury ('Therapeutic Cooling'), as a result of the associated birth trauma and oxygen deprivation (from blood loss occurring immediately upon rupture of membranes).

We requested (but were regrettably not given) any assistance from HSIB in clarifying whether the diagnosis of Vasa Previa (given to us initially and in subsequent correspondence from the Trust) was or was not an accurate diagnosis. To date, we remain unclear as to whether Vasa Previa was, or was not, the primary cause of the medical emergency and trauma that ensued in our case.

In undertaking our own independent research we, as a family, have been dismayed to learn of the large number of infants lost and devastating harmed caused as a result of Vasa Previa each year. We have been similarly dismayed to learn that, despite it being identified by the National Screening Council back in 2017 that more data was needed to inform screening recommendations, that no

organisation has in fact been actively tracking and disseminating data regarding the occurrence rate and consequences of this condition (or at least that data has not, thus far, been disclosed transparently to the public).

HSIB is clearly an organisation able to collate and disclose relevant data, given the active role it has in maternity investigations over the last 5 years.

I note the abundance of medical opinion which indicated that each baby lost / harmed as a result of antenatally undetected Vasa Previa is an entirely avoidable loss / casualty of this often fatal medical condition. The colour antenatal scanning technology which now exists in every hospital throughout the country makes it possible to detect those cases early, and prevent that harm / save those lives. The vast devastation caused by the antenatally undetected instances of this condition is no doubt very clear to your investigators.

As you know, I lodged with the National Screening Council (on 5th December 2022) a referral / submissions re the need for national screening for Vasa Previa (during the NSC's annual call for topics), reflecting the concerns I summarise above.

In advance of lodging my submissions on 5th December 2022 I repeatedly asked, and chased, statistical data from HSIB. I believe that HSIB as an organisation (given its unique remit) must have, and be capable of collating, a wealth of relevant statistical information on this issue. However, regrettably, I was not provided with that assistance from HSIB. Nor have I had, to date, any substantive response to my many chasing emailed (see for eg correspondence of 21.11.22, 2.12.22, 23.1.23, 31.3.23, and 10.2.23). See also my National Investigation proposal (ref 2023/22065) which also made reference to the considerable difficulties thus far encountered in obtaining HSIB's assistance and transparency re HSIB data (I attach a copy here for ease of reference).

It is clear from my previous correspondence with yourselves that my request for data constitutes 'Freedom of Information requests' to HSIB. I note HSIB's legal obligation to assist and provide that data. I write at this stage to, once again, make **that Freedom of Information Request for relevant data re the occurrence rates and outcomes of those Vasa Previa case**. I now also expand upon my original request (of November 2022), with additional tailored questions (as set out in red on pages 4-5 below).

Whilst I note that one of your colleague (XXXX) relayed to me (in email correspondence of 31st January 2023) her prediction that limited relevant data will be held by HSIB, I do not accept that is the case. It can not be the case given the scope of cases which must be referred to HSIB clearly encompasses all cases of infant fatality and all the cases of actual or suspected severe brain damage. It is, sadly, well established that almost all cases of vasa previa (were not diagnosed prior to labour) have those extremely poor and tragic outcomes. It thus follows that HSIB Maternity Investigation Programme must be a clear source of relevant data; albeit as an organisation may not have yet usefully collated or disseminated it appropriately, and may not have seen it to be within its remit nor to verify the accuracy of a Vasa Previa diagnosis in the cases referred to it.

> I note that, HSIB's referral / investigation criteria, published at https://www.hsib.org.uk/what-we-do/maternity-investigations/what-we-investigate, is as follows:-

'Babies who meet our criteria to be referred to us by NHS trusts for investigation include all term babies born following labour (at least 37 completed weeks of gestation), who have one of the following outcomes:

- *intrapartum stillbirth (defined as 'where the baby was thought to be alive at the start of labour and was born with no signs of life').*
- *early neonatal death (defined as 'When the baby died within the first week of life (0-6 days) of any cause')*
- *Potential severe brain injury diagnosed in the first seven days of life, when the baby:*

- *Was diagnosed with moderate or severe (grade III) hypoxic ischaemic encephalopathy (HIE). This is brain injury caused by the baby's brain not getting enough oxygen.*
- *Was therapeutically cooled (active cooling only). This is where the baby's body temperature was lowered using a cooling mattress or cap, with the aim of reducing the impact of HIE.*
- *Had decreased central tone (was floppy) and was comatose and had seizures of any kind*
- *Had decreased central tone (was floppy) and was comatose and had seizures of any kind.'*

I note that the HSIB website currently states, re brain injury

'We no longer routinely investigate cases involving therapeutically cooled babies where there is no apparent ongoing neurological injury following cooling therapy. This would usually mean a brain MRI showing no hypoxic damage (a type of brain injury that occurs when there is a disruption in supply of oxygen to the brain) and the baby demonstrating no ongoing neurological signs or symptoms. However, this remains as one of our criteria. NHS trusts should continue to refer cases to us. We'll decide which investigations proceed based on an individual baby's clinical outcome, after discussion with the family and the NHS trust.)'

We know that all cases of (antenatally) undiagnosed Vasa Previa will result in life threatening blood loss at the point of rupture of membranes. We know that the vast majority of those cases result in baby's death, either in utero or shortly after birth. We know that of those few babies who do survive (through a combination of rapid c-section and prompt blood transfusion post birth), the vast majority of those babies will show signs of HIE through the extremely rapid blood loss they have endured at the point of rupture of membranes. All research tells us that in cases of antenatally undetected vasa previa it is rare that the baby would survive and is almost unheard of that a surviving baby would not show any signs of HIE upon delivery.

Thus (with reference to the above criteria, and known consequences of previously undiagnosed Vasa Previa) all cases of newborns subject to therapeutic cooling amidst suspected Vasa Previa should still have been referred to HSIB in the first instance, even if HSIB does not go on to complete a full HSIB investigation. **Logically therefore HSIB must therefore hold relevant data re not only the cases of**

infant fatality involving Vasa Previa, but also those cases of actual or suspected brain injury; even if not then choosing to fully investigate them all. HSIB should (if the Trusts are reporting as they should) have a record of all cases of Vasa Previa which lead to adverse presentation at birth; even if a decision is later taken (after a reassuring MRI scan and/ or after placental analysis and confirmation of a post-natal Vasa Previa diagnosis) to not then not progress a wider HSIB investigation into the wider circumstances of the case.

Whilst I accept that not all Trusts are always reporting to you as they should, and there may well be a degree of underreporting of these cases to yourselves, I would assume that at least some of the Trusts are following the guidelines and ensuring appropriate reporting of cases to HSIB in line with the referral criteria. **Therefore, you will have relevant data that can be utilised (even if appropriately approached with caution that your statistics may only represent an underreporting).**

You will see that I have already highlighted many of the above points within the referral I made to the National Screening Council on 5th December 2022 (cc'd to yourselves since). I very much hope that efforts have already been made by HSIB over recent weeks / months to start to collate that in order to assist the National Screening Council; who announced the start of their 3 month consultation period at the start of March 2023.

PLEASE CONSIDER THIS LETTER MY FORMAL FREEDOM OF INFORMATION REQUEST, ANSWERING THE FOLLOWING QUESTIONS **WITHIN THE REQUIRED 20 WORKING DAYS:-**

FREEDOM OF INFORMATION QUESTIONS

1) PLEASE PROVIDE ALL STATISTICAL DATA HELD, ALREADY COLLATED, OR CAPABLE OF BEING COLLATED BY HSIB, RE THE KNOW OCCURANCE RATE AND OUTCOMES OF VASA PREVIA CASES, BASED UPON CASES REPORTED TO HSIB SINCE THE INCEPTION / THE COMMENCEMENT OF THE MATERNITY INVESTIGATION PROGRAMME.

In doing so, please consider the below additional specific questions.

2. Re Occurrence of *intrapartum stillbirth*
   a) How many cases of *intrapartum stillbirth (defined by HSIB as 'where the baby was thought to be alive at the start of labour and was born with no signs of life') has HSIB had referred to it? (Please break down figured annually)*

   b) Of those cases, how many of those interpartum still births were known, or suspected, to have involved Vasa Previa?

3. Re Occurrence of *neonatal death*

a) How many cases of early neonatal death (defined by HSIB as 'When the baby died within the first week of life (0-6 days) of any cause'), has HSIB had referred to it? (Please break down the figures annually).

b) Of those cases how many were know, or suspected, to have involved Vasa Previa?

4. *Re Occurrence of potentially severe brain injury*
   a) How many cases involving potential severe brain injury (as defined by HSIB at https://www.hsib.org.uk/what-we-do/maternity-investigations/what-we-investigate/) have been referred to HSIB? (Please break down the figures annually)
   b) Of those cases how many were know, or suspected, to have involved Vasa Previa? (Please break down the figures annually).

5. *Re 'Theraputic Cooling'*
   a) How many cases referred to HSIB involved a newborn who has undergone 'therapeutic cooling'?
   b) How many of those cases involved a suspected or confirmed diagnosis of Vasa Previa (whether that be Vasa Previa diagnosed antenatally, during labour, or postnatally)?
   c) Of those cases how many newborns have reassuring MRI scans following the 72 hour colling period, and how many have non-reassuring MRI scans indicative of brain damage?

6. *Is HSIB confident that it is always informed of all cases of actual / suspected Vasa Previa (which have adverse outcomes falling under its criteria) or are there any concern that such cases are not referred consistently or otherwise under reported to HSIB?*

7. *When a Trust reports to HSIB a case involving suspected case of Vasa Previa what steps, if any, are taken by HSIB to confirm that diagnosis? Does HSIB (always or ever) seek to independently verify the diagnosis via for eg*

   i) sight of the histological reports re the placenta
   ii) via scan review, or
   iii) otherwise undertaken any independent review of the accuracy of that diagnosis?

8. *Is HSIB willing to share with the NSC and or other investigatory bodies a list of cases of confirmed and / or suspected cases of Vasa Previa so that the same might be appropriately retrospectively reviewed and learnt from? (I note that HSIB has declined to undertake its own such national review of these cases).*

9. *Of the cases of death or harm involving actual or suspected cases of Vasa Previa, how many of those cases have been fully investigated by HSIB, and how many have been closed to HSIB without full investigation?*

10. *Is there any regional discrepancy in the data, or otherwise any information held by HSIB, which might indicate that certain Trusts, or Trusts in certain geographical areas, are more or less effective in identifying Vasa Previa effectively antenatally and / or managing the medical emergency that arises as a result of the condition not being diagnosed and managed antenatally?*

Urgency of Response amidst the Live National Screening Council consultation

The NSC consultation is live and it is imperative, to allow me to engage appropriately in that consultation, that you do not further delay in providing a substantive response to the above data requests**.** It is clearly appropriate and imperative that there is transparency re numbers of families effected, and babies unnecessarily lost and sustaining brain damage from the this condition year upon year.

I note from the (8th March 2023) letter from XXXX XXXX (Deputy Medical Director HISB) to myself that HSIB has recently decided not to undertake its own national investigation re Vasa Previa cases; rather XXXX stated that is is *'felt that the National Screening Committee (NSC) would be best placed to address these concerns; we understand that you have raised this matter with them and support your decision to do so. Thank you for updating us on their response, we are pleased to hear that they will be progressing your referral'*. I am grateful for that indication of support, and clearly the NSC will be assisted by the answers to the above questions (an no doubt other questions which they may have raised with HSIB directly in recent weeks). I would respectfully highlight that HSIB now need to collate, and transparently share, its data re Vasa Previa case, and that now need to be done as a matter of urgency and priority.

I would welcome responses to each of the above questions as soon as possible, and within the 20 day statutory time frame. Please keep me updated if there is likely to be any delay in answering any of the individual questions. For the avoidance of doubt I am content to receive the data and answers to the separate questions in separate batches if all can not be answered promptly. I would anticipate that you should readily be able to answer questions 1-5 quickly, and would welcome that data as a priority (being data of great significance in the live Vasa Previa National Screening Council consultation).

Please let me know promptly if you have any queries re the above. I would be grateful if you could response to a) confirm safe receipt of this letter, and b) confirm, promptly upon receipt, if you need any further clarity from me which I will happy provide promptly as necessary. *Please do not wait until day 20 until you ask for any further clarification you may need from me.*

I do very much hope to receive, at this stage, HSIB's active support in pressing for improved screening, and to receive the appropriate transparency; noting HSIB as an organisation shares my wish to highlight the sheer number of deaths and avoidable harm being caused by this condition.

Yours faithfully

XXXX XXXX

Cc: MP / NSC / XXXX XXXX

XXXX XXXX

NHS Foundation Trust

XXXX
XXXXXX
XXXX
XXXX
XXXX XXXX

31 May 2023

XXXX XXXX
XXXX XXXX

Dear XXXX XXXX

Re: FOI request XXXX XXXX

Further to your request under the Freedom of Information Act 2000, please find a response to your questions below.

We note that Greentop Guildline 27b requires as follows in relation to cases of suspected Vasa Previa, that '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'.

Accordingly I understand that the labs at XXXX are utilised by XXXX, and also other local hospitals, for such analysis, and that your organisation will therefore hold data regarding the number of suspected / confirmed cases of Vasa Previa regionally.

Please can I provided with the following data within

Q1 Which hospitals, locally or nationally, routinely utilise the labs at XXXX to perform any required placental analysis.

A1
XXXX XXXX
XXXX XXXX
XXXX XXXX
XXXX XXXX
XXXX XXXX
XXXX XXXX
XXXX XXXX
XXXX XXXX
XXXX XXXX
XXXX XXXX

Q2 How many years / months has XXXX been providing that placental analysis service.

A2 More than 20 years

Q3 How many placental specimens are received and reviewed at XXXX each year for analysis, for any reason. (Please provide annual data over the last three years)

A3

Year	Total
Apr 2020-Mar 2021	1297
Apr 2021-Mar 2022	1983
Apr 2022-Mar 2023	2288
Grand Total	5568

Q4 How many cases of suspected Vasa Previa are referred to XXXX each year for relevant placental analysis (as is required under Greentop Guildline 27b)? (Please provide annual data over the last three years)

A4 Information not held – the Trust does not routinely collate or hold this information centrally as part of its management or performance data.

Q5 Of those, how many examines placenta's show evidence of either

i) marginal cord insertion
ii) velamentous cord insertion
iii) a bilobed placenta.
iv) or other histopathological evidence associated with Vasa Previa,
(Please provide annual data over the last three years)

A5 Information not held – the Trust does not routinely collate or hold this information centrally as part of its management or performance data.

Q6 Please provide all statistical data available to XXXX re

a) the number of cases, annually, where a Vasa Previa diagnosis is suggested or confirmed by the placental analysis undertaken.
b) the rate of occurrence of Vasa Previa, if possible, breaking down how many of those cases were / were not diagnosed prior to labour, and the known outcome of cases of Vasa Previa being undetected prior to labour.

A6 Information not held – the Trust does not routinely collate or hold this information centrally as part of its management or performance data.

Q7 What records are made / kept of each placental analysis undertaken? Please also specifically clarity whether photographs are taken and how they are stored, and whether the photographs and / or records are shared with the patient and / or the referring hospital.

A7 Records are kept in our local Laboratory Information Management System. Selected placentas are photographed. Photographs are shared at local perinatal morbidity and mortality meetings as required. They are not shared with the patient by XXXX XXXX.

Q8 What happens to the placenta specimen post examination, and is there ever any consultation with the family with regard to obtaining stem cells from the same before disposal?

A8 The placenta we receive are not fresh and are fixed in formalin, making them unsuitable for stem cell harvest. Information on consultation with the family would need to be sought from the obstetric centres as this need to be considered at delivery.

Placenta are disposed of via our local policy for disposal of tissue in line with Human Tissue Authority (HTA) guidance.

Q9 How are the findings of the placental analysis routinely shared with the patient and with the referring hospital?

A9 Electronic reports are sent to requesting hospitals; they would then share with patients as per their local protocol.

Should you not be happy with the information provided you have a right to request a review of our response. In the first instance this should be addressed to:

XXXX XXXX
XXXX XXXX
XXXX
XXXX
XXXX

If you ask for a review and are dissatisfied with the outcome, under Section 50 of the Freedom of Information Act you then have a right of appeal to the Information Commissioner. The Information Commissioner's address is:

XXXX XXXX
XXXX XXXX
XXXX XXXX
XXXX
XXXX
XXXX
XXXX

Yours sincerely

Information Governance Team
XXXX XXXX **NHS Foundation Trust**