



HEALTHCARE SAFETY
INVESTIGATION BRANCH

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Summary report

The diagnosis of ectopic pregnancy

Independent report by the
Healthcare Safety Investigation Branch I2018/021

March 2020



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About HSIB

The Healthcare Safety Investigation Branch (HSIB) conducts 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 recommendations we make aim to improve healthcare systems and processes, to reduce risk and improve safety. Our organisation values independence, transparency, objectivity, expertise and learning for improvement. We work closely with patients, families and healthcare staff affected by patient safety incidents, and we never attribute blame or liability to individuals.

A note of acknowledgement

We are grateful to the patient whose experience is central to this investigation for sharing her story. With her permission, she is referred to by her name, Abby, throughout this report. Abby's experience provided an invaluable insight into the care of those with an ectopic pregnancy.

We also thank the NHS staff, subject matter advisors and members of stakeholder organisations who gave their time to provide us with information and expertise which has contributed towards this report.

Our investigations

Our team of investigators and analysts have diverse experience working in 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

Our national investigations can encompass any patient safety concern that occurred within NHS-funded care in England after 1 April 2017. We consider potential incidents or issues for investigation based on wide sources of information including that provided by healthcare organisations and our own research and analysis of NHS patient safety systems.

We decide what to investigate based on the scale of risk and harm, the impact on individuals involved and on public confidence in the healthcare system, and the learning potential to prevent future harm. We welcome information about patient safety concerns from the public, but we do not replace local investigations and cannot investigate on behalf of families, staff, organisations or regulators.

Our investigation reports identify opportunities for relevant organisations with power to make appropriate improvements though:

- 'Safety recommendations' made with the specific intention of preventing future, similar events; and
- 'Safety observations' with suggested actions for wider learning and improvement.

Our reports also identify 'safety actions' taken during an investigation to immediately improve patient safety.

We ask organisations subject to our recommendations to respond to us within 90 days. These responses are published on our website.

More information about our national investigations including in-depth explanations of our criteria, how we investigate, and how to refer a patient safety concern is available on our [website](#).

Maternity investigations

From 1 April 2018, we have been responsible for all NHS patient safety investigations of maternity incidents which meet criteria for the **Each Baby Counts programme** (Royal College of Obstetricians and Gynaecologists, 2015) and also maternal deaths (excluding suicide). The purpose of this programme is to achieve learning and improvement in maternity services, and to identify common themes that offer opportunity for system-wide change. For these incidents HSIB's investigation replaces the local investigation, although the trust remains responsible for meeting the Duty of Candour and for referring the incident to us. We work closely with parents and families, healthcare staff and organisations during an investigation. Our reports are provided directly back to the families and to the trust. Our safety recommendations are based on the information derived from the investigations and other sources such as audit and safety studies, made with the intention of preventing future, similar events. These are for actions to be taken directly by the trust, local maternity network and national bodies.

Our reports also identify good practice and actions taken by the Trust to immediately improve patient safety.

Since 1 April 2019 we have been operating in all NHS Trusts in England.

We aim to make safety recommendations to local and national organisations for system-level improvements in maternity services. These are based on common themes arising from our trust-level investigations and where appropriate these themes will be put forward for investigation in the National Programme. More information about our maternity investigations is available on our [website](#).

Executive Summary

Introduction

This investigation explores the diagnosis of ectopic pregnancy; a condition where a pregnancy develops in an abnormal location outside the lining of the uterus. The majority of ectopic pregnancies occur within one of the Fallopian tubes. Left untreated, a tubal ectopic pregnancy can lead to a rupture of the Fallopian tube. The resultant internal bleeding is a known cause of maternal death (death of the mother during pregnancy or up to 42 days after giving birth or the end of pregnancy) and was highlighted in the findings of the UK National Confidential Enquiry into Maternal Deaths. In addition, an ectopic pregnancy may impact on a woman's fertility. The majority of ectopic pregnancies can be diagnosed by a transvaginal ultrasound scan (TVUS); these scans are commonly undertaken in hospital-based early pregnancy units (EPU).

The reference event

A 26-year-old woman, Abby, attended a minor injuries unit on a Saturday morning. She was complaining of abdominal pain. She was suspected of having a urinary tract infection with urine retention (inability to pass urine). Abby was advised to attend the emergency department (ED) where she was triaged by an ED nurse and assessed by an ED doctor. The doctor thought that Abby may be experiencing a miscarriage and her symptoms warranted referral to the EPU for further investigation. Following a telephone referral to the early pregnancy service, the ED doctor understood that Abby would be triaged by a specialist nurse over the phone that day and receive a TVUS within 24 hours.

Abby was discharged home, accompanied by her mother. She continued to experience pain and, that same day, called the EPU to arrange her scan appointment. She was initially offered an appointment on Wednesday, four days later. Abby requested an earlier appointment and it was agreed that she would attend for a TVUS on the following Monday, two days later. On Monday morning, the EPU phoned Abby to postpone her scan until Tuesday because a member of staff was off sick. When Abby attended for her scan, 72 hours after being discharged from the ED, she was found to have a suspected ruptured ectopic pregnancy. She was admitted to hospital and underwent emergency surgery three hours later to remove her left Fallopian tube. Abby was discharged from hospital after four days.

The national investigation

Failure to diagnose and treat ectopic pregnancy is a nationally recognised patient safety risk. The Healthcare Safety Investigation Branch (HSIB) contacted the hospital where the reference event occurred after it was reported as an incident on the national serious incident reporting database. Following initial information gathering and evaluation against the HSIB patient safety risk criteria (see section 3.2 in the full report), the Chief Investigator authorised a national safety investigation. The investigation reviewed the processes for assessment and decision making in the ED and the organisation of early pregnancy services to meet the national standard as recommended by the National Institute for Health and Care Excellence (NICE). The investigation saw different models of service delivery around the country and identified variations in the care pathway. Drawing on evidence from the reference event, the investigation paid particular attention to the relationship between the ED and the EPU. However, the conclusions of this investigation may also be applicable to referral from primary care.

Findings

- There is variation in the provision of early pregnancy services across the NHS in England.
- There can be challenges with providing a seven-day-a-week early pregnancy scanning service. Trusts have developed different operational models to accommodate these challenges.
- Referral systems should include standardised information that supports triage and decision-making by early pregnancy services.
- There may be benefits in standardising the information leaflets given to women in early pregnancy who are discharged from an ED.
- The Care Quality Commission's assessment framework for early pregnancy units does not currently include NICE guideline 126, which sets out important aspects of service provision related to diagnosis and treatment of ectopic pregnancy.
- Women with an ectopic pregnancy often attend healthcare services with non-specific symptoms that may indicate other common conditions such as urinary tract infections. It may be beneficial to

clinical staff if NICE clinical knowledge summaries (which provide information about the current evidence base and guidance on best practice for different health conditions) included ectopic pregnancy as a possible diagnosis for consideration.

- It is possible to carry out a pregnancy test using a blood sample. Where there may be delay in obtaining a urine sample, this alternative should be considered.

Local learning for NHS trusts

The HSIB investigation identified local learning that may assist NHS trusts when considering preventing the delayed diagnosis of ectopic pregnancy:

- Trusts can seek to understand hazards within a care pathway by undertaking a systemic risk analysis. When trusts are identifying hazards within the care pathway, they should involve staff who deliver care. This will ensure that trusts' understanding of what actually happens in the work place ('**work as done**') is comprehensive.
- When developing policies and flowcharts ('**work as prescribed**'), trusts can take a systems safety approach and involve human factors thinking in their design and testing. This will help align '**work as prescribed**', and '**work as done**'.
- Where service provision changes at weekends and out of hours, referral systems should seek to simplify processes for staff by identifying and mitigating hazards.
- Trusts can observe services on a regular basis to understand where '**work as done**' has drifted from the assumptions of managers about how it is done ('**work as imagined**'). Identifying local solutions and work-arounds may help to refine the design of systems and policies.
- Trusts may wish to review options for pregnancy testing in urgent care settings.
- Where women experiencing complications in early pregnancy cannot be offered a TVUS straight away, trusts can provide information to ensure that women understand the signs and symptoms of ectopic pregnancy. Information should be clear about what actions a woman should take in the event of deterioration.

HSIB makes the following safety recommendations

Safety recommendation R/2020/075:

The National Institute for Health and Care Excellence should review and revise the clinical knowledge summary for '**urinary tract infection (lower) – women**' to include ectopic pregnancy as a category under '**alternative or serious diagnoses**'.

Safety recommendation R/2020/076:

The Royal College of Emergency Medicine should provide standardised discharge information for clinicians to offer to women following discharge from the emergency department with a problem in early pregnancy and while awaiting further assessment by early pregnancy services.

Safety recommendation R/2020/077:

The Royal College of Obstetricians and Gynaecologists should provide guidance on the information that should be provided during referral to early pregnancy units to standardise and improve the flow of information required to identify those most at risk from ectopic pregnancy and any consequent deterioration.

Safety recommendation R/2020/078:

It is recommended that the Care Quality Commission Services Framework for Gynaecology and Termination Services includes an assessment of early pregnancy services, using as a reference the National Institute for Health and Care Excellence Guideline 126, Ectopic pregnancy and miscarriage: diagnosis and initial management.

HSIB makes the following safety observations

Safety observation O/2020/063:

There is insufficient capacity to meet the demand for sonography if early pregnancy units are to deliver a seven-day-a-week service. It may be beneficial for NHS England/Improvement and Health Education England to carry out a workforce review to identify a strategy to meet this demand.

Safety observation O/2020/064:

Care providers may benefit from conducting a proactive systematic risk analysis when designing or reviewing care pathways. Such an analysis should consider '**work as done**' (the way work is actually carried out, which may differ from written policies and procedures) in order to identify and mitigate hazards that impact patient safety.

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Further information

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If you would like to request an investigation then please read our **guidance** before submitting a safety awareness form.

 @hsib_org is our Twitter handle. We use this feed to raise awareness of our work and to direct followers to our publications, news and events.

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