HSIB

HEALTHCARE SAFETY INVESTIGATION BRANCH

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Summary

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

Independent report by the
Healthcare Safety Investigation Branch NI-006522

December 2022

Providing feedback and comment on HSIB reports

At the Healthcare Safety Investigation Branch (HSIB) we welcome feedback on our investigation reports. The best way to share your views and comments is to email us at **enquiries@hsib.org.uk** or complete our online feedback form at **www.hsib.org.uk/tell-us-what-you-think**.

We aim to provide a response to all correspondence within five working days.

About HSIB

We conduct independent investigations of patient safety concerns in NHS-funded care across England. Most harm in healthcare results from problems within the systems and processes that determine how care is delivered. Our investigations identify the contributory factors that have led to harm or the potential for harm to patients. The safety recommendations we make aim to improve healthcare systems and processes, to reduce risk and improve safety.

We work closely with patients, families and healthcare staff affected by patient safety incidents, and we never attribute blame or liability.

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.

Our investigations

Our investigators and analysts have diverse experience of healthcare and other safety-critical industries and are trained in human factors and safety science. We consult widely in England and internationally to ensure that our work is informed by appropriate clinical and other relevant expertise.

We undertake patient safety investigations through two programmes:

National investigations

Concerns about patient safety in any area of NHS-funded healthcare in England can be referred to us by any person, group or organisation. We review these concerns against our investigation criteria to decide whether to conduct a national investigation. National investigation reports are published on our website and include safety recommendations for specific organisations. These organisations are requested to respond to our safety recommendations within 90 days, and we publish their responses on our **website**.

Maternity investigations

We investigate incidents in NHS maternity services that meet criteria set out within one of the following national maternity healthcare programmes:

- Royal College of Obstetricians and Gynaecologists' 'Each Baby Counts' report
- MBRRACE-UK 'Saving Lives, Improving Mothers' Care' report.

Incidents are referred to us by the NHS trust where the incident took place, and, where an incident meets the criteria, our investigation replaces the trust's own local investigation. Our investigation report is shared with the family and trust, and the trust is responsible for carrying out any safety recommendations made in the report.

In addition, we identify and examine recurring themes that arise from trust-level investigations in order to make safety recommendations to local and national organisations for system-level improvements in maternity services.

For full information on our national and maternity investigations please **visit our website**.

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 guidelines for the care and treatment of pregnant women and pregnant people at risk of VTE to ensure it is safe and effective.

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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