



HEALTHCARE SAFETY
INVESTIGATION BRANCH

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INTERIM BULLETIN

THE DIAGNOSIS OF ECTOPIC PREGNANCY

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This interim bulletin contains facts which have been determined up to the time of issue. It is published to inform the NHS and the public of the general circumstances of events and incidents and should be regarded as tentative and subject to alteration and correction if additional evidence becomes available.



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NOTIFICATION OF EVENT AND DECISION TO INVESTIGATE

The Healthcare Safety Investigation Branch (HSIB) identified the delayed diagnosis of ectopic pregnancy as a significant patient safety risk for investigation.

Having reported the event as a serious incident, the Trust was contacted by HSIB seeking their cooperation in gathering evidence for a national investigation.

Following a preliminary scoping investigation, the Chief Investigator authorised a full investigation as the risk met the following criteria:

Outcome Impact – what impact has a safety issue had, or is having, on people and services across the healthcare system?

A delayed or missed diagnosis of an ectopic pregnancy can be fatal. Of the 12 maternal deaths in early pregnancy in the UK between 2009-14, nine were related to ectopic pregnancy.

A delayed diagnosis may also increase the likelihood that patients will be exposed to the risks of emergency surgery¹.

Ectopic pregnancy can also have an adverse effect on future fertility and its psychological impact can be significant.

¹Data from the Intensive Care National Audit and Research Centre (ICNARC) Case-Mix Programme (CMP)



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Systemic Risk - how widespread and how common a safety issue is this across the healthcare system?

Early pregnancy complications, including ectopic pregnancy, are common and account for the majority of emergency work performed in gynaecology departments throughout the UK. Between six and 16% of women who attend an ED with vaginal bleeding or abdominal pain in the first trimester of pregnancy will have an ectopic pregnancy.

In the UK, around one in every 80 to 90 pregnancies is ectopic, therefore approximately 12,000 women per year will be diagnosed in the UK².

The maternal mortality rate for ectopic pregnancy is two per 10,000.

Between April 2017 and August 2018, 30 incidents of missed diagnosis of ectopic pregnancy, resulting in serious harm or death, were reported to the StEIS national database.

Between 2009 and 2012 there were 289 women admitted for critical care with ectopic pregnancy as the primary cause in England, Wales and Northern Ireland.

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

Delayed diagnosis of ectopic pregnancy continues to occur despite outputs of local investigations and guidance from National Institute for Health and Care Excellence (NICE) and Royal Colleges. An HSIB investigation brings a systemic approach and recommendations at a national level.

²NHS Overview of ectopic pregnancy



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HISTORY OF THE EVENT

A 26-year-old woman presented at a minor injuries unit shortly after it opened at 08:00 on a Saturday morning having had increasing abdominal pain over the previous 12 hours.

The patient was suspected to have a urinary tract infection at the minor injuries unit. It was thought that she may be in retention of urine and require catheterisation, therefore she was advised to attend the Emergency Department (ED) of a nearby hospital.

She was accompanied by her mother to the ED where she arrived at 08:47 and was assessed at 09:14 by a triage nurse who recorded the presenting complaint as urinary retention. She was then assessed by a nurse and at that time reported her pain score as 8/10. An ultrasound scan of the bladder revealed that she was not in retention of urine. When a urine sample was provided, it contained significant traces of blood. A pregnancy test carried out on the urine sample was positive. This was unexpected as she had been prescribed a Depo-Provera contraceptive injection.

At 10:00, a locum junior ED doctor assessed the patient. The doctor considered the patient's previous medical history, conducted a physical examination and reviewed the results of blood tests before contacting the gynaecological assessment unit (GAU) to refer her for gynaecological assessment and a transvaginal ultrasound scan (TVS).



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The GAU provided a clinic staffed by clinical nurse specialists (CNS) with additional qualifications in ultrasound scanning. The clinic ran a list of elective scans from 19:30 to 20:00 on weekdays and, during working hours, also took urgent referrals from the ED. At weekends, these services were provided by a sister hospital in the same Trust between 08:00 and 20:00. Details of the referral made by the ED doctor were faxed to the sister hospital for the CNS to follow-up. This follow-up involved contacting the patient and deciding the urgency of the scan appointment based on the medical records and the patient's symptoms.

Following the referral to the GAU, the ED doctor expected the patient would be contacted and receive a scan within the next 24 hours. The patient was given analgesia for her pain and at 12:20 the doctor returned to review her; her pain was less severe and she wanted to go home. The doctor provided a contact number for the GAU.

When she arrived home she was still in pain. She phoned the GAU at 13:03 and was given an appointment for the clinic at the sister hospital two days later, on the following Monday. She did not recall being asked any questions about her condition during the call. Later that day she collapsed twice at home. By the following day the pain had eased and she went to work on the Monday. That morning she received a phone call postponing her appointment until 14:00 on the Tuesday. Again, she could not recall any questions being asked about her condition.



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At the Tuesday appointment, the CNS conducted a TVS which indicated an ectopic pregnancy³. The patient was admitted to hospital and plans were made for surgery. During surgery she was found to have a ruptured left fallopian tube, which was removed. The surgery took longer than expected due to complications during the procedure. The patient was discharged from hospital after four days.

NATIONAL CONTEXT

In November 2015, the Secretary of State for Health announced an ambition to reduce maternal mortality by 20% by 2020 and 50% by 2025. The early detection and management of ectopic pregnancy has a significant role to play in achieving this target.

NICE guidance on the diagnosis and management of ectopic pregnancy is currently under review. Both the Royal College of Obstetricians and Gynaecologists and Royal College of Emergency Medicine have published clinical guidance and there is considerable academic research about the subject.

IDENTIFIED SAFETY ISSUES

The following safety issues were identified during the HSIB's initial investigation and will form the basis for the ongoing investigation:

- Referral from the emergency department into early pregnancy services
- Provision of early pregnancy assessment services that allow for the timely diagnosis and optimum management of ectopic pregnancies.

NEXT STEPS

HSIB will continue to explore the identified safety issues and welcomes further information that may be relevant, regardless of source.

³ An ectopic pregnancy is when a fertilised egg implants itself outside of the uterus, usually in one of the fallopian tubes. Left untreated, the egg can grow and cause the fallopian tube to rupture.