Health Services Safety Investigations Body

Investigation report

Investigation report: The assessment of venous thromboembolism risks associated with pregnancy and the postnatal period

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A note of acknowledgement

We would like to thank Alice, who shared the events documented in this report. She gave generously of her time and was involved and supportive throughout the investigation. In accordance with her wishes, Alice is referred to by name throughout the report.

We would also like to thank the healthcare staff who engaged with the investigation for their openness and willingness to support improvements in this area of care.

About Alice

Alice lives with her partner and their two young children. She works in education. Alice has a number of hobbies and particularly likes keeping herself fit at the gym. Alice wanted to share her experiences with the hope that it will help other pregnant women and pregnant people and healthcare professionals understand the importance of knowing the signs, symptoms and the risks associated with blood clots (venous thrombosis) in pregnancy and during the 6 weeks after the birth of a baby.

About this report

This report is intended for healthcare organisations, policymakers and the public to help improve patient safety in relation to the assessment of venous thromboembolism risk in pregnancy and the period after birth. For readers less familiar with this area of healthcare, medical terms are explained within the report.

Executive Summary

Background

This investigation explores the issues associated with the assessment of risk factors for venous thrombosis in pregnancy and the first 6 weeks after birth. Venous thrombosis occurs when a blood clot forms and causes a blockage in a person's vein. This can lead to venous thromboembolism (VTE), when part of the clot breaks off and travels through the bloodstream, blocking a blood vessel elsewhere in the body.

Pregnant women and pregnant people are at greater risk of developing a venous thrombosis than those who are of the same age and not pregnant. Venous thrombosis related to pregnancy can occur at any stage of pregnancy and for 6 weeks after birth. Because of the increased risk, healthcare staff assess a pregnant woman's and pregnant person's risk factors for VTE at key stages before and after the birth so that they can be given preventative treatment if necessary.

While rare, in the UK venous thrombosis and VTE is the leading direct cause of death of pregnant women and pregnant people during pregnancy or up to 6 weeks after the end of pregnancy. Pregnant women and pregnant people who develop a VTE must undergo additional treatment and this can cause distress and anxiety at a time when they may already feel vulnerable.

This investigation uses a real patient safety incident, referred to as the 'reference event', to explore factors that can impact on the way staff assess a pregnant woman's and pregnant person's risk of VTE. It aims to support ongoing national work in this area.

The reference event

At the time of the reference event, Alice was 26 years old and was pregnant with her second child. A VTE risk assessment was completed for Alice at her first antenatal appointment, when she was admitted to hospital for the birth of her child, and 24 hours after admission. Her score was zero each time, meaning no risk factors were identified for VTE. During her pregnancy Alice reported experiencing some pain in her calf; she was examined by a doctor who referred her for a scan. This ruled out a deep vein thrombosis (DVT).

Alice had her baby by emergency caesarean birth and in line with national guidance her VTE risk assessment was repeated. This indicated that a preventative dose of a blood-thinning medication would be required. Alice was started on a daily injection of low-molecular-weight heparin and was discharged from hospital.

Eleven days after the birth of her baby, Alice was taken by ambulance to the emergency department with chest pain, shortness of breath and leg cramps. She was diagnosed with a pulmonary embolism (PE) and was started on a treatment dose of blood-thinning injections. Following investigation, it was found that Alice may not have received an appropriate preventative dose of low-molecular-weight heparin to help prevent the VTE.

The national investigation

The investigation found that the evidence about risk factors and the occurrence of VTE in pregnancy and the first 6 weeks after giving birth is imprecise. In addition, while there are recommendations for prescribing of medication to thin the blood if a pregnant woman/pregnant person is identified as being at risk, the preventative and treatment dose(s) have not been formally tested in clinical trials.

Research studies are ongoing to address identified knowledge gaps within the evidence base. Safety risks have also been reported in research literature and are reiterated in national reports which make recommendations to improve care during pregnancy and in the first 6 weeks after birth.

In view of the national work to address gaps in the current evidence base and to avoid duplicating existing work, the HSIB investigation considered that the biggest opportunity for learning was to better understand why healthcare professionals find existing risk scoring systems difficult to apply consistently in practice. As a result, HSIB launched this investigation to identify factors that limit the effectiveness of VTE risk assessment policies and identify opportunities to further improve patient safety in this area.

Findings

- For healthcare staff, carrying out a robust assessment of risk factors for VTE is challenging, particularly in the complex and busy environment of antenatal clinics, the labour ward and on postnatal wards.
- Multiple competing demands, exacerbated by distractions and interruptions, mean healthcare professionals are constantly having to balance risk and safety for the pregnant women/pregnant people they care for and are trading off the thoroughness of assessments to improve efficiency.

- Midwives are asked to complete a number of risk assessments and screening tools to assess pregnant women's/pregnant people's risk at their first antenatal appointment (known as the booking appointment). However, the time needed to carry out these risks assessments may not be reflected in the time allocated for appointments.
- Risk assessments and screening tools are not all designed and presented in a consistent and logical way that would aid staff in completing the task.
- Assessment of VTE risk factors should take place routinely due to body changes in pregnancy and increased risk of VTE.
- Although assessing VTE risk is important, it is a relatively rare condition and there are a number of other competing risks that may take priority.
- Staff do not always involve pregnant women and pregnant people in, or discuss with them, the assessment of their risk factors for VTE. This means pregnant women and pregnant people may not be aware of the signs and symptoms of a possible VTE.
- The importance of knowing the signs and symptoms of VTE may not be fully understood or prioritised by pregnant women and pregnant people who may have other competing concerns and questions about their antenatal and postnatal care.
- National guidance recommends that assessment of VTE risk factors should be repeated when a pregnant woman/pregnant person presents with an 'intercurrent problem' (a new health issue which may or may not be related to the pregnancy). However, not all healthcare professionals understand the meaning of 'intercurrent problem' and therefore opportunities to reassess risk factors are missed.
- There is a mix of paper-based and electronic record keeping in antenatal and postnatal care. Electronic records systems may lack interoperability and suffer from poor connectivity which limits the ability of staff to access all the data, information, and knowledge they need at the time of assessment.
- Recommendations by MBRRACE-UK (Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK) for the development of a tool to make the current assessment of VTE risk factors simpler and more reproducible, have not been acted on.

HSIB makes the following safety observations

Safety observation O/2022/199:

It may be beneficial for organisations to consider guidance, such as the ‘principles for effectiveness and usability’ provided by the Chartered Institute of Ergonomics and Human Factors, when developing risk assessment tools. The aim being to ensure assessments are simple to use and therefore staff being more likely to do them thoroughly and avoid tick-box fatigue.

Safety observation O/2022/200:

It may be beneficial for organisations that make recommendations to improve the safety and care of pregnant women and pregnant people during their pregnancy and up to 6 weeks after birth, to have a process for reporting on responses to their recommendations. This would support transparency, making it easy to see what has been achieved and what remains outstanding. The aim being to enable tracking of the implementation of actions designed to improve safety and outcomes to ensure they happen.

Safety observation O/2022/201:

It may be beneficial if future research or funding is directed towards identifying the evidence base for the prescribing of low-molecular-weight heparin for venous thromboembolism risk in pregnancy and the first 6 weeks after birth. This will support the production of evidence-based clinical

Local learning for maternity healthcare providers and local maternity systems

The HSIB investigation identified local learning that may assist maternity healthcare providers and local maternity systems (regional groupings of maternity service providers) when considering how to support the assessment of risk factors for VTE.

It may be beneficial for individual organisations to review how their staff involve pregnant women and pregnant people in the assessment of risk factors for venous thromboembolism and to identify any barriers that may be preventing such involvement. Greater involvement of pregnant women/pregnant people may enable more robust assessments and may make it more likely that VTE risk will be identified and acted upon and enable pregnant women/pregnant people to recognise signs and symptoms sooner.

It may be beneficial for organisations to employ quality improvement tools to implement and monitor pregnant women and pregnant people self-completing risk assessment forms in advance of their appointments.

It may be beneficial if organisations review the extent to which national guidance on the assessment of risk factors for venous thromboembolism is understood and implemented across their organisations. This will help to identify whether local barriers exist and if so, which of these to address for improved implementation.

It may be beneficial if organisations undertake their own observations to see how staff complete their assessment of risk factors for venous thromboembolism to identify pregnant women and pregnant people at high risk, and whether what happens ‘in reality’ is in line with local and national policy. This would help to identify gaps in ‘work as imagined’ versus ‘work as done’ and identify ways to make the process safer.

It may be beneficial if organisations review the existing paper-based and electronic maternity record systems in use and assess how these are used throughout pregnancy and birth. This will help organisations to identify mobile and Wi-Fi access issues and establish whether existing systems are capable of interoperability.

1 Background and context

1.1 Venous thromboembolism

1.1.1 A venous thrombosis is a blood clot (thrombus) that forms in a person’s vein, reducing the flow of blood. Venous thromboembolism (VTE) occurs when part of a blood clot breaks off, moves through the blood stream and creates a blockage in a blood vessel (embolism) in another part of the body.

Deep vein thrombosis (DVT)

1.1.2 A deep vein thrombosis (DVT) is a blood clot that forms in a deep vein, often in a person's leg, calf, or pelvis. The danger of a DVT is that the blood clot may break off and travel in the blood stream until it gets stuck in another part of the body, such as the lung (pulmonary embolus), causing serious illness.

1.1.3 DVTs may occur spontaneously and in healthy people, for example when sitting in one position during a long-haul flight. They may also be associated with periods of immobility in hospital, following surgery for example.

Pulmonary embolism (PE)

1.1.4 Pulmonary embolism (PE) is usually caused by a small piece of blood clot which has travelled through the body to a pulmonary (lung) artery (or arteries), where it can partially or fully block the artery.

1.1.5 PE is a complex condition. The way the PE can affect people ranges from mild symptoms through to sudden cardiac arrest. PE is a serious condition and can cause death, although this is rare. The symptoms of a PE may include:

- sudden unexplained difficulty in breathing
- tightness in the chest or chest pain
- coughing up blood
- feeling very unwell or collapsing.

Effects of pregnancy on risk of venous thrombosis

1.1.6 The NHS advises that pregnant women and pregnant people are more likely to develop venous thrombosis than those who are of the same age and not pregnant (NHS, 2021). This is due to changes in the body that pregnancy brings about.

1.1.7 Pregnant women and pregnant people who have additional risks for developing a venous thrombosis during pregnancy and in the first 6 weeks after giving birth include those who:

- have had a previous thrombosis
- have a condition called thrombophilia, which makes a blood clot more likely
- have a close family member who has had a venous thrombosis
- are over 35 years of age
- are overweight – body mass index over 30 (expected range is 18.5 to 24.9)

- have a condition called pre-eclampsia, which is a complication of pregnancy. This condition may cause high blood pressure, high levels of protein in the urine or other symptoms of organ damage that develops during pregnancy or in the first 6 weeks after giving birth
- have just had a caesarean birth
- have just needed a blood transfusion or have lost more than 1,000ml of blood at birth
- have had more than two children
- are immobile for prolonged periods of time
- are smokers.

1.2 National guidelines for treatment of venous thromboembolic disease (VTE)

1.2.1 The diagnosis and management of venous thromboembolic disease in adults is set out in the National Institute for Health and Care Excellence (NICE) Quality Standard 201 (National Institute for Health and Care Excellence, 2021a) and National Guideline 158 (National Institute for Health and Care Excellence, 2020). Neither of these national standards specifically apply in pregnancy. NICE National Guideline 89 does include a brief section on interventions for pregnant women and pregnant people and those who have given birth or had a miscarriage or termination of pregnancy in the past 6 weeks (National Institute for Health and Care Excellence, 2019).

1.2.2 The risk of developing VTE is assessed at a pregnant woman's and pregnant person's first appointment with a midwife (known as the 'booking appointment') (Royal College of Obstetricians and Gynaecologists, 2015a). Risk assessment is ongoing throughout pregnancy and should take place routinely during key phases in the maternity care journey:

- at the booking appointment
- at 28 weeks
- during any admission to hospital during the pregnancy
- post-birth in all settings
- before being discharged from hospital after the birth
- during any readmission to hospital after the birth.

1.2.3 The Royal College of Obstetricians and Gynaecologists published national guidance to inform the treatment of women's health (Royal College of Obstetricians and Gynaecologists, 2015a; 2015b). These documents set out both the assessment of risk in the antenatal period (before the birth) and postnatal period (after the birth) and the way in which the condition should be managed.

1.2.4 Small doses of blood-thinning medication can reduce the risk of blood clots but they also slightly increase the risk of bleeding. Currently whether a pregnant woman and pregnant person is offered blood-thinning medication to prevent blood clots depends on whether they are considered to have a high, medium, or low risk of developing blood clots.

1.2.5 There are different types of medicine that thin the blood. The most used is low-molecular-weight heparin (LMWH). This is safe to use in pregnancy and when breast feeding. It is given as an injection under the skin at the same time every day. The dose is worked out according to the person's weight.

1.2.6 Pregnant women and pregnant people at high risk of developing VTE may need to self-administer LMWH throughout their pregnancy and for 6 weeks after birth. Those who are at moderately increased risk of VTE are recommended to have LMWH injections for 10 days after birth.

1.3 National data on deaths from VTE during pregnancy and in the postnatal period

1.3.1 Thrombosis and VTE continue to be the leading cause of direct obstetric deaths – that is, deaths of people that occur either during pregnancy or up to 6 weeks after giving birth, caused by complications with the pregnancy or birth, or the way complications are managed. According to a report by MBRRACE-UK (Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK), in the UK and Ireland during the 3-year period from 2017 to 2019, 21 women died during or up to 6 weeks after the end of pregnancy, among an estimated 2,352,291 women giving birth. This equates to 0.89 deaths per 100,000 women/ people during pregnancy or postnatal period (MBRRACE-UK, 2021). While still reported as the leading cause of direct deaths, the report refers to a decrease in the number of deaths of people during pregnancy and after the birth from VTE, which is now at a similar rate to 2012 to 2014 and an encouraging sign of improved detection of risk and better prevention.

1.3.2 The findings of an enquiry into the care of women who died from PE (MBRRACE-UK, 2020) highlighted errors and inconsistencies in the way they were scored for their risk of VTE, suggesting a need for additional actions to ensure consistent risk assessment. Examples include healthcare professionals not recognising or acting on risk factors, healthcare professionals not appreciating the significance of signs and symptoms in the light of known risk factors, and treatment with inadequate doses of blood-thinning medication based on the person's weight.

1.3.3 The evidence to support a relationship between risk factors and the occurrence of VTE during pregnancy and up to 6 weeks after the end of pregnancy is imprecise. For example, there are competing risks and challenges associated with the use of medicines to thin the blood and prevent clots, and while there are recommendations for prescribing of medication to thin the blood, this approach has not been formally tested in clinical trials.

Existing recommendations to address the known risks of venous thrombosis

1.3.4 In the most recently published report by MBRRACE-UK, there is evidence that doctors and midwives find existing risk scoring systems difficult to apply consistently in practice. The report made recommendations to NHS England (and equivalent organisations in the devolved nations and Ireland) that 'there is a need for development of a tool to make the current risk assessment system simpler and more reproducible' (MBRRACE-UK, 2020; 2021).

1.4 The Efficiency-Thoroughness Trade-Off principle

1.4.1 The investigation analysis in section 4 refers to the Efficiency-Thoroughness Trade-Off (ETTO) principles (Hollnagel, 2009). Hollnagel proposes that it is 'fundamental characteristic of human performance … that the resources needed to do something often, if not always, are too few'. This means people (or organisations) have to make a trade-off between the resources (primarily time and effort) they spend on preparing to do something and the resources (primarily time and effort) they spend on doing it. Hollnagel describes what he calls the ETTO fallacy - that is, a mistaken belief that people can be efficient and thorough at the same time.

1.4.2 The investigation used the ETTO principles in its consideration of the way staff carried out VTE risk assessments, looking at whether competing pressures on their time and attention led to trade-offs between thoroughness and efficiency.

2 The reference event

This investigation used the following patient safety incident, referred to as 'the reference event', to examine the safety issues around the assessment of venous thromboembolic (VTE) risks associated with pregnancy and the first 6 weeks after giving birth.

Specifically, the investigation used the reference event to help understand why there might be inconsistencies in the way VTE risk assessments are carried out. The patient, Alice, developed a pulmonary embolism (PE) 11 days after the birth of her second baby. The investigation's analysis of Alice's care is provided in **section 4**.

2.1 On 27 January 2021, Alice was seen in the antenatal clinic at the hospital for her booking appointment. She was 26 years old. The appointment was with a midwife who took Alice's history, discussed the dating scan to help confirm her estimated due date, took samples for routine blood tests and to confirm Alice's blood group, and completed a number of screening tools and risk assessments. Specifically included within Alice's notes was her past medical history in which it is recorded 'no history of ... thromboembolism…'. Alice is a non-smoker. Her risk factors were recorded in the booking notes as 'underweight, previous caesarean, anxiety, and previous bleeding prior to the birth of her first baby'.

2.2 An on-paper risk assessment for VTE was completed, among other risk assessments. The risk assessment did not evidence any conversations that were had with Alice and it recorded a score of zero, meaning no risk factors were identified for VTE.

2.3 Alice's weight was recorded as 48kg with a body mass index (BMI) of 18. BMI is a measure that uses an individual's height and weight to work out whether their weight is healthy. The expected BMI range for most adults is 18.5 to 24.9. Alice's estimated due date was recorded as 31 August 2021 based on the date of her last menstrual period.

2.4 On Tuesday 13 April 2021 Alice went to a routine antenatal appointment and at 10:45 hours she attended maternity triage where she was seen by a midwife. Alice told the investigation that she had been sent to maternity triage following her antenatal appointment in which she had described pain in her leg which she had put down to 'general aches and pains'. In triage, it is recorded in her medical notes taken during triage that she presented with a month-long history of leg cramps. She described to the midwife that she had a tender right calf and was struggling to walk.

2.5 Alice was seen by a specialty trainee doctor in year 2 of their training (ST2). The doctor recorded that her weight at booking was 47kg and that her VTE risk assessment score was zero. The ST2 documented in the medical records that Alice had had an emergency caesarean birth in 2017 and a 4-day history of right calf pain that meant she was struggling to walk properly. Alice described to the doctor that she had a similar problem in her left calf 2 weeks previously and this had completely resolved with no return of symptoms.

2.6 The doctor examined Alice's right and left calf. Both were recorded as 31cm. If Alice's right calf had been larger than her left calf, this could have indicated a deep vein thrombosis (DVT), although this is not a sensitive enough indicator to be used in isolation. It was recorded that her legs were not hot, red or swollen, although the right calf was tender. The doctor suggested the tenderness in her right calf to be an indicator of a DVT and planned for a scan of her right calf. The doctor prescribed a dose of 40mg low-molecular-weight heparin (LMWH) (enoxaparin)

twice daily by injection. The first dose was administered by a midwife in triage. The doctor also arranged for a scan of Alice's leg called a Doppler scan, which is a special type of ultrasound that can be used to check for blockages in blood vessels.

2.7 On Thursday 15 April 2021, the Doppler ultrasound scan of Alice's lower right leg was performed and reported at 13:54 hours. The report concluded that there were no signs of DVT above the right knee. The findings of the report were shared with the doctor who saw Alice on 13 April 2021. As there was no DVT and no additional risk factors, a decision was made to discontinue the blood-thinning injections, as their purpose was to treat and there was nothing to treat.

2.8 On 8 August 2021 at 23:45 hours Alice had a spontaneous rupture of her membranes (her waters broke). She went to her local hospital and it is recorded in the notes that VTE risk assessments were completed when she was admitted and within 24 hours of admission. Both risk assessments scored zero. Alice wore stockings that reduce the risk of blood clots and had been wearing these since 9 August 2021.

2.9 On 11 August 2021, Alice had an emergency caesarean and her baby was born at 06:21 hours.

2.10 A further VTE risk assessment was completed after the birth of her baby which indicated that Alice should receive thromboprophylaxis treatment (an injection to thin the blood and prevent a blood clot). This was because Alice had had a caesarean birth. Alice was started on a daily injection of low-molecular-weight heparin (LMWH) enoxaparin 20mg once a day for 10 days. The dose of enoxaparin was calculated based on her booking weight of 48kg.

2.11 Alice's postnatal records state that the first dose of enoxaparin was administered at 18:00 hours on 11 August 2021 with a plan for the second dose 24 hours later. Alice told the investigation that on 12 August 2021 she asked to stay an extra night in hospital as she "just did not feel right". She shared that she had told the midwife that she wasn't worried about the baby, but that her back and her chest did not feel right. She said: "I had to beg them to let me stay an extra night."

2.12 On 13 August 2021 Alice was discharged from hospital with the remainder of the 10-day supply of preventative blood-thinning injections. Alice told the investigation she was familiar with the injections as she had to have them after the birth of her first baby. Alice told the investigation she was not aware of the risks of VTE at this point, only that the "injections thin the blood".

2.13 Alice told the investigation that approximately 4 days after having her baby, she had a pain in her calf. She said she could not put her foot down. Alice stated she put the pain down to having just had an operation and not moving around as much. Alice then described how she

experienced pains in her chest and could not lie down without feeling breathless and in pain. Alice told the investigation she was not aware that calf pain, shortness of breath or pain in her chest maybe signs of something more serious. Alice put the pain in her chest down to anxiety and the fact she had just had her second baby earlier than expected and that her body “was just being lazy”.

2.14 Alice told the investigation that on 22 August 2021 her chest pain was crushing and she could not breathe. Alice called for an ambulance and was taken to the emergency department (ED). The ambulance records refer to Alice experiencing chest pain, shortness of breath and leg cramps. Alice told the investigation that the ambulance crew thought she may have mastitis; however, she told them the pain was not in her breasts and her chest felt “crushed” and she could not breathe.

2.15 At the hospital, Alice had a CT pulmonary angiogram, which is a diagnostic test to obtain an image of the pulmonary arteries. Alice was diagnosed with a PE and was started on LMWH 85mg for 2 weeks with a request for the GP to continue prescribing this. It was recorded in the ED summary report that Alice’s weight on 22 August 2021 was 56kg. This meant that the preventative dose of LMWH prescribed on 11 August 2021, which was based on her previous recorded weight of 48kg on 27 January 2021, may have been inaccurate as preventative doses are different for pregnant women and pregnant people under 50kg and over 50kg.

3 Involvement of the Healthcare Safety Investigation Branch

This section outlines how HSIB was alerted to the issue of caring for people at risk of venous thrombosis during pregnancy and in the first 6 weeks after birth. It describes the criteria HSIB used to decide whether to go ahead with the investigation, and the methods and evidence used in the investigation process.

3.1 Notification of the reference event and decision to investigate

3.1.1 HSIB was made aware, via an internal referral from the HSIB maternity investigation programme, of a safety issue relating to the assessment of venous thromboembolism (VTE) risks associated with pregnancy and in the 6 weeks after birth.

3.1.2 A reference event was identified, involving Alice, and a scoping investigation was commenced.

3.2 Decision to conduct a national investigation

3.2.1 HSIB conducted an initial scoping investigation which determined that the patient safety concern met the criteria for investigation (see below). HSIB's Chief Investigator authorised a national investigation. A summary of the analysis against HSIB's investigation criteria is given below.

Outcome impact – what was, or is, the impact of the safety issue on people and services across the healthcare system?

Pregnant women and pregnant people who develop a VTE undergo additional treatment and this can cause distress and anxiety at a time when they may already feel vulnerable. In a very small number of cases, VTE can lead to the death of pregnant women/pregnant people.

Systemic risk – how widespread and how common a safety issue is this across the healthcare system?

While rare, thrombosis and VTE during or up to 6 weeks after the end of pregnancy is the leading direct cause of maternal death in the UK (see 1.3.1). It is therefore important that assessment of VTE risk is simple to implement and identifies and prioritises those at risk. Healthcare providers responsible for delivering care to pregnant women and pregnant people use national guidance to produce local policy and care pathways for VTE risk assessment. However, the overwhelming theme identified in national reviews of the care of those who died from VTE was inconsistency of risk assessment.

Learning potential – what is the potential for an HSIB investigation to lead to positive changes and improvements to patient safety across the healthcare system?

HSIB was aware of a range of national work programmes that were conducting surveillance and investigating the causes of maternal deaths including confidential enquiries into maternal deaths. The investigation established that the evidence shows the relationship between risk factors and the occurrence of VTE in pregnancy and the first 6 weeks after giving birth period is imprecise. In addition, while there are recommendations for prescribing of medication to thin the blood if a pregnant person is identified as at risk, this approach has not been formally tested in clinical trials.

HSIB was told there is a tension in identifying a tool that has a high enough sensitivity rate for identifying the risk of VTE during and just after pregnancy, and specific enough not to result in exposing a high proportion of pregnant women and pregnant people to preventative blood-thinning injections unnecessarily and at significant cost. The National Institute for Health and

Care Excellence Guideline 89 (National Institute for Health and Care Excellence, 2019) recommends that further research should be done to determine the accuracy of risk assessment tools.

Funding has been awarded by the National Institute for Health and Care Research (2020) to establish what further research should be done to improve outcomes for pregnant women and pregnant people at risk of blood clots during pregnancy and in the early weeks after pregnancy. The investigation is aware that the research began in January 2021 and the estimated publication date is April 2023. The research involves undertaking a study to determine the clinical and cost-effectiveness of risk stratification tools for the prediction of VTE and appropriate provision of medicine that will prevent VTE during pregnancy and the first 6 weeks after birth. In addition, the researchers' scoping review suggests that further primary research will be needed to address gaps in the current evidence base. This research is timely because there are now a number of published risk assessment tools available, and it is unclear whether offering preventative blood-thinning injections according to these tools would be more cost-effective than the current practice of using the Royal College of Obstetricians and Gynaecologists guidelines.

In view of the national work underway to address gaps in the current evidence base and to avoid duplicating existing work, the HSIB investigation considered that the biggest opportunity for learning was to better understand why healthcare professionals find existing risk scoring systems difficult to apply consistently in practice. Consequently, HSIB launched this investigation to identify factors that limit the effectiveness of VTE risk assessment policies and opportunities to further drive safety improvements in this area.

3.3 Evidence gathering

3.3.1 The investigation wanted to understand how staff work within the clinical environment and the factors that impact on them when assessing pregnant women and pregnant people for VTE risk at their initial booking appointment, throughout their pregnancy and during the 6 weeks after giving birth. This approach to HSIB investigations has been described in previous reports (**Healthcare Safety Investigation Branch, 2019**).

3.3.2 The investigation considered the challenges faced by staff and how they must use their knowledge, skills, and experience to adapt their work to the challenges posed by the system in which they operate.

3.3.3 To gain an insight into how best to explore the way staff work in the clinical environment it is important to understand the varieties of human work, as described by Shorrock (2016). Shorrock refers to four basic varieties of work to be considered: work-as-imagined; work-as-prescribed; work-as-disclosed; and work-as-done. These are illustrated in **figure 1**, which

shows that the varieties of human work do usually overlap, but not completely, leaving areas of commonality, and areas of difference. Shorrock (2016), concludes that, ‘the analysis of work cannot be limited to work as prescribed in procedures for example, nor to the observation of work actually done. Similarly, it cannot be limited to work as we imagine it, nor work as people talk about it. Only by considering all four of these varieties of human work can we hope to understand what’s going on’.

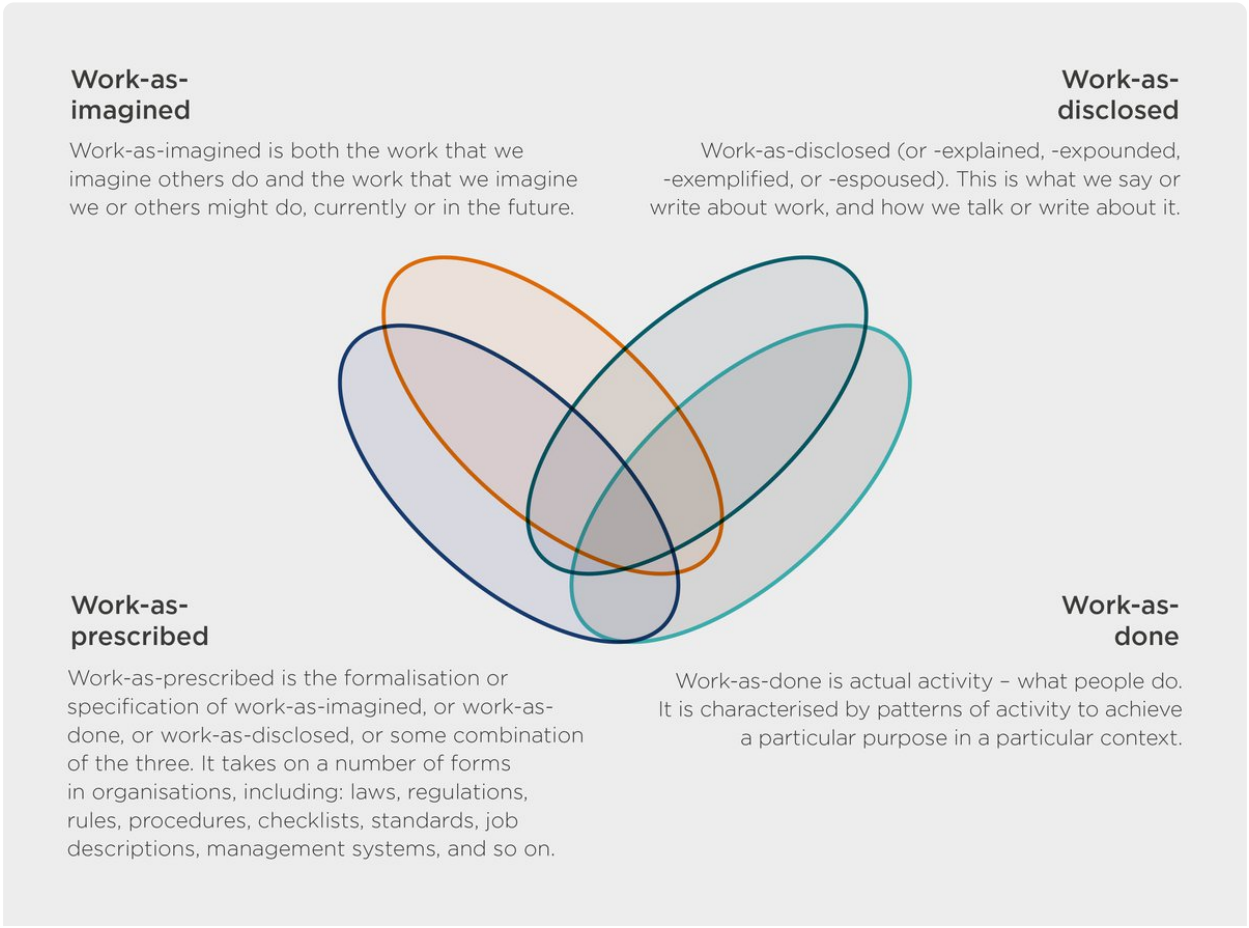


Figure 1 The varieties of human work (Shorrock, 2016)

3.3.4 Healthcare is a complex system in which staff are required to adapt and respond to the changing circumstances they are faced with (Woodward, 2019). The ability to make adaptations is understood to be an essential part of work within a complex system. Safety science aims to understand how organisations may be able to utilise adaptive and flexible work processes to deliver safe care (Macrae and Draycott, 2019).

3.3.5 The investigation considered other sources of evidence which were gathered and analysed by the investigation, including:

- review of Alice’s clinical records
- an interview with Alice

- review of national guidance and standards
- interviews with staff members who undertake VTE risk assessments as part of their daily work
- review of the reference event hospital's internal incident investigation report
- review of research literature relevant to the safety risks
- observation of VTE risk assessments being completed in antenatal clinics, antenatal wards, labour wards and postnatal wards.

3.3.6 Stakeholders with national influence on the safe care of pregnant women and pregnant people during pregnancy and in the first 6 weeks after birth were identified. These stakeholders informed the investigation of the current national work in relation to prevention and treatment of VTE, and included:

- Royal College of Obstetricians and Gynaecologists (RCOG)
- Royal College of Midwives
- Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK (MBRRACE–UK)
- British Society of Haematology
- Thrombosis UK
- VTE National Nursing and Midwifery Network.

3.4 Systems analysis of the evidence

3.4.1 The investigation used the Systems Engineering Initiative for Patient Safety (SEIPS) framework (Holden et al, 2013) to collect and analyse evidence gathered during the visit to the hospital where the reference event took place and examine safety factors influencing the assessment of risk of VTE during pregnancy and in the first 6 weeks after giving birth.

3.4.2 SEIPS provides a human factors framework for understanding work system interactions (that is, the external environment, organisation, internal environment, tools, and technology, tasks, and person-level factors) and work processes (including physical, cognitive and social/ behavioural aspects), and how these combine to influence healthcare outcomes.

4 Analysis and findings – the reference event

This section describes the investigation's findings in relation to the reference event and specifically to better understand and identify factors that limit the effectiveness of venous thromboembolism (VTE) risk assessment processes in practice. The findings are grouped according to three key processes:

- engaging pregnant women and pregnant people in the assessment of risk factors for VTE
- VTE risk assessment documentation and processes
- the prescribing of medication to prevent VTE.

The above areas were identified using the analysis method described in **section 3** and using the Systems Engineering Initiative for Patient Safety (SEIPS) model below (**figure 2**).

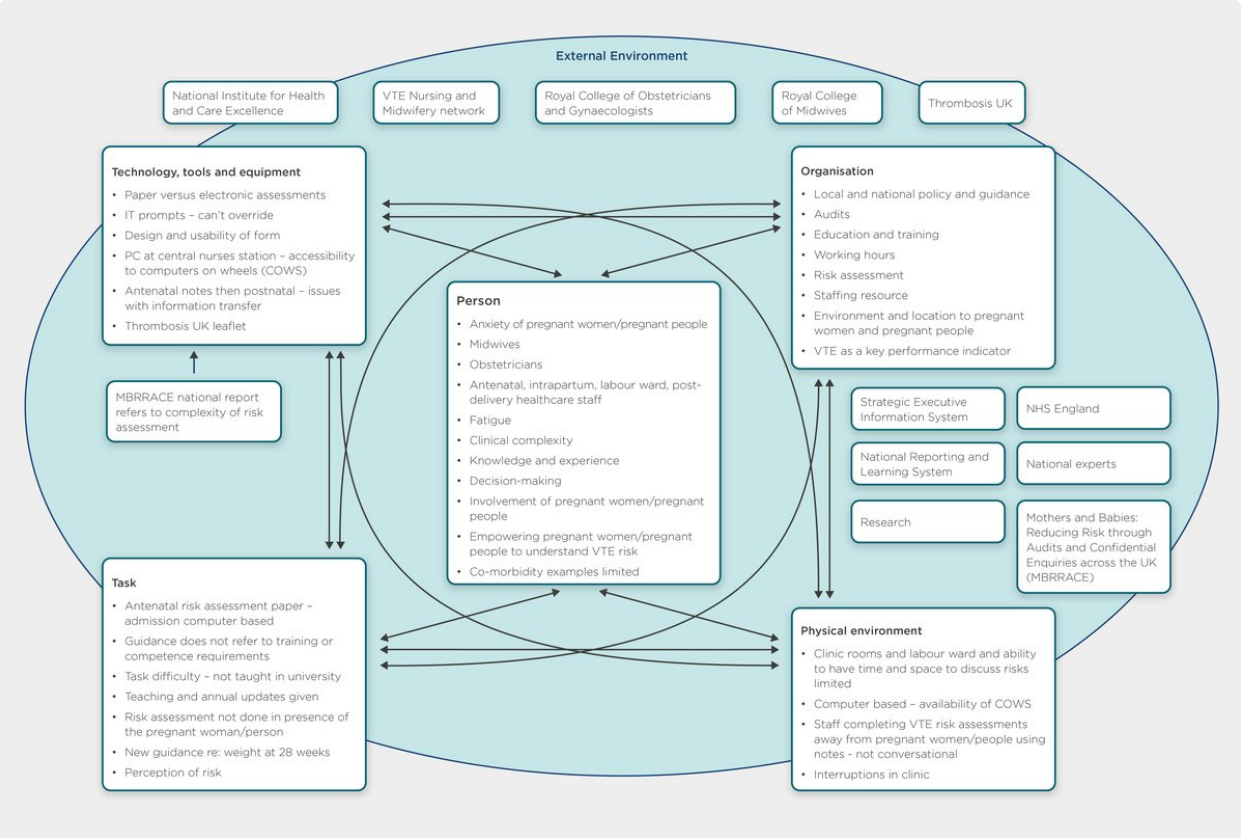


Figure 2 Work system factors explored in this investigation

Note: this diagram provides a general overview of the areas explored as part of this investigation; the areas listed are not exhaustive. The investigation considered local and national policies and guidance, and practices evidenced in the research literature. This enabled a detailed analysis of how the healthcare system influenced the reference event and allowed potential recommendations for improvement to be considered.

4.1 Engaging pregnant women and pregnant people in the assessment of risk factors for VTE

4.1.1 Evidence from Alice's care suggests she was not involved in her assessment of risk for VTE. Alice told the investigation that she did not recall a VTE risk assessment being completed at any point in her care or having any engagement with staff about this. Alice stated: "I didn't even know it was a thing until I got my clot." In particular, Alice told the investigation that most of the booking appointment time was spent discussing the fact that her pregnancy was classed as high-risk because she had had complications during the birth of her first baby.

4.1.2 Alice's initial VTE assessment was completed at her booking appointment using a paper-based system and she was scored with a risk factor of zero (no identified risk factors). The investigation has reviewed the records and the paper copy of the VTE risk assessment. It is not possible to determine how the risk assessment was completed from the paper assessment alone.

4.1.3 The investigation was told by staff working at the hospital that Alice would have been asked a predetermined list of questions to calculate her score. Based on the scoring Alice would be placed into one of four categories, as shown in **figure 3**.

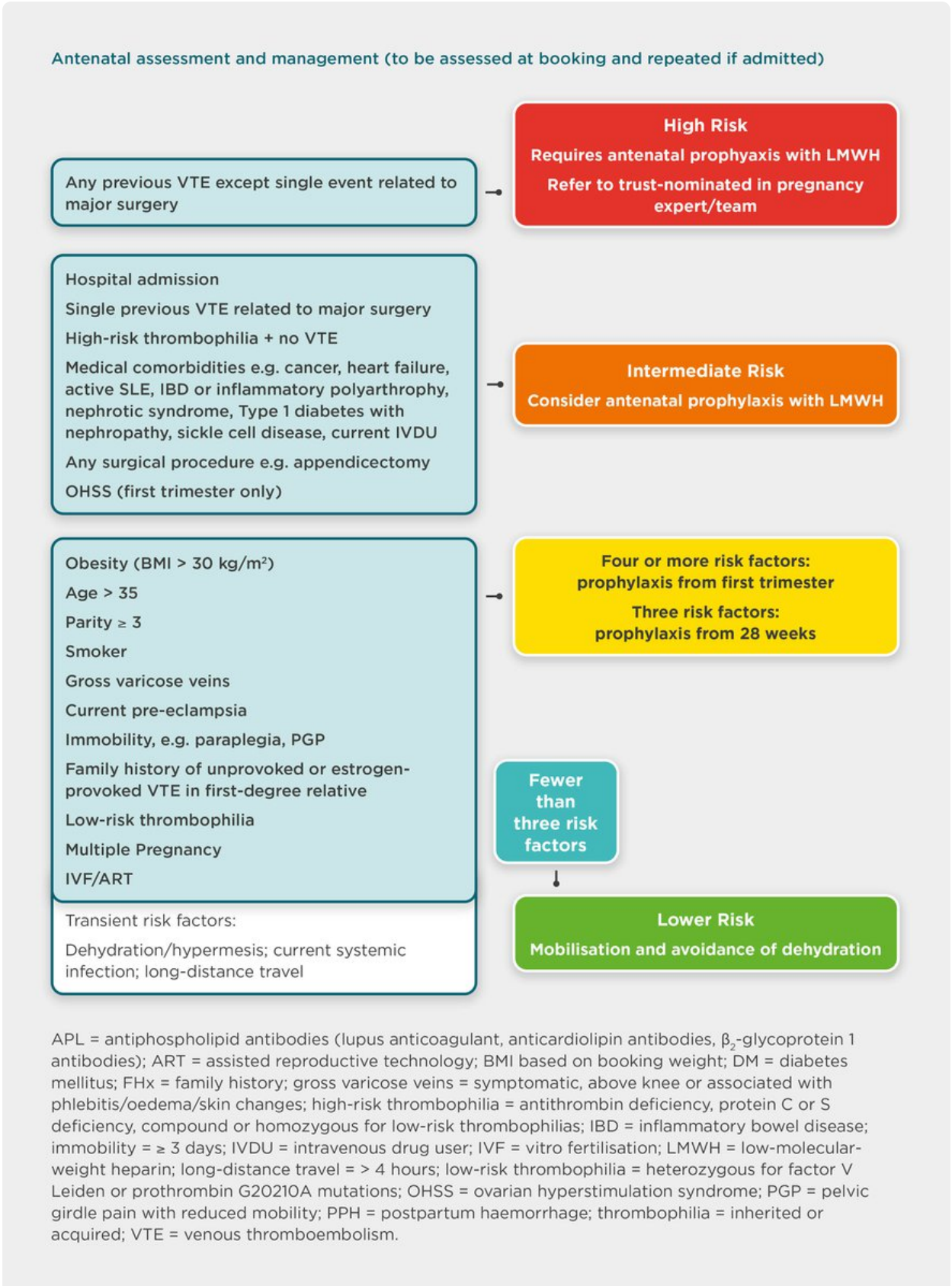
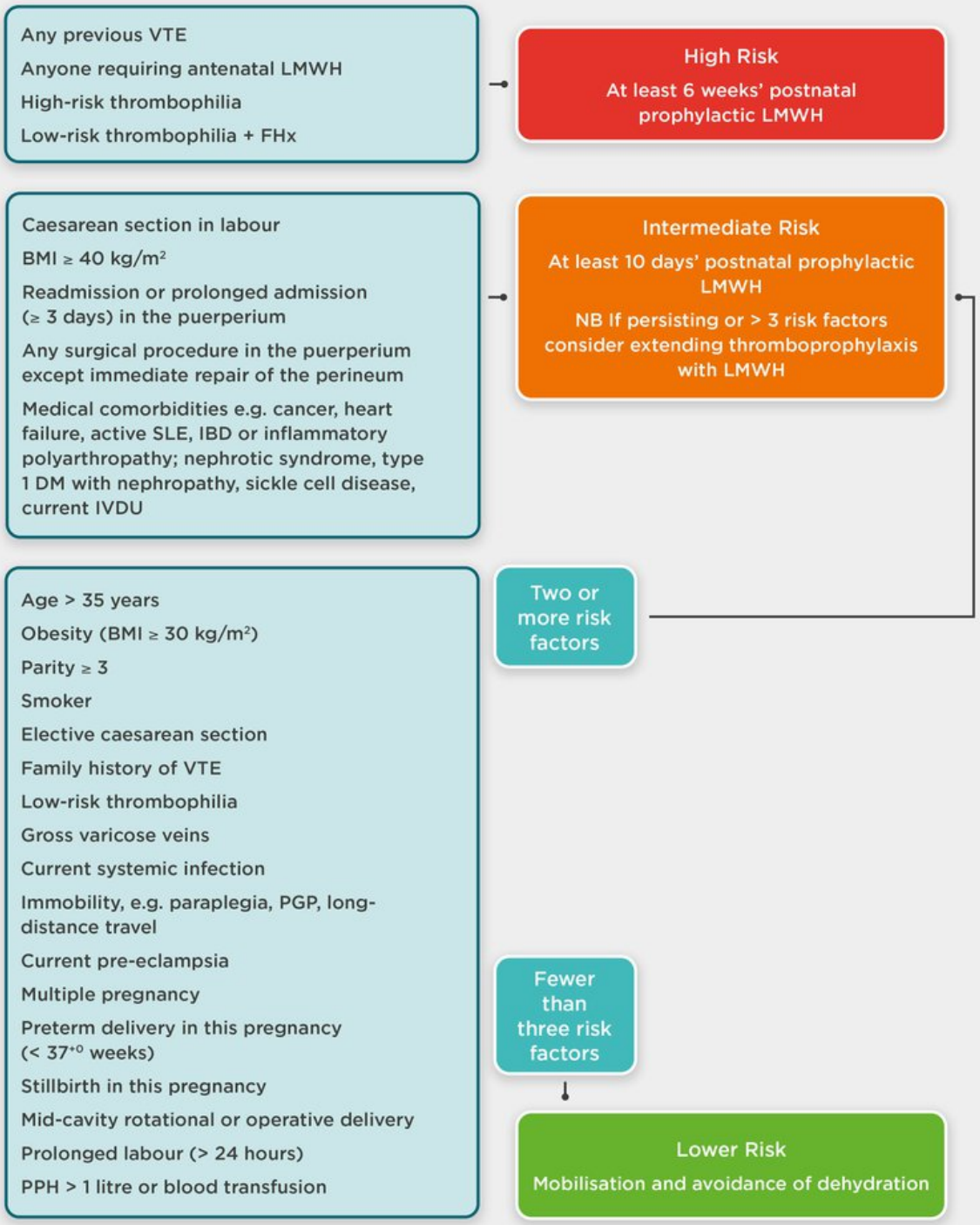


Figure 3a Risk categories assigned following a VTE risk assessment (Royal College of Obstetricians and Gynaecologists, 2015a)

Postnatal assessment and management (to be assessed on delivery suite)



Antenatal and postnatal prophylactic dose of LMWH

Weight < 50 kg = 20 mg enoxaparin/2500 units dalteparin/3500 units tinzaparin daily

Weight 50–90 kg = 40 mg enoxaparin/5000 units dalteparin/4500 units tinzaparin daily

Weight 91–130 kg = 60 mg enoxaparin/7500 units dalteparin/7000 units tinzaparin daily

Weight 131–170 kg = 80 mg enoxaparin/10000 units dalteparin/9000 units tinzaparin daily

Weight > 170 kg = 0.6 mg/kg/day enoxaparin/ 75 u/kg/day dalteparin/ 75 u/kg/day tinzaparin

Figure 3b Risk categories assigned following a VTE risk assessment (Royal College of Obstetricians and Gynaecologists, 2015a)

4.1.4 The investigation reviewed Alice's antenatal booking appointment assessment which included an assessment of her medical family and obstetric history and risk factors. Specifically, it was recorded in her medical history that she had no history of thromboembolism. The investigation has been unable to clarify how this information was obtained as Alice does not recall being asked.

4.1.5 The investigation was told that when completing a VTE assessment at a booking appointment, staff may complete the assessment without actively asking the pregnant woman or pregnant person about all the risk factors documented on the assessment form: "I don't always go through all of the prompts." Staff told the investigation that often the assessment is completed from the information available in the notes and a general conversation with the pregnant woman/pregnant person. The rationale given to the investigation was that there is limited time available to complete all the required risk assessments at the booking appointment (see section 4.2).

4.1.6 Each of the antenatal appointments has a list of associated checks and screenings that need to be carried out. At the booking appointment, the midwife will take the pregnant person's medical history, including their family medical history. In addition, the midwife will request a dating scan and any further screening that is required, carry out blood tests and start to document a wellbeing plan. The booking appointment may be the first time the pregnant woman/pregnant person will have seen a healthcare professional in relation to their pregnancy, so they may wish to ask questions or discuss any concerns.

4.1.7 National guidance (Royal College of Obstetricians and Gynaecologists, 2015a; 2015b) recommends that 'the risk of VTE should be discussed with women at risk and the reasons for individual recommendations explained'.

4.1.8 The investigation observed that staff would not routinely revisit the VTE risk assessment unless a pregnant woman/pregnant person informed them of changes that might affect their risk score. The investigation discussed with staff whether pregnant women/pregnant people are advised to inform staff if their risk factors change throughout the antenatal period. Some staff told the investigation that they are told generally if anything changes to inform staff, however this was rarely specific to VTE risk assessment.

4.1.9 VTE assessment is a dynamic process (meaning the risk is continually assessed to allow for unknown factors and to handle uncertainty) and consideration should be given that a pregnant woman's/pregnant person's risk profile may change during their pregnancy. National

guidance (Royal College of Obstetricians and Gynaecologists, 2015a) recommends that a VTE risk assessment is repeated when a pregnant woman/pregnant person sees a medical professional about an ‘intercurrent problem’.

4.1.10 An intercurrent problem is described in the guidance as a disease that occurs during the course of another disease with which it has no connection. The investigation has reviewed the local and national guidance and neither gives guidance on what is meant by an intercurrent problem. Some staff told the investigation that they did not understand what is meant by ‘intercurrent problem’ and would not always consider undertaking a repeat VTE assessment unless the problem specifically related to symptoms associated with a clot.

4.1.11 Alice told the investigation that before she was discharged from hospital, she was not given information to help her identify the signs and symptoms of a VTE (shortness of breath, swollen calf). Staff told the investigation that pregnant women and pregnant people who score for VTE risks are provided with an information leaflet on discharge. Alice does not recall receiving a leaflet. Those with a score of zero do not receive written information.

4.1.12 Healthcare professionals told the investigation that empowering pregnant women and pregnant people to understand their risks could help to improve knowledge, experience and understanding of the risks associated with VTE. Thrombosis UK has produced information in various formats (z-cards, video, image-based and written) to help support this goal (**see figures 4a, 4b and 4c for some examples**). This information is available on the Thrombosis UK website (Thrombosis UK, n.d.).

Figure 4a Card showing signs and symptoms of thrombosis/VTE

Figure 4b ‘What is thrombosis?’ card

Figure 4c Z-cards giving information about blood clots and pregnancy

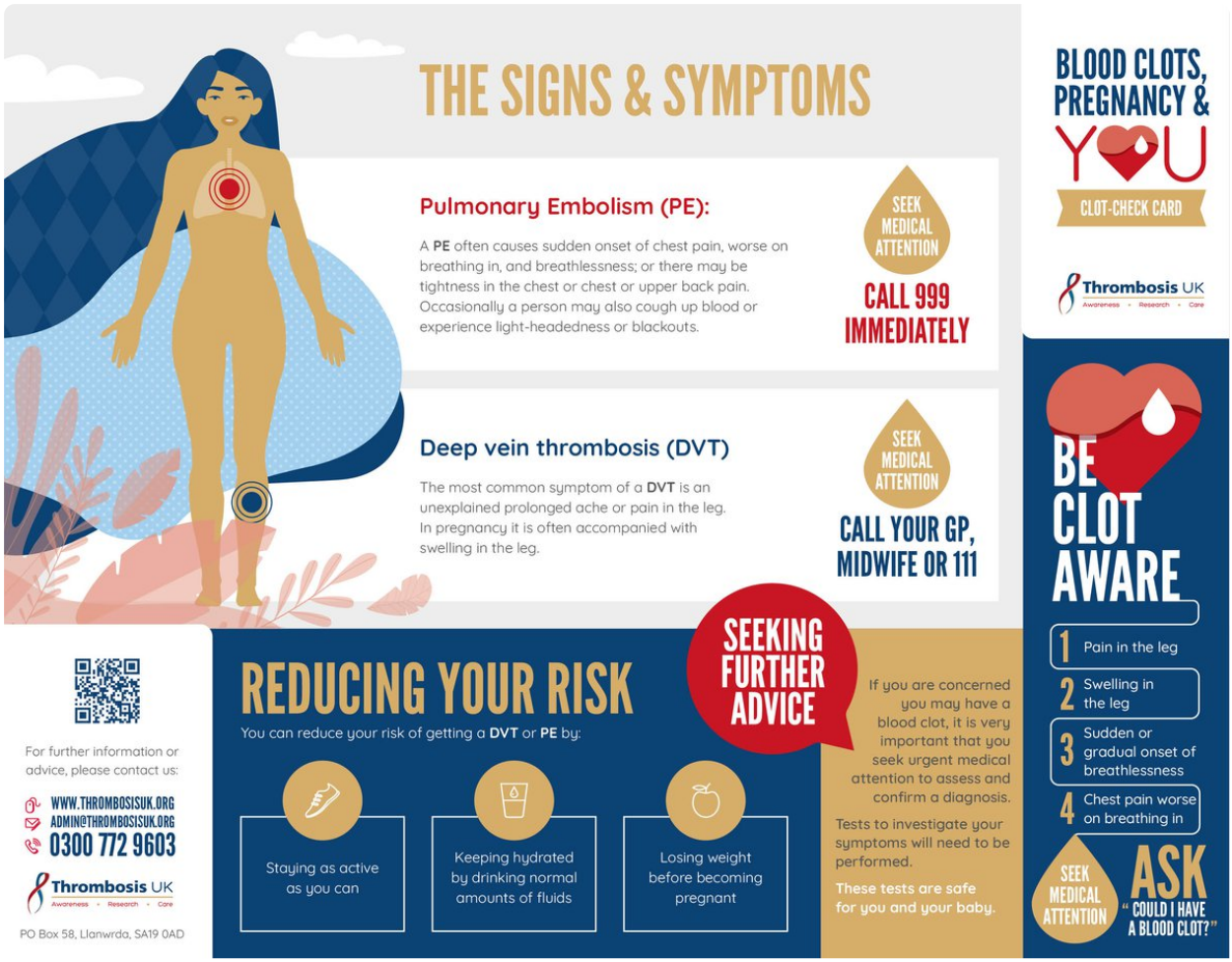


Figure 4a Card showing signs and symptoms of thrombosis/VTE

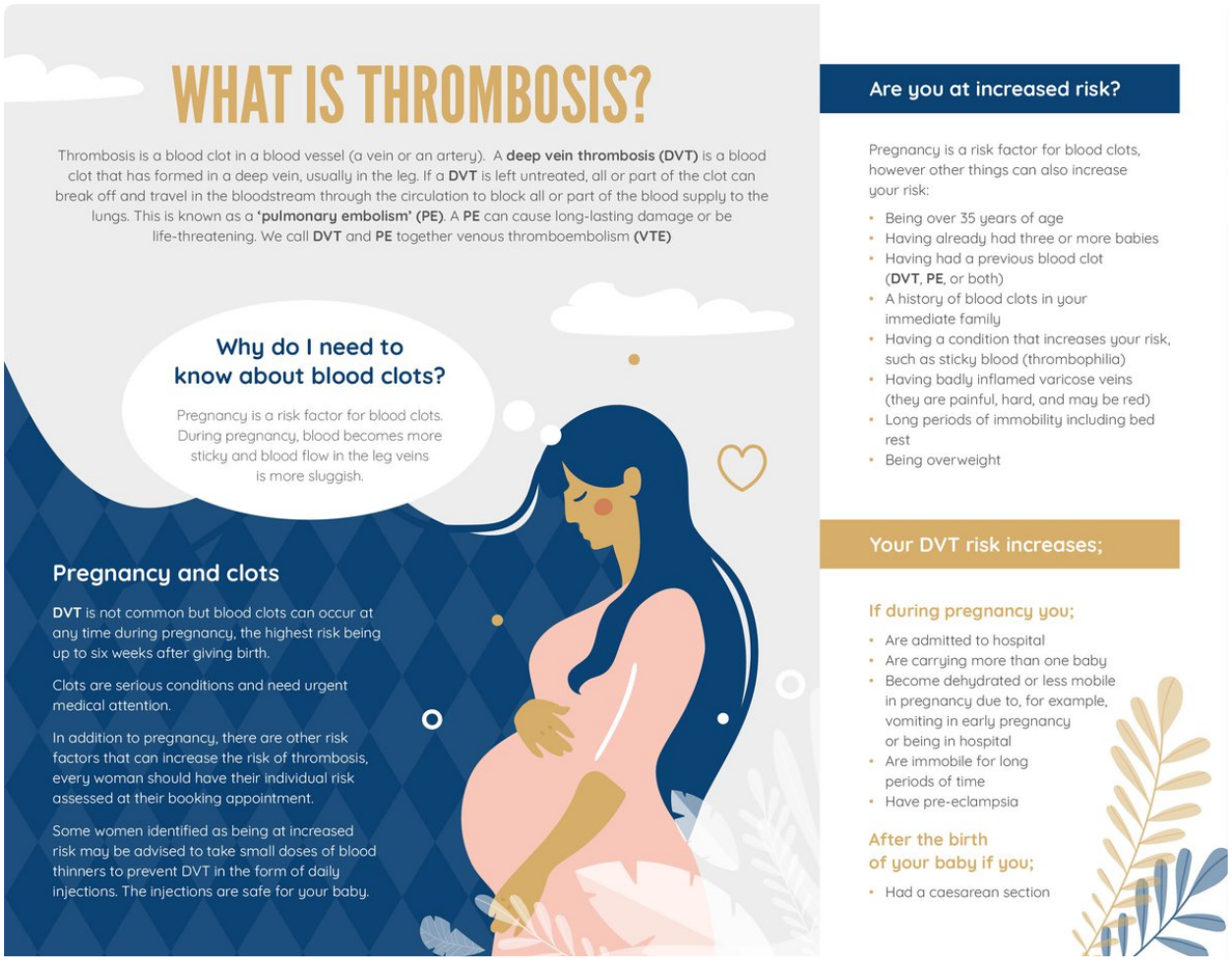


Figure 4b 'What is thrombosis?' card



Figure 4c Z-cards giving information about blood clots and pregnancy

4.1.13 The investigation was told by several people that education on ways to minimise getting a blood clot as well as signs and symptoms to look out for, may have a value in helping pregnant women and pregnant people during pregnancy and in the first 6 weeks after birth. The investigation was also told that in addition to informing pregnant women/pregnant people about the signs and symptoms of VTE, they may also be made aware that their risk factors may change (for example if they get an infection or their mobility is reduced) and to seek medical attention when their VTE risk profile changes.

4.1.14 The investigation was told by Thrombosis UK that Alice's experience is not unique. Thrombosis UK referred the investigation to case stories on its website of women who had developed blood clots after the birth of their babies (Thrombosis UK, n.d.). Thrombosis UK noted that pregnant women and pregnant people who have developed a blood clot during pregnancy or within 6 weeks of giving birth are very keen to help raise awareness and share their experiences.

4.1.15 The investigation was told that the hospital where the reference event took place had introduced a 'mum and baby' app which is now used across multiple local maternity service networks. The app enables pregnant women and pregnant people to explore maternity units in their area, add appointments and develop their own personal care plans. This was designed

using experience-based co-design methodology (a quality improvement methodology and means service users were involved in the design) to move towards empowering pregnant people to be an equal partner in their maternity care. The investigation was told that the app does not however interface with the existing electronic maternity health records (see section 4.2.28).

4.1.16 A consultant obstetrician told the investigation about another postnatal quality improvement project in progress, aiming to provide pregnant women and pregnant people with personalised postnatal information, including what symptoms are ‘red flags’ and how they should seek help if they have a symptom of concern. The consultant told the investigation that this app will give pregnant women and pregnant people personalised information on their risks and what they can do to help themselves and directs them to sources of further advice and guidance. The consultant said: “Let’s use technology where it can help us and empower women to understand their individual risk factors for their individual needs.”

HSIB identifies the following local learning for maternity healthcare providers and local maternity systems

It may be beneficial for individual organisations to review how their staff involve pregnant women and pregnant people in the assessment of risk factors for venous thromboembolism and to identify any barriers that may be preventing such involvement. Greater involvement of pregnant women/pregnant people may enable more robust assessments and may make it more likely that VTE risk will be identified and acted upon and enable pregnant women/pregnant people to recognise signs and symptoms sooner.

It may be beneficial for organisations to employ quality improvement tools to implement and monitor pregnant women and pregnant people self-completing risk assessment forms in advance of their appointments.

It may be beneficial if organisations review the extent to which national guidance on the assessment of risk factors for venous thromboembolism is understood and implemented across their organisations. This will help to identify whether local barriers exist and if so, which of these to address for improved implementation.

4.2 VTE risk assessment documentation and processes

Demands on staff

4.2.1 The reference event hospital told the investigation that it does undertake audit and monitoring to assess whether VTE risk assessments are being carried out, and whether the calculated risk scores are correct. This is in line with recommendations made by MBRRACE-UK. The audits have previously identified compliance issues at all stages of the assessment process. The resulting actions have included education and training for staff. It was reported that this had improved compliance in the short term, but that the improvement had not been maintained. The investigation was told that reasons for the compliance issues were turnover of staff and other priorities potentially taking precedence.

4.2.2 The investigation observed that staff in antenatal clinics, on the labour suite and on the postnatal ward had multiple competing priorities relating to required education, risk assessments and screening, of which VTE was only one.

4.2.3 During observations of the various antenatal appointments, the investigation saw multiple competing demands being made on midwives. These included:

- interruptions from colleagues for advice and guidance
- assessing the wellbeing of the pregnant woman/pregnant person and the fetus
- responding to the pregnant woman's/person's concerns, which were unpredictable and did not always fit with the required assessment of risks
- providing emotional support to the pregnant woman/pregnant person.

4.2.4 The following observation summaries demonstrate some of the challenges described by midwives:

An observation in an antenatal appointment

The midwife asked the woman how she was. The woman was anxious as she had had previous miscarriages and the estimated due date was getting close (she was 38 weeks pregnant). The woman had taken aspirin and a preventative dose of blood-thinning injection during her pregnancy which had been stopped at 36 weeks. The midwife asked about pains and general wellbeing and the woman stated she had pains in her legs and was short of breath, saying that “stairs aren’t my friend”.

The midwife remained curious about the leg pains and asked more specific questions about them. This was explored further during the appointment and the midwife was sufficiently reassured by what the woman was saying that she did not think there was a risk of VTE. The midwife talked to the woman about the signs and symptoms of VTE and who and when to contact if she had concerns. The midwife and the woman discussed VTE risks and the importance of walking around.

At the end of the consultation, after the woman had left the room, the midwife shared with the investigation that she would not have ordinarily spent as much time talking about the risk of VTE, but that the woman’s notes referred to a clotting history and therefore she made this a focus of her appointment. However, as a result the midwife described to the investigation that she felt rushed for the rest of the appointment as she only had 20 minutes in total per appointment, and this included arrangements for a planned caesarean birth. The appointment overran by 8 minutes.

An observation in an antenatal appointment

The appointment was with a woman who was 34 weeks pregnant and recovering from COVID-19. This was her second pregnancy. The woman had described experiencing involuntary passing of urine when coughing, laughing, or lifting shopping. She also described that she was generally “worn out”. The woman described how she had experienced pelvic pain for most of her pregnancy and was seeking private physiotherapy. The woman shared that because of COVID she had been in her bed much more. She also described that since having COVID she had experienced pain in her ribs at night. The midwife spent time talking through the urinary incontinence and referred the woman to a specialist for follow-up after the birth. The midwife was keen to ensure plans were in place for the woman to speak to the birth choices team as it was likely that the woman would receive care out of the area after the birth.

The investigation did not witness a re-assessment of VTE risk even though the woman had described being in bed a lot of the time because of tiredness from COVID and not moving much when she was up because of the pelvic pain. A risk factor for VTE is immobility in addition to COVID and there may have been a missed opportunity to reassess the woman's risk of VTE.

However, the midwife described feeling rushed trying to cover what she considered to be the priorities for this woman before being able to explore other issues, such as VTE risk.

An observation in a high-risk clinic for pregnant women/pregnant people with complex cardiac (heart) conditions

During the appointment, the midwife completed a VTE assessment and explained the risks and assessment process to the woman. At this time, the assessment did not indicate any VTE risk.

At the end of the appointment, while discussing a previous hospital admission, the woman told the midwife that she had had a previous pulmonary embolism (PE) and was already taking a preventative dose of blood-thinning injections. The midwife and the woman discussed the importance of keeping mobile and hydrated as this could reduce her risks.

The midwife explained to the investigation that most pregnant women/pregnant people are mainly concerned about their babies' growth and listening to the fetal heartbeat at these appointments. The midwife informed the investigation that they considered that pregnant women/pregnant people may not understand the risks associated with VTE and unless the midwife had specifically asked probing questions, it is unlikely the woman would have revealed her history of a previous PE.

4.2.5 The investigation was told by staff that examples such as those above represented an "average" day in antenatal clinic. As a result of the competing demands in the time available, staff were having to "prioritise the priorities", meaning they had to arrange in order of what they thought was the most important issue amongst many demands. Therefore, it is possible the thoroughness of assessments was reduced to improve their time management and ensure a 'good enough' overall assessment. This is a recognised risk (Hollnagel, 2009).

4.2.6 Staff told the investigation that while they understood that the identification of risks to pregnant people and their subsequent care is guided by nationally recognised evidence and best practice, they sometimes felt overwhelmed by "the bureaucracy of form filling". Staff told the investigation that some risk assessments felt like a tick box exercise and therefore they felt they could miss key clinical factors that may affect the pregnant woman/pregnant person.

4.2.7 Alice’s maternity notes included ‘antenatal checklists’ listing topics to be considered at each appointment in line with national guidance (National Institute for Health and Care Excellence, 2021b). For the booking appointment, a checklist of 28 items is included. Seven of these are screening tools which include:

- screening for infectious disease
- screening for sickle cell and thalassemia (types of blood disorder)
- fetal anomaly screening
- VTE
- gestational diabetes (diabetes during pregnancy)
- pre-eclampsia and hypertension (high blood pressure) in pregnancy
- mental health.

4.2.8 Each of the screening tools require an additional task/s to be completed. Specifically, the VTE risk assessment involves checking 26 risk factors for VTE (**figure 5**). The individual assessment for referral checklist includes 80 further items. Some of the checklists require the healthcare professional to make additional follow-up appointments for the pregnant woman/ pregnant person. Other checklists appear to have no actionable outcome and simply form part of the maternity notes.

Figure 5 Identification of risk factors for VTE (Royal College of Obstetricians and Gynaecologists, 2015a)

Risk assessment for venous thromboembolism (VTE)

- If total score ≥ 4 antenatally, consider thromboprophylaxis from the first trimester.
- If total score 3 antenatally, consider thromboprophylaxis from 28 weeks.
- If total score ≥ 2 postnatally, consider thromboprophylaxis for at least 10 days.
- If admitted to hospital antenatally consider thromboprophylaxis.
- If prolonged admission (≥ 3 days) or readmission to hospital within the puerperium consider thromboprophylaxis.

For patients with an identified bleeding risk, the balance of risks of bleeding and thrombosis should be discussed in consultation with a haematologist with expertise in thrombosis and bleeding in pregnancy.

Risk factors for VTE		
Pre-existing risk factors	**Tick**	**Score**
Previous VTE (except a single event related to major surgery)		4
Previous VTE provoked by major surgery		3
Known high-risk thrombophilia		3
Medical comorbidities e.g. cancer, heart failure; active systemic lupus erythematosus, inflammatory polyarthropathy or inflammatory bowel disease; nephrotic syndrome; type I diabetes mellitus with nephropathy; sickle cell disease; current intravenous drug user		3
Family history of unprovoked or estrogen-related VTE in first-degree relative		1
Known low-risk thrombophilia (no VTE)		1(a)
Age (> 35 years)		1
Obesity		1 or 2(b)
Parity ≥ 3		1
Smoker		1
Gross varicose veins		1
Obstetric risk factors		
Pre-eclampsia in current pregnancy		1
ART/IVF (antenatal only)		1
Multiple pregnancy		1
Caesarean section in labour		2
Elective caesarean section		1
Mid-cavity or rotational operative delivery		1
Prolonged labour (> 24 hours)		1
PPH (> 1 litre or transfusion)		1
Preterm birth < 37+0 weeks in current pregnancy		1
Stillbirth in current pregnancy		1
Transient risk factors		
Any surgical procedure in pregnancy or puerperium except immediate repair of the perineum, e.g. appendicectomy, postpartum sterilisation		3
Hyperemesis		3
OHSS (first trimester only)		4
Current systemic infection		1
Immobility, dehydration		1
Total		

Risk factors for VTE

Abbreviations: ART assisted reproductive technology; IVF in vitro fertilisation; OHSS ovarian hyperstimulation syndrome; VTE venous thromboembolism.

(a) If the known low-risk thrombophilia is in a woman with a family history of VTE in a first-degree relative postpartum thromboprophylaxis should be continued for 6 weeks.

(b) BMI ≥ 30 = 1; BMI ≥ 40 = 2

Contraindications/cautions to LMWH use

Contraindications/cautions to LMWH use
Known bleeding disorder (e.g. haemophilia, von Willebrand's disease or acquired coagulopathy)
Active antenatal or postpartum bleeding
Women considered at increased risk of major haemorrhage (e.g. placenta praevia)
Thrombocytopenia (platelet count < 75 × 109/l)
Acute stroke in previous 4 weeks (haemorrhagic or ischaemic)
Severe renal disease (glomerular filtration rate [GFR] < 30 ml/minute/1.73m2)
Severe liver disease (prothrombin time above normal range or known varices)
Uncontrolled hypertension (blood pressure > 200 mmHg systolic or > 120 mmHg diastolic)
Clinical and laboratory thresholds are taken from the Department of Health's guidelines based on evidence from the non pregnant population.

4.2.9 The time allocated for a booking appointment was 1 hour. For routine antenatal appointments, the time allocated was 20 minutes. Staff told the investigation that often this was not enough time to carry out all the required checks.

4.2.10 Staff told the investigation that the number of assessments to be completed at booking appointments has increased over the years and the time allocated to complete booking assessments had remained static. Staff described feeling rushed in completing their risk assessments and that the number of subjects to cover did not support a more holistic assessment of the pregnant woman/pregnant person. One senior midwife stated: "The opportunity for a conversation is lost and assessment of risk has become a tick box exercise." Another told the investigation: "Something has got to give." Another said: "We are trying to cram in too much information, what is the most important thing gets lost."

4.2.11 The investigation observed that staff may be experiencing 'checklist fatigue', whereby they become overburdened with completing these lists (Hales et al, 2008; Burian et al, 2018). The fatigue is often a result of poor design, which, in turn, results in an onerous and time-consuming process. This has been highlighted in other HSIB investigation reports (**Healthcare Safety Investigation Branch, 2022**).

4.2.12 The investigation observed that maternity appointments often overran, creating further time pressure on the staff involved. The investigation observed that staff had very little time, if any, to check the pregnant woman's/pregnant person's notes from previous appointments before they entered the room.

4.2.13 Staff reported that they were rarely able to follow the booking process from end to end because the pregnant woman/pregnant person would want to address their own questions and concerns during their first appointment, diverting staff from the process.

4.2.14 The volume of people in the clinical area was significant, with pregnant women/pregnant people looking visibly frustrated at having to wait. The examination of demand and capacity was outside of the scope of this investigation; however, the investigation was able to observe that staff were trying to consistently balance risk and safety for those they care. Working in these conditions may result in trading off thoroughness for efficiency if demand and resource challenges are not addressed (**see 1.4**).

4.2.15 A consultant obstetrician told the investigation that “managing a woman’s risk requires constant awareness balancing of VTE risk, among other risks and in a busy environment”. They went on to say that even when a pregnant person is assessed as being at risk and requiring a preventative dose of blood-thinning injections, there can be significant delays in administering the first dose due to the busyness of the working environment and the movement of the pregnant person between the antenatal ward, the labour ward and the postnatal ward.

HSIB identifies the following local learning for maternity healthcare providers and local maternity systems

It may be beneficial if organisations undertake their own observations to see how staff complete their assessment of risk factors for venous thromboembolism to identify pregnant women and pregnant people at high risk, and whether what happens ‘in reality’ is in line with local and national policy. This would help to identify gaps in ‘work as imagined’ versus ‘work as done’ and identify ways to make the process safer.

VTE checklist

4.2.16 The investigation found that while healthcare professionals were familiar with the guidance on VTE risk assessment, they did not always prioritise this risk assessment over others. This may be because of the time available and other factors influencing the prioritisation of the identification of other risks.

4.2.17 The investigation was provided with the various records and forms used in the hospital relevant to antenatal and postnatal care and these contained procedures for staff to follow when assessing risk and using the relevant screening tools. All this information is recorded and stored in the ‘My Maternity Notes’ booklets given to the pregnant woman/pregnant person during the booking appointment. These booklets are intended to support a consistent way of assessing their health and well-being.

4.2.18 Work procedures are intended to provide a ‘logical step-by-step way of doing things at work, often in the form of written instructions, checklists, decision aids, diagrams, or flow charts’ (Chartered Institute of Ergonomics and Human Factors, 2020). They standardise tasks, enhance best practice and reduce reliance on memory.

4.2.19 The investigation observed that instructions for VTE risk assessment were not presented in a way that was easy to follow. In addition, the items on the checklist for the whole booking appointment were not listed in order of risk and there was no prioritisation in terms of the questions asked or the importance of the responses. For example, the initial section of the booking appointment starts with information to be given to the pregnant woman/ pregnant person. Some of this information is pertinent to early pregnancy, for example dietary advice and the importance of folic acid. However, other information, such as infant feeding and post-birth contraception, could potentially be provided later.

4.2.20 Checklists are used in both medical and non-medical industries as cognitive aids to guide users through accurate task completion (Hales et al, 2008). Guidance has been published to facilitate the development of well-designed checklists. In healthcare, the intention of checklists is to improve patient safety, but large-scale implementations have revealed variable outcomes, suggesting that these tools are not as simple or effective as hoped (Clay-Williams et al, 2015).

4.2.21 During its observations of antenatal appointments, the investigation noted that the midwife had to locate screening tools and risk assessments from elsewhere in the maternity notes, before they were required to complete them, then remember to return to the initial checklist to continue the process. This can lead to distraction or certain questions being omitted.

4.2.22 Each of the screening tools viewed by the investigation were designed differently. Some followed a clear flow chart that allows the healthcare professional to clearly see when further referrals are necessary (for example, the scanning request form), others required the staff to add up scores within tick boxes and refer if appropriate (for example the aspirin assessment and VTE risk assessment). Certain assessments required comments to be made elsewhere in the document, again potentially leading to omissions being made or delays in identifying relevant information later.

4.2.23 To successfully complete all the assessments, the staff needed to be familiar with the documentation. Similarly, to extract the relevant information at other points of care, this knowledge is required to ensure that nothing is missed.

4.2.24 The investigation is aware that maternity records are not standardised and people attending hospital from different trusts may have notes that follow a different format and have the information presented and stored differently, again potentially adding to staff workload and

increasing the likelihood of something being missed. This was a theme identified in the HSIB national learning report on Never Events, which is particularly relevant to bank and locum staff (**Healthcare Safety Investigation Branch, 2021**).

4.2.25 The format of the notes used for Alice's care has since been updated. A number of the checklists and assessments have been removed to streamline the document. However, the new format may mean that staff have to refer to additional paper documents, which could make the task more complex.

HSIB makes the following safety observation

Safety observation O/2022/199:

It may be beneficial for organisations to consider guidance, such as the 'principles for effectiveness and usability' provided by the Chartered Institute of Ergonomics and Human Factors, when developing risk assessment tools. The aim being to ensure assessments are simple to use and therefore staff being more likely to do them thoroughly and avoid tick-box fatigue.

Interoperability between paper-based and electronic record systems

4.2.26 Alice's VTE assessment was completed on a paper-based risk assessment which was a standalone piece of paper. Staff at the hospital where the reference event took place told the investigation that it was not unusual for individual pieces of paper to get lost. The pregnant woman/pregnant person would retain the paper records and would not always bring the individual pieces of paper with them to their next appointment.

4.2.27 There is a local maternity and neonatal system (LMNS) in the geographical region where Alice had her baby, which is in line with the recommendations of Better Births (NHS England, 2016), a national programme to improve maternity outcomes. An LMNS is a collaboration of maternity service providers and stakeholders, voluntary organisations and service users. Its aim is to provide safe maternity care that offers choice and this is achieved by working in partnership and breaking down barriers across the region. The investigation was told that while the LMNS is trying to make care consistent, there are issues with interoperability of paper and electronic systems, especially when a pregnant woman or pregnant person chooses to have their baby at one hospital and then receives postnatal care from the community teams where they live.

4.2.28 The reference event hospital had plans to move to an electronic maternity healthcare record system, which was intended to replace the traditional paper pregnancy notes in line with national guidance. The transition had been delayed as there were issues with access to IT and Wi-Fi. The investigation was told this was being addressed. However, the hospital staff were also concerned that organisations within the LMNS network used different electronic maternity record systems and that the existing systems, including the 'mum and baby' app, were not interoperable. In addition, mobile internet access was not possible in all areas.

4.2.29 The investigation is aware that NHS Digital and NHS England were jointly leading work at a national level to deliver the digital recommendations in Better Births (NHS England, 2016). This included setting standards for interoperability of electronic maternity systems (NHS England, 2017). The lack of infrastructure in terms of access to fit-for-purpose equipment, connectivity issues, and IT support for community midwives, were key themes identified as part of the maternity digital maturity assessment project (NHS Digital, 2020). The NHS Long Term Plan has committed to rolling out 'Maternity Digital Care Records' for all women/pregnant people by 2023/24 (NHS, 2019). The investigation has since learned that NHSX has taken over responsibility for the birth of the digital maternity programme.

4.2.30 In April 2022 the reference event hospital also introduced new handheld notes and all booking appointment risk assessments are documented in one place. However, there are inconsistencies between hospitals/healthcare settings in the region regarding paper-based and electronic risk assessments. The investigation was told that antenatal risk assessments are completed on paper and if a pregnant woman/pregnant person is admitted to hospital, then electronic records are used. The investigation was told that "this is how things get missed when we are working with paper and electronic systems". Staff working in antenatal clinics using paper records were unable to access the electronic healthcare records.

4.2.31 During its observations the investigation noted that labour ward staff were using electronic versions of the VTE risk assessment tool. The investigation was told that the software prompts staff to complete the risk assessment and that this could not be overridden.

4.2.32 The investigation observed that the electronic version of the VTE risk assessment was completed at a central station on the ward and was not always done with the pregant woman/ pregnant person present. Staff told the investigation team it is common in areas like the labour ward to complete the assessment in the pregnant woman's/pregnant person's absence because the computer is at the central station on the ward and there is limited facility for getting a computer to people's bedsides. The investigation visited the labour ward and observed risk assessments being undertaken:

An observation of assessment of risk factors for VTE on the labour ward

The investigation observed a midwife completing a computer-based online VTE assessment on the labour ward. There was the option of ticking a ‘no risks’ box. The investigation observed that the midwife was going to choose that option. The investigation asked the midwife to run through the risk assessment process. It was during this discussion that the midwife was prompted to go through, in detail, the risk assessment as a way of explanation. While doing so, the midwife recognised an additional risk factor for the woman. This related to the woman having pre-eclampsia. This was only identified because the midwife started to go through the tick box list and recognised a risk factor. This was not a risk factor she held in her head when she was talking to the woman. The midwife shared that because there were not enough computers on wheels on the labour ward, midwives were often unable to complete risk assessments with the pregnant woman/pregnant person present.

4.2.33 The investigation observed that staff on the labour ward had multiple competing priorities. Some staff did understand why the VTE risk assessment was important. However, staff described that it was not uncommon to tick the boxes from what was in the notes and ‘in their heads’ from conversations with the pregnant woman/pregnant person, without undertaking a full face-to-face assessment. In addition, this was a task that needed completing multiple times a day. The investigation considered it was possible that staff had become complacent with the process of VTE risk assessment as, while it could not be bypassed on the electronic maternity record, ‘no risk factors’ could easily be ticked without systematically reviewing the risk factors. This means staff may see the checklist as a repetitive task and form bad habits by making assumptions that there are no risk factors without cross-checking against the risk assessment questions.

4.2.34 The investigation found that the current design of information on the computer-based checklist allows for staff to easily tick ‘no risk factors’ and while it is not possible to override completing the risk assessment, its design, like the paper form, has the potential to create checklist fatigue.

4.2.35 When Alice was 20 weeks pregnant, she experienced pain in her calf and was initially treated for a potential blood clot. The investigation did not observe any further evidence in the medical records that this history was shared with the team that cared for Alice when she gave birth or in the postnatal period. Alice stated that she was not asked about the potential blood clot again and that she did not offer the information. The investigation was unable to explore this further as some members of staff who had cared for Alice had left the organisation and others could not specifically remember Alice’s pregnancy and birth and what may have been

handed over to them. However, the investigation learned that the antenatal maternity records and postnatal notes were kept separately with no shared access, with the pregnant woman/ pregnant person being responsible for bringing their antenatal records to all appointments. This was another example of a lack of interconnectivity of records affecting the birth of patient care.

HSIB identifies the following local learning for maternity healthcare providers and local maternity systems

It may be beneficial if organisations review the existing paper-based and electronic maternity record systems in use and assess how these are used throughout pregnancy and birth. This will help organisations to identify mobile and Wi-Fi access issues and establish whether existing systems are capable of interoperability.

4.3 The prescribing of medication to prevent VTE

4.3.1 Alice told the investigation she did not understand why she was taking medication in the form of an injection to minimise the risk of developing blood clots other than it being “just what happens when you have a caesarean”.

4.3.2 The investigation was told by the reference event hospital that pregnant women and pregnant people are taught how to administer their blood-thinning injections by the staff on the postnatal ward. However, the investigation was told that training is not provided to staff on how and what to teach, meaning that there may be an inconsistent approach to the content and practice of the teaching. Alice confirmed that she had completed the course of injections and that she knew how to do this following her first pregnancy.

4.3.3 The investigation was told by a student midwife that some postnatal people who are discharged with low-molecular-weight heparin (LMWH) (see 1.2.5) wait for community midwives to visit to administer the medication, because they don’t understand the risks and/or are concerned about administering it themselves. This results in delays in their treatment.

4.3.4 The guidance in place at the time of the reference event (Royal College of Obstetricians and Gynaecologists, 2015a) refers to doses of LMWH being based on the pregnant woman’s and pregnant person’s weight. For prescribing preventative blood-thinning injections, the weight at the booking appointment or most recent weight can be used to calculate the dose. Alice’s most recent recorded weight was her booking weight. The hospital’s local guidance stated ‘at least 10 days postnatal enoxaparin thromboprophylaxis [LMWH] (use booking weight) if no contraindications present [no medical reasons not to prescribe this] and thromboprophylactic

enoxaparin doses are based on booking weight'. Alice recalled that she was weighed prior to discharge as "I sat on some weighing scales". However, there is no evidence in her postnatal records that a weight was recorded.

4.3.5 The investigation was unable to speak directly with the healthcare professional who prescribed Alice's LMWH as they had left the organisation and staff that were present could not remember Alice. They did however follow guidance at the time and based the dose on Alice's booking weight.

4.3.6 The MBRRACE-UK report (2021), which was published after Alice was discharged from hospital, discusses that 'when women's weights are close to dosage thresholds at booking, reweighing may be appropriate if it is likely, that weight gain would have led to a change in dosage regimen'. If Alice had been re-weighed during the postnatal period in hospital, it is likely that her weight would have been above the 50kg threshold given her weight on admission for her PE was 56kg. Therefore, the prophylactic (preventative) dose of LMWH needed would have been 40mg, rather than 20mg, for 10 days.

4.3.7 MBRRACE-UK (2021) recommends that 'Trusts Develop guidance on reweighing women at 28 weeks and postpartum [after the birth] to more accurately determine their VTE risk score and the appropriate prophylactic dose of LMWH if it is felt that weight gain in pregnancy may have led to either an increase in their VTE risk score or a change in the weight appropriate prophylactic LMWH dose'.

4.3.8 The hospital where the reference event took place highlighted in its own VTE root cause analysis investigation that 'the main learning point is that weight/BMI [and other variables that are VTE risk factors] are a continuum, so for women who book with a weight of 48kg or 88kg for example, consideration of reweighing in the immediate postnatal period as this may not only change their VTE risk, but also the required dose of LMWH'. The reference event hospital has, following publication of the MBRRACE-UK (2021) report and Alice's case, updated its local guidelines on the reweighting of women.

4.3.9 The hospital had a local system in place in which pharmacy staff would check the dosage and duration of prescribed postnatal prophylactic LMWH and would contact medical staff to clarify both. This acts as a second check to review the rationale for the prescription and reduce the risk of inappropriate prescribing. The investigation was unable to identify whether a pharmacist reviewed Alice's prescription.

4.3.10 Alice was not aware that her medication to prevent VTE was based on her weight and that her booking weight had been used to calculate the dose. Alice told the investigation: "Oh I put loads of weight on when pregnant."

4.3.11 The investigation was told by a professor of thrombosis and haemostasis: “The issues are that there is lack of research evidence to know how to manage VTE in pregnancy globally and the leading UK clinical academic in the area and the NIHR [National Institute for Health and Care Research] know this and are pulling together research themes to address these issues over the next few years. We cannot improve care and processes within care without more research”.

4.3.12 The investigation found that risk assessment in pregnancy and recommendations regarding thromboprophylaxis (medication to prevent VTE) are still supported only by weak clinical evidence and that the majority of recommendations are based on expert opinion rather than information from randomised clinical trials. The Royal College of Obstetricians and Gynaecologists (2015a) guideline makes recommendations for thromboprophylaxis for those at higher risk because there is indirect evidence from medical and surgical patients that thromboprophylaxis reduces the risk of VTE by 60% and 70% respectively.

4.3.13 The investigation was told that research studies have struggled to recruit pregnant women and pregnant people to trials regarding prophylaxis, and there are a number of factors that affect whether pregnant people are willing to participate in research studies, including perceptions of risk, and inconvenience factors. This is supported in research literature (Rodger et al, 2003; van der Zande et al, 2018).

4.3.14 The investigation was told about research into the use of a ‘clot calculator’ to predict the risk of a VTE in the 6 weeks following childbirth (Sutan et al, 2016). The purpose of the clot calculator is to support healthcare professionals in their decisions about which pregnant women and pregnant people would receive preventative blood-thinning injections with LMWH for 10 days. When entering Alice’s information into the calculator, it returned ‘Out of 1000 postpartum women with the risk factors entered on this page, less than 1 will develop VTE within 6 weeks of birth’. The clot calculator is currently undergoing further external validation.

4.3.15 The investigation has been told that the NIHR (2020) research methodology will allow researchers to explore whether it would be better to offer blood-thinning medication to more pregnant women/pregnant people to prevent more blood clots or whether it would be better to offer it to fewer pregnant women/pregnant people to minimise the numbers being exposed to an increased risk of bleeding. The researchers will identify where more information is needed to make the best decisions about using blood-thinning medication and what further research would be most valuable and cost efficient.

HSIB makes the following safety observations

Safety observation O/2022/200:

It may be beneficial for organisations that make recommendations to improve the safety and care of pregnant women and pregnant people during their pregnancy and up to 6 weeks after birth, to have a process for reporting on responses to their recommendations. This would support transparency, making it easy to see what has been achieved and what remains outstanding. The aim being to enable tracking of the implementation of actions designed to improve safety and outcomes to ensure they happen.

Safety observation O/2022/201:

It may be beneficial if future research or funding is directed towards identifying the evidence base for the prescribing of low-molecular-weight heparin for venous thromboembolism risk in pregnancy and the first 6 weeks after birth. This will support the production of evidence-based clinical guidelines for the care and treatment of pregnant women and pregnant people at risk of VTE to ensure it is safe and effective.

5 Summary of findings and safety observations

5.1 Findings

- For healthcare staff, carrying out a robust assessment of risk factors for VTE is challenging, particularly in the complex and busy environment of antenatal clinics, the labour ward and on postnatal wards.
- Multiple competing demands, exacerbated by distractions and interruptions, mean healthcare professionals are constantly having to balance risk and safety for the pregnant women/pregnant people they care for and are trading off the thoroughness of assessments to improve efficiency.
- Midwives are asked to complete a number of risk assessments and screening tools to assess pregnant women's/pregnant people's risk at their first antenatal appointment (known as the booking appointment). However, the time needed to carry out these risks assessments may not be reflected in the time allocated for appointments.
- Risk assessments and screening tools are not all designed and presented in a consistent and logical way that would aid staff in completing the task.

- Assessment of VTE risk factors should take place routinely due to body changes in pregnancy and increased risk of VTE.
- Although assessing VTE risk is important, it is a relatively rare condition and there are a number of other competing risks that may take priority.
- Staff do not always involve pregnant women/pregnant people in, or discuss with them, the assessment of their risk factors for VTE. This means pregnant women/pregnant people may not be aware of the signs and symptoms of a possible VTE.
- The importance of knowing the signs and symptoms of VTE may not be fully understood or prioritised by pregnant women and pregnant people who may have other competing concerns and questions about their antenatal and postnatal care.
- National guidance recommends that assessment of VTE risk factors should repeated when a pregnant woman/pregnant person presents with an ‘intercurrent problem’ (a new health issue which may or may not be related to the pregnancy). However, not all healthcare professionals understand the meaning of ‘intercurrent problem’ and therefore opportunities to reassess risk factors are missed.
- There is a mix of paper-based and electronic record keeping in antenatal and postnatal care. Electronic records systems may lack interoperability and suffer from poor connectivity which limits the ability of staff to access all the data, information, and knowledge they need at the time of assessment.
- Recommendations by MBRRACE-UK (Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK) for the development of a tool to make the current assessment of VTE risk factors simpler and more reproducible, have not been acted on.

5.2 HSIB makes the following safety observations

Safety observation O/2022/199:

It may be beneficial for organisations to consider guidance, such as the ‘principles for effectiveness and usability’ provided by the Chartered Institute of Ergonomics and Human Factors, when developing risk assessment tools. The aim being to ensure assessments are simple to use and therefore staff being more likely to do them thoroughly and avoid tick-box fatigue.

Safety observation O/2022/200:

It may be beneficial for organisations that make recommendations to improve the safety and care of pregnant women and pregnant people during their pregnancy and up to 6 weeks after birth, to have a process for reporting on responses to their recommendations. This would support transparency, making it easy to see what has been achieved and what remains outstanding. The aim being to enable tracking of the implementation of actions designed to improve safety and outcomes to ensure they happen.

Safety observation O/2022/201:

It may be beneficial if future research or funding is directed towards identifying the evidence base for the prescribing of low-molecular-weight heparin for venous thromboembolism risk in pregnancy and the first 6 weeks after birth. This will support the production of evidence-based clinical guidelines for the care and treatment of pregnant women and pregnant people at risk of VTE to ensure it is safe and effective.

5.3 Local learning for maternity healthcare providers and local maternity systems

The HSIB investigation identified local learning that may assist maternity healthcare providers and local maternity systems (regional groupings of maternity service providers) when considering how to support the assessment of risk factors for VTE.

It may be beneficial for individual organisations to review how their staff involve pregnant women and pregnant people in the assessment of risk factors for venous thromboembolism and to identify any barriers that may be preventing such involvement. Greater involvement of pregnant women/pregnant people may enable more robust assessments and may make it more likely that VTE risk will be identified and acted upon and enable pregnant women/pregnant people to recognise signs and symptoms sooner.

It may be beneficial for organisations to employ quality improvement tools to implement and monitor pregnant women and pregnant people self-completing risk assessment forms in advance of their appointments.

It may be beneficial if organisations review the extent to which national guidance on the assessment of risk factors for venous thromboembolism is understood and implemented across their organisations. This will help to identify whether local barriers exist and if so, which of these to address for improved implementation.

It may be beneficial if organisations undertake their own observations to see how staff complete their assessment of risk factors for venous thromboembolism to identify pregnant women and pregnant people at high risk, and whether what happens ‘in reality’ is in line with local and national policy. This would help to identify gaps in ‘work as imagined’ versus ‘work as done’ and identify ways to make the process safer.

It may be beneficial if organisations review the existing paper-based and electronic maternity record systems in use and assess how these are used throughout pregnancy and birth. This will help organisations to identify mobile and Wi-Fi access issues and establish whether existing systems are capable of interoperability.

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