Health Services Safety Investigations Body

Investigation report

The diagnosis of ectopic pregnancy

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Emergency care, Communication and decision making

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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.

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.

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

Glossary of abbreviations

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CASE	Consortium for the Accreditation of Sonographic Education
CNS	clinical nurse specialist
CQC	Care Quality Commission
ED	emergency department
ENP	emergency nurse practitioner
EPU	early pregnancy unit
EWS	early warning score
GMC	General Medical Council
Hb	haemoglobin
hCG	human chorionic gonadotrophin
HSIB	Healthcare Safety Investigation Branch
MIU	minor injuries unit
NICE	National Institute for Health and Care Excellence
OOH	out of hours
RCEM	Royal College of Emergency Medicine
RCOG	Royal College of Obstetricians and Gynaecologists
SCoR	Society and College of Radiographers

SMA	subject matter advisor
StEIS	Strategic Executive Information System
TVUS	transvaginal ultrasound scan
UTI	urinary tract infection
HRO	high reliability organisation

1 Background

1.1 Introduction

1.1.1 This investigation followed the care of a woman who experienced a delayed diagnosis of an ectopic pregnancy. Following an analysis of that event the scope of the investigation was broadened to include a review of the wider contributory factors identified in the context of the early pregnancy care pathway. The investigation focused specifically on the relationship between early pregnancy services and hospital emergency departments.

1.1.2 An estimated 12,000 women experience an ectopic pregnancy each year in the UK. The 2016 report Saving Lives, Improving Mothers' Care (Knight et al, 2016) states that of the 12 women who died in early pregnancy between 2009 and 2014, nine died as a direct result of ectopic pregnancy. During the care of five of these women, the diagnosis of ectopic pregnancy was never considered by the staff who treated them.

1.1.3 The national ambition, as announced by the Secretary of State for Health in November 2015, was to reduce maternal deaths1 by 50% by 2030 and by 20% by 2020. In 2017, this ambition was revised to halve the rate of maternal deaths by 2025 (Department of Health, 2017). The prompt diagnosis of ectopic pregnancy will play a role in this ambition

1.2 Ectopic pregnancy

1.2.1 An ectopic pregnancy occurs when a fertilised egg implants itself outside of the cavity of a woman's uterus (Figure 1). The most common site for an ectopic pregnancy is the Fallopian tube (known as a tubal ectopic pregnancy). It may also occur in or on the ovaries, abdomen, cervix, muscle of the uterus wall, or the fertilised egg may attach to the scar from a previous caesarean section (BMJ est Practice, 2019; The Ectopic Pregnancy Trust, 2019).

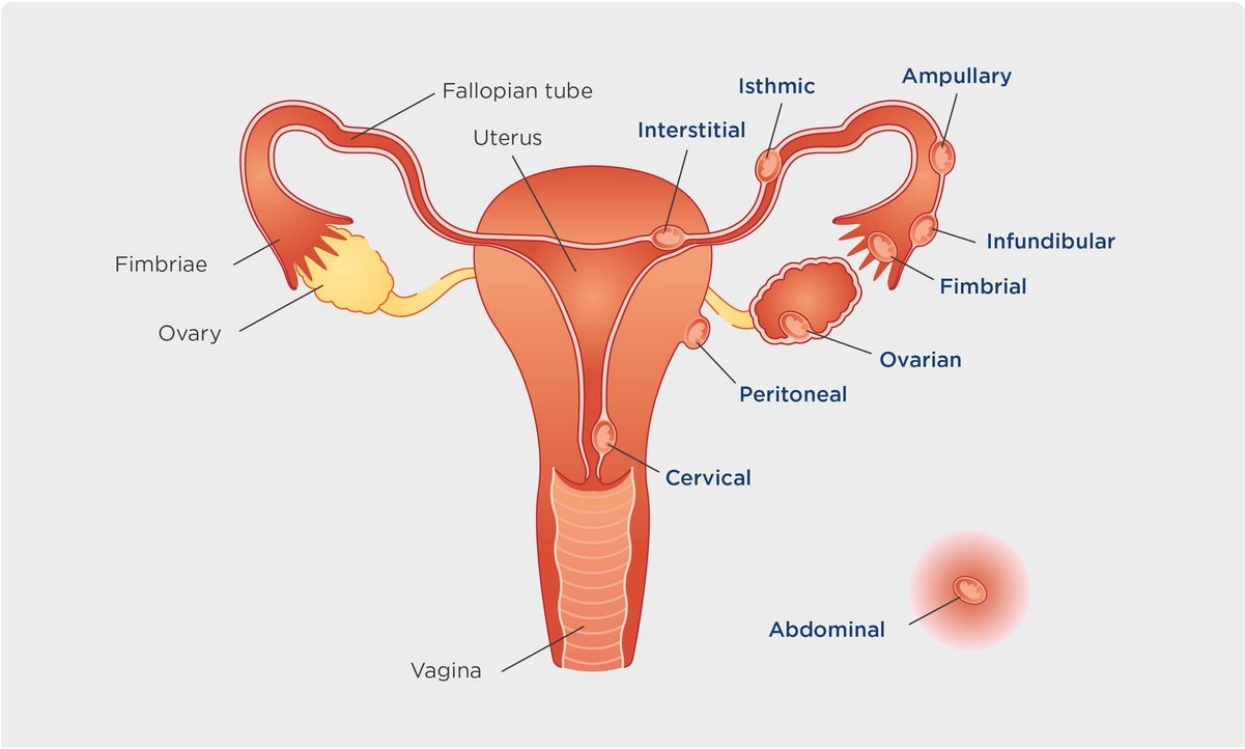


Fig 1 Diagram showing female reproductive organs and possible sites for ectopic pregnancy

1.2.2 Unlike the uterus, the Fallopian tube cannot stretch to accommodate a growing embryo. If a tubal ectopic pregnancy is undiagnosed and left untreated, it can damage the tube or cause it to rupture, with potentially fatal consequences for the woman due to internal bleeding. An ectopic pregnancy will not progress to a viable pregnancy.

1.2.3 The symptoms of ectopic pregnancy are often non-specific and difficult to differentiate from those of other gynaecological problems and disorders of the bladder or bowel, such as urinary tract problems and gastrointestinal problems like appendicitis (NICE, 2019a).

The common symptoms are abdominal or pelvic pain, amenorrhoea (missed period) and vaginal bleeding. Other symptoms include:

- breast tenderness
- dizziness or fainting
- shoulder tip pain
- rectal pressure or pain on defecation.

1.2.4 The diagnosis of ectopic pregnancy can be difficult unless the condition is suspected. It can be confused with miscarriage, ovarian conditions or pelvic inflamatory disease. Taking a medical history and physical examination alone cannot reliably diagnose or exclude ectopic pregnancy (Tay et al, 2000).

1.2.5 The amount of vaginal bleeding associated with ectopic pregnancy varies, although classically the patient will complain of ‘spotting’. Between 10% and 20% of women with ectopic pregnancy report no bleeding (Jurkovic and Wilkinson, 2011).

1.2.6 Pain is usually a late feature in the clinical presentation of ectopic pregnancy and usually isolated to one side of the abdomen. Nine per cent of women diagnosed with ectopic pregnancy report no pain and 36% lacked tenderness around the uterus, ovaries, and Fallopian tubes. The majority of women with abdominal pain in early pregnancy do not have an ectopic pregnancy (Bottomley et al, 2009).

1.2.7 A transvaginal ultrasound scan (TVUS) is the most common way to diagnose an ectopic pregnancy (Royal College of Obstetricians and Gynaecologists, 2016).

1.2.8 Ultrasound imaging uses high-frequency sound waves to assess organs and structures within the body to assist in the screening and diagnosis of a wide range of conditions.

TVUS is used to examine the female reproductive organs. Unlike an abdominal or pelvic ultrasound, where the ultrasound probe rests on the outside of the pelvis or abdomen, this procedure involves inserting an ultrasound probe into the vagina.

1.2.9 With increasingly high-resolution ultrasound and expert operators (ultrasound practitioners), TVUS is accurate in the diagnosis of ectopic pregnancy. In a study of over 5,000 women attending an early pregnancy service, 73.9% of ectopic pregnancies were diagnosed on the first TVUS (Kirk et al, 2014).

1.2.10 Not all ectopic pregnancies can be seen on TVUS. Those women with a positive pregnancy test but whose pregnancy was not identified during a scan are considered to have a pregnancy of unknown location (PUL). These women must be followed up by early pregnancy services, as a proportion will be at risk of an ectopic pregnancy that was not visualised on the initial scan.

1.2.11 During pregnancy, the body produces increasing levels of hormones, including human chorionic gonadotrophin (hCG) and progesterone. In the first weeks of a normal pregnancy, the levels of hCG will normally increase by 63% in 48 hours, peaking after 8 to 11 weeks (NICE, 2019). The levels of these hormones in the blood are frequently used to assess how a pregnancy is progressing. Having been diagnosed by TVUS, the management of an ectopic pregnancy will be informed by these chemical indicators.

1.2.12 Once diagnosed, a tubal ectopic pregnancy may be treated in three ways:

- **Expectant management**. If a patient has no symptoms, or mild symptoms, and the pregnancy is very small, the patient's hCG levels may be closely monitored over 48 to 96 hours. In these circumstances, the ectopic pregnancy may well resolve by itself.
- **Medical management**. If an ectopic pregnancy is diagnosed early but expectant management is not suitable, treatment with a drug that works by stopping the pregnancy from developing (methotrexate) may be recommended (BMJ Best Practice, 2019).
- **Surgical management**. A surgical procedure is required for ruptured ectopic pregnancy or when expectant and medical management are not suitable or have failed. Surgery is normally conducted laparoscopically (using 'key-hole' surgery) under general anaesthetic. Small incisions are made into the abdomen and a thin viewing tube (laparoscope) and small surgical instruments are inserted through the incisions. In most cases of tubal ectopic pregnancy, the affected Fallopian tube is removed (salpingectomy), but in some cases it is possible to remove only the pregnancy and leave the tube (salpingostomy) (BMJ Best Practice, 2019).

1.2.13 Women with problems in early pregnancy will typically be cared for by a specialist early pregnancy unit (EPU). There are over 200 EPUs in NHS hospitals across the UK. EPUs are staffed by specialist nurses, midwives, sonographers, doctors and other health professionals. They provide ultrasound scans to confirm the location and viability of a pregnancy and treat women diagnosed with complications such as miscarriage or ectopic pregnancy. The Association of Early Pregnancy Units provides professional input to maintain standards in early pregnancy care and offers information to patients via a website.

1.2.14 The Royal College of Obstetricians and Gynaecologists (RCOG) produces clinical guidance on a range of subjects including ectopic pregnancy. It publishes this guidance in documents, known as '**green□top guidelines'**, which establish recognised methods and techniques for clinical practice. It also sets competencies in ultrasonography for its members. Women experiencing problems in early pregnancy will usually be treated by gynaecologists, often with a specialist interest in early pregnancy.

2 The reference event

2.1 The patient's story

2.1.1 Abby, a 26-year-old woman, experienced increasing abdominal pain from 20:00 hours on a Friday night, continuing into Saturday morning.

2.1.2 By 06:30 hours on Saturday, Abby's pain was so intense that she woke her mother and took pain relief (ibuprofen and paracetamol). Abby's mother drove her to a nearby minor injuries unit (MIU) where they arrived at 08:03 hours.

2.1.3 At 08:10 hours, Abby was seen by an emergency nurse practitioner (ENP) and it was documented that Abby was complaining of severe abdominal pain radiating to her right lower back. Her self-assessed pain score (a subjective measurement of a person's experience of their pain) was recorded as 9/10. Abby was noted as attending a genitourinary clinic and having a history of pelvic inflammatory disease(2) and multiple urinary tract infections (UTIs). There is no record that Abby was asked about her menstrual history, but she did not consider that she could be pregnant because she had received a long-acting contraceptive injection (Depo-Provera).

2.1.4 Abby had not passed urine since midnight, had been drinking water and reported her lower abdomen was very swollen. The ENP suspected that she had a UTI and was in urine retention (unable to empty her bladder). Urine retention can cause discomfort or pain and is treated by draining the bladder by inserting a urinary catheter(3). Following a review by the senior nurse, after 16 minutes in the MIU Abby was told she may need catheterisation and was advised to attend the local emergency department (ED) for treatment. The MIU produced a summary of Abby's attendance but this was not available to either Abby or the local ED when she attended there soon after.

2.1.5 The ED attendance summary noted that Abby arrived at the ED at 08:47 hours. She explained to the navigation nurse(4) at the ED reception that the MIU had advised her to attend, accompanied by her mother. Abby was documented as being in urine retention and directed to the 'majors'(5) area.

2.1.6 Abby was assessed by a triage nurse(6) at 09:14 hours. Observations were recorded as follows: temperature 36.8°C (normal 36 to 37.6°C), pulse of 110 (normal 51 to 100), respiratory rate 16 breaths/minute (normal 9 to 16), oxygen saturation at 98% (normal 94% and over), and blood pressure of 116/71mmHg(7) (normal systolic pressure(8) above 100mmHg). Although only experiencing a high heart rate, Abby was given an early warning score of 4 (EWS 4)(9). The triage form recorded that Abby reported she had been experiencing lower abdominal pain radiating into her back since the previous night. Abby's pain score was noted as 8/10.

2.1.7 Abby was unable to provide a urine sample. The triage nurse conducted an abdominal ultrasound scan which showed Abby did not have retention of urine. At 09:30 hours the nurse prescribed 60mg of codeine phosphate to relieve Abby's pain. This was administered 10 minutes later.

2.1.8 At some point after the triage assessment Abby was able to provide a urine sample. This was analysed at 09:42 hours and found to contain blood as well as identifying that Abby was pregnant. This was a shock to Abby because she was receiving the contraceptive injection.

2.1.9 Abby was assessed by a junior ED doctor at 10:00 hours. The doctor reviewed the triage notes and was aware that Abby was pregnant. The doctor asked Abby how quickly her symptoms had developed, took her medical history and conducted a physical examination.

The medical assessment was documented in Abby's medical notes. The ED doctor recorded that Abby was experiencing pain in the lower abdomen and vagina but described the pain as non-radiating. The ED doctor documented that Abby had no vaginal bleeding but that she reported brown staining on toilet paper when passing urine, similar to that experienced at the end of a menstrual period. During interview the ED doctor explained that they had recorded 'no bleeding' after exploring with Abby whether there was any indication of fresh, red blood. Under past medical history, the ED doctor noted that Abby was normally fit and well, had no known allergies and was not taking any medications.

(2) Pelvic inflammatory disease is a common condition in women. It is an infection of the upper genital tract, including the womb, Fallopian tubes and ovaries (NHS, 2018).

(3) A small, flexible tube inserted into the bladder through the urinary opening to drain the bladder.

(4) When the ED was busy the hospital had a policy of positioning a senior nurse at the first point of patient contact to improve patient flow.

(5) The ED had two areas: 'majors' staffed by specialist doctors and nurses for more serious cases, and 'minors' staffed predominantly by emergency nurse practitioners for less serious cases.

(6) The triage nurse normally worked as a senior nurse in the surgical assessment unit at the same hospital. On this Saturday they were working an additional shift in the emergency department. Shortly after the incident the nurse took planned retirement from the NHS and the investigation was therefore unable to hear their story.

(7) Millimetres of mercury.

(8) Systolic refers to the blood pressure when the heart beats while pumping blood. It is the first figure shown in a blood pressure measurement.

(9) EWS is an aggregate scoring system which takes key physiological measurements (respiration rate/oxygen saturation/ systolic blood pressure/pulse rate/level of consciousness or confusion/temperature) to give an early indication of the deterioration of a patient's condition. A score of 1 is low with 7 being high.

2.1.10 The ED doctor saw from Abby's observations that her heart rate was slightly fast. The doctor considered that this could be due to the shock of discovering she was pregnant and the pain she was experiencing. Alert to the possibility that this might be an early pregnancy with complications, the doctor ordered a set of blood tests. The results of the venous blood gas sample(10) taken from Abby were reported at 10:34 hours and reviewed by the doctor. The results were normal.

2.1.11 Having completed Abby's medical examination, the ED doctor decided to refer Abby to the early pregnancy unit (EPU) for a transvaginal ultrasound scan (TVUS) to determine the details of Abby's pregnancy. The doctor reported that at this stage they thought Abby may be having a threatened miscarriage(11). The EPU was situated on the gynaecology ward in the hospital and was staffed by early pregnancy clinical nurse specialists (CNSs)(12). The ED doctor telephoned the EPU to refer Abby and to discuss the need for a scan.

(10) A venous blood gas test measures the amount of oxygen and carbon dioxide in the blood sample and can be used to determine the acidity (pH) of the blood.

(11) Threatened miscarriage is diagnosed when there is vaginal bleeding in the presence of a viable pregnancy in the first 24 weeks of gestation (NICE, 2018).

(12) A clinical nurse specialist is an advanced practice nurse who can provide expert advice related to specific conditions or treatment pathways.

2.1.12 The EPU was not open at weekends but EPU services, including CNSs, were provided by another hospital within the same trust. The ED doctor spoke to a member of staff, whom they believed to be a midwife. Following this telephone conversation, the doctor's understanding was that Abby would receive a telephone triage call from the EPU later that day and a scan would be booked within the next 24 hours.

2.1.13 In response to the telephone call from the ED doctor, a referral form was completed by a staff member on the gynaecology ward where the call was taken. This form was transmitted by fax to the hospital that provided EPU services at the weekend. Having been received, the form was subsequently annotated by a member of EPU staff to indicate that a message had been left on Abby's voicemail. The investigation was unable to establish who had sent, or annotated, Abby's form.

2.1.14 Abby remained in pain despite the ibuprofen, paracetamol and codeine phosphate painkillers which she had received. The ED doctor prescribed 5mg of oral morphine which was administered at 10:45 hours. The doctor said at interview that they had prescribed oral morphine because it was not appropriate to prescribe further doses of previously given pain relief within the timeframe. The doctor planned to review Abby's symptoms once sufficient time had elapsed for the pain relief to take effect.

2.1.15 During interview, Abby's mother reported asking both the triage nurse and the ED doctor whether her daughter might be experiencing an ectopic pregnancy but did not recall receiving an answer.

2.1.16 Staff described the ED as being very busy. Abby was nursed in a treatment cubicle over the next 90 minutes but described being "left for hours" not knowing "what was going on".

2.1.17 Abby was reviewed by nursing staff and observations were taken at 10:25 and 11:45 hours. The calculated EWS from these observations were recorded as 1 and 4 respectively. The higher value was as a result of a high respiration rate (26 breaths/min), a fall in blood pressure (92/61mmHg) and a pulse of 105. Abby was given some water and a further set of observations were taken at 11:50 hours. Her blood pressure had improved (103/71mmHg), her respiratory rate remained raised at 22 and pulse at 101. An EWS of 3 was recorded. The nursing notes recorded ‘patient appears agitated’ and ‘Doctor informed’.

2.1.18 At 12:20 hours the ED doctor reviewed Abby. The doctor said at interview that Abby’s pain had lessened, she had walked to the toilet unaided and said she wanted to go home. Abby told the investigation that she saw “no point” in staying in the ED as the next step was to await a TVUS. The doctor recalled advising Abby to return to the ED if her bleeding or pain increased or if she was concerned. This advice was referred to as ‘SOS’ in medical notes and “safety netting” during interview. Abby was advised to rest until the scan. In interview, Abby could not remember being given advice about returning to the ED.

2.1.19 Abby was given a ‘Bleeding in early pregnancy’ discharge advice leaflet because it contained the telephone number for both the EPU and the ED in case Abby should need them.

2.1.20 Abby told the investigation she had a missed call on her phone from a local number while she was in the ED. She recalled asking the doctor if this might have been about the TVUS. The doctor telephoned the EPU and remembers being told that Abby had not been contacted, but she would receive a call that afternoon.

2.1.21 Abby was prescribed co-codamol for pain relief and discharged home to be with her mother at 12:44 hours, 3 hours and 57 minutes after arrival.

2.1.22 Abby told the investigation that she was still in pain when she arrived home. She called the EPU at 13:03 hours using the telephone number in the discharge advice leaflet. She remembers recounting her story during the call but said she was not asked any questions about her symptoms. She was given an appointment for a TVUS for Wednesday (four days later) at the EPU at the hospital where she attended the ED. Abby said she could not wait that long and was instead offered an appointment at the other hospital site on Monday (48 hours later), which she accepted.

2.1.23 Later on Saturday, Abby described collapsing twice at home and being in considerable pain. She said that she did not return to the ED because she had already sought medical advice from two hospitals that day and felt she would be “stupid to go back again”. By Sunday she reported that the pain had lessened and on Monday she went to work, although still experiencing pain.

2.1.24 On Monday morning, one of the two CNSs from the hospital where Abby was due to have her TVUS went home due to illness. The clinic was fully booked, with 18 elective (pre-booked, non-urgent) scan appointments scheduled for that day. The remaining CNS reviewed the list and decided to postpone eight appointments.

2.1.25 Abby's telephone records show she received a call from the EPU at 07:43 hours that morning. She was informed by a member of clerical staff that owing to staff sickness, her appointment would have to be postponed until 14:00 hours on Tuesday. Abby could not recall any questions being asked about her health.

2.1.26 On Tuesday, Abby attended for her TVUS. The CNS conducted the TVUS which showed an empty uterus and a mass in the peritoneal cavity (the space between the rectum and the back wall of the uterus). The CNS recorded a suspected ectopic pregnancy in Abby's medical records.

2.1.27 Abby was seen by a doctor at 16:00 hours and admitted to the gynaecology ward. Following a consultant review, Abby gave her consent for a diagnostic laparoscopy, the removal of an ectopic pregnancy and a salpingectomy(13).

2.1.28 The final pre-operative checklist was completed at 18:55 hours. The laparoscopic procedure was commenced by a gynaecology registrar under the supervision of the consultant.

2.1.29 The laparoscopic procedure continued until, following an increase in internal bleeding which reduced visibility, the consultant decided to perform a laparotomy(14). The consultant called for a senior colleague to assist. During surgery the patient was found to have a ruptured left Fallopian tube which was removed along with ectopic pregnancy tissue.

2.1.30 Abby was admitted to the recovery unit at 22:15 hours where the consultant explained the outcome of the surgery to her at 22:40 hours.

2.1.31 Abby was discharged from hospital after four days.

(13) See paragraph 1.2.12.

(14) Where an incision is made to allow access to the abdominal cavity

3 Involvement of the Healthcare Safety Investigation Branch

3.1 Referral of the reference event

3.1.1 The safety risk of delayed diagnosis of ectopic pregnancy was identified by the Healthcare Safety Investigation Branch (HSIB) following routine review of incidents reported to the Strategic Executive Information System (StEIS), the national database for reporting serious incidents in healthcare.

3.1.2 A detailed search of StEIS on 20 August 2018 for incidents reported between 1 April 2017 and 20 August 2018, using the search term ‘ectopic’, returned 59 results. Thirty of these results represented missed diagnosis of ectopic pregnancy, with serious harm occurring as a result. Of these diagnoses, 43% were reported as missed in the emergency department (the search criteria are detailed in Appendix 1)

3.2 Decision to conduct a national investigation

3.2.1 HSIB conducted an initial scoping investigation and assessed the findings against its investigation criteria, as follows:

Outcome impact – What was, or is, the impact of the safety issue on people and services across the healthcare system? A delay in or failure to diagnose ectopic pregnancy can be life threatening to women. Incidents resulting in serious harm and death were highlighted by the Confidential Enquiry into Maternal Deaths (Centre for Maternal and Child Enquiries, 2011) and recommendations made to address the issue, but incidents of missed diagnosis continue to occur.

The longer-term implications following ectopic pregnancy are also significant. Where young women are affected, an ectopic pregnancy and its management puts future fertility at risk and has a psychological impact on wellbeing. This has implications for the health service associated with the potential need for fertility treatment, including in vitro fertilisation (IVF).

The earlier a diagnosis of ectopic pregnancy is made, the better the chance of non-surgical management, probably with more positive implications for the woman’s future fertility. As well as the human cost, such incidents undermine patient confidence and trust in healthcare services.

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

Ruptured ectopic pregnancy is a life‐threatening emergency for which the only definitive management is surgical, usually resulting in the removal of the ruptured Fallopian tube.

Each year, NHS Digital publishes maternity statistics for England. According to data published in 2018, the number of ectopic pregnancies resulting in an NHS hospital stay was between 10,000 and 11,000 annually, from 2007/2008 until 2018. This represents a ratio of around 1.6 ectopic pregnancies per 100 deliveries.

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

Initial information gathered by the investigation identified that different processes have evolved in different organisations to address how the national guidance for provision of early pregnancy services should be implemented. This variation in service would suggest that there may be opportunities to share learning to positively influence processes and practices across organisations.

3.3 Evidence gathering and methodology

3.3.1 A range of methods were used in this investigation, including:

- a review of the patient's clinical records, and of Trust policies, procedures and practice regarding management of early pregnancy
- analysis of the reference event using Sequential Timed Event Plotting (Hendrick and Benner, 1987)
- an interview with Abby and her family • interviews with 10 staff at the Trust where the reference event occurred
- a review of the findings of the Trust's internal serious incident investigation report
- a review of relevant incidents reported to StEIS and the National Reporting and Learning System
- a review of literature relevant to the safety risk
- interviews, telephone calls and email correspondence with relevant national organisations and subject matter advisors, both clinical and non-clinical, regarding the diagnosis of ectopic pregnancy
- attendance at the Association of Early Pregnancy Units' annual scientific conference
- discussions with The Ectopic Pregnancy Trust to gain a wider patient perspective
- engagement of two subject matter advisors endorsed by the Royal College of Emergency Medicine and the Royal College of Obstetricians and Gynaecologists

- visits to five trusts with different models for the provision of early pregnancy services to see systems in action.

3.3.2 The investigation started three months after the incident had occurred. Given the event may have seemed unremarkable at the time, it was accepted the recall of events would be prone to error. Interviews and observations were, nonetheless, valuable in gaining an understanding of '**work as imagined**', '**work as disclosed**' and '**work as done**'.

3.3.3 'Work as imagined' refers to assumptions that may be made as to how work is carried out by staff doing their work in practice. However, people making these assumptions may be removed in time and space from the '**front line**' with limited ability to observe work being carried out in the workplace (Hollnagel et al, 2014). '**Work as prescribed**' is set out in policy or processes that staff are asked to follow and adhere to (Shorrock, 2016).

3.3.4 Incident investigation has traditionally placed emphasis on statements from staff in order to understand what has occurred. Shorrock refers to this as '**work as disclosed**' (Shorrock, 2018). '**Work as done**' refers to how people actually carry out their work. Understanding '**work as done**' requires observing work in the environment in which it takes place in order to inform ideas about how work should be planned and managed. Without understanding '**work as done**', it is not possible to accurately know how a system is functioning and whether it is drifting into an unwanted state or an improved state (Shorrock, 2018).

3.3.5 Using this information, the investigation applied systems modelling to represent the key steps in processes in order to identify factors that may have influenced system performance and thereby system safety. The Clinical Human Factors Group defines system safety as a 'focus on all aspects of the system that affect safety, i.e. people, processes, technology and environment. System design, inadequate management systems or poor training can induce errors' (Clinical Human Factors Group, 2015).

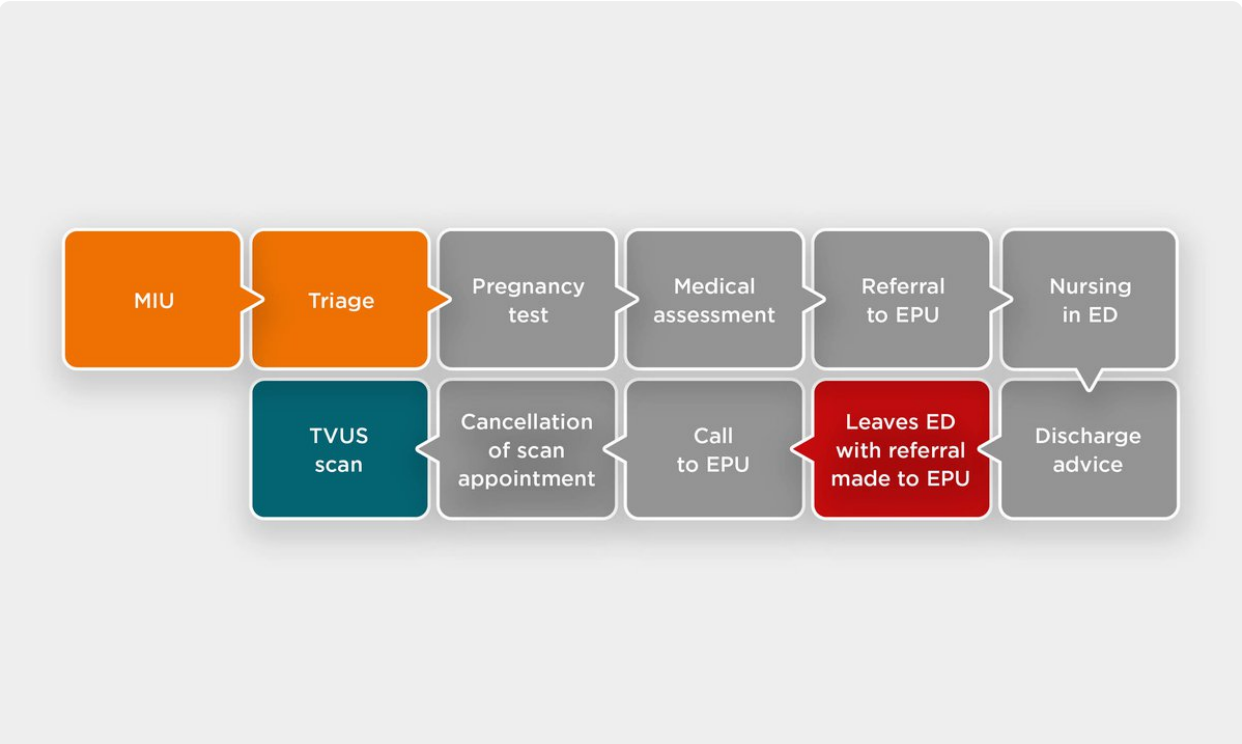
3.3.6 It was considered that the systemic factors highlighted in the reference case with respect to recognising ectopic pregnancy in the ED and the appropriate consideration of risk during referral into early pregnancy services, were symptomatic of those in other areas of the early pregnancy care pathway.

3.3.7 As well as maternal death statistics, searches of StEIS and the National Reporting and Learning System (see Appendix 1), a report by the Intensive Care National Audit and Research Centre case mix review programme (ICNARC, 2013) and accounts from The Ectopic Pregnancy Trust, revealed to the investigation that the diagnosis of ectopic pregnancy was a factor beyond the ED and EPU. Pregnant women and those unaware they are pregnant also present to their GP with signs and symptoms of ectopic pregnancy.

Ambulance services also need to be alert to the potential for ectopic pregnancy when responding to emergency calls. The investigation was also told about non-NHS-funded organisations offering ultrasound scanning services in early pregnancy which may result in subsequent contact with NHS-funded care when an ectopic pregnancy is suspected.

3.3.8 The investigation limited the terms of reference for the investigation to the study of the care pathway from the ED to the EPU during a seven-day week; the lessons identified will be pertinent to other areas of healthcare.

4 Findings and analysis



Process factors that may have influenced the delay in recognising and diagnosing ectopic pregnancy 1

Abby had a number of contacts with the healthcare system during her treatment. For each contact the investigation focused specifically on the factors that may have influenced the delay in recognising and diagnosing ectopic pregnancy.

4.1 Consideration of alternative diagnoses in urgent and emergency care

4.1.1 Abby's pregnancy was not identified during her attendance at the minor injuries unit (MIU) where it was thought that a urinary tract infection (UTI) was the possible cause of her abdominal pain. While her symptoms could have been related to a UTI, they are also symptoms of an ectopic pregnancy.

4.1.2 On arrival at the emergency department (ED), Abby was unable to provide a urine sample, so there was a delay of some 30 minutes before a pregnancy test could be performed. The investigation found that this minimal delay did not impact upon Abby's subsequent treatment in ED.

However, failure to perform a pregnancy test for a woman of childbearing age is a known factor in other instances of delayed diagnosis of ectopic pregnancy in ED, and in five maternal deaths it was considered that had a pregnancy test been carried out it 'might have alerted the clinical team to the possibility of ectopic pregnancy as the cause of collapse' (Knight et al, 2016). In 2011, the Confidential Enquiry into Maternal Deaths made the following specific recommendation:

'All women of reproductive age presenting to Emergency Departments with gastrointestinal symptoms should have a pregnancy test.'

(Centre for Maternal and Child Enquiries, 2011) The importance of services considering the possibility of pregnancy in all women of childbearing age was outlined in the National Institute for Health and Care Excellence (NICE) guideline 126, Ectopic pregnancy and miscarriage: diagnosis and initial management (NICE, 2019a), which states:

'During clinical assessment of women of reproductive age, be aware that: they may be pregnant, and think about offering a pregnancy test even when symptoms are non-specific.'

The investigation found that the NICE recommendation for pregnancy testing of all women of reproductive age attending ED was included in local Trust policy:

'All women of child-bearing age should have a pregnancy test if assessed in the 'majors'...'

4.1.3 The investigation was told by the early pregnancy subject matter advisor (SMA), how quickly the health of women suffering a ruptured ectopic pregnancy can deteriorate and how important testing for pregnancy was in the consideration of the condition.

4.1.4 A urine test is the most commonly available and used pregnancy test in the ED. It tests for the presence or absence of human chorionic gonadotrophin (hCG) in the urine. However, there are instances where a woman may be unable to produce a urine sample, as in Abby's case.

4.1.5 The ED SMA explained that when a patient is unable to give a urine sample because their condition is too unstable or they are dehydrated, it is possible to use a blood sample instead of urine in many pregnancy tests to achieve the same effect (Fromm et al, 2012).

4.1.6 The investigation also observed a point-of-care hCG test in use in an early pregnancy unit (EPU). This test used a blood sample from a vein, which was dropped onto a cassette and then analysed by a hand-held machine.

4.1.7 The investigation found that the Trust involved in the reference event did have care pathways appropriate to pregnant and non-pregnant women presenting with symptoms where a referral to gynaecology services might be indicated. These included protocols for women presenting with vaginal bleeding which contained actions to take if an ectopic pregnancy was suspected. However, because Abby's pregnancy was not known when she attended the ED, initial assessment focused on the presenting problem which was considered to be urine retention.

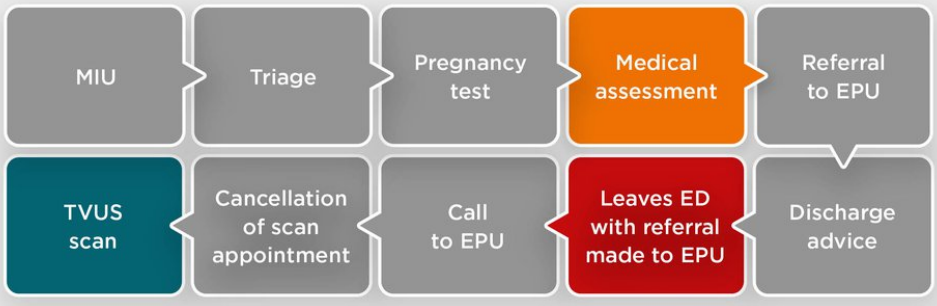
4.1.8 Suspected retention of urine is investigated by means of an ultrasound scan which detects the residual volume of urine in the bladder. A bladder scan conducted promptly during triage excluded urine retention as a diagnosis. A pregnancy test was performed and identified that Abby was pregnant. She was then assessed in accordance with local relevant pathways, which included considering the possibility of an ectopic pregnancy.

4.1.9 The NICE clinical guideline for ectopic pregnancy and miscarriage contains advice about potential differential diagnoses based on the clinical symptoms with which a woman with an ectopic pregnancy may present:

'…the symptoms and signs of ectopic pregnancy can resemble the common symptoms and signs of other conditions – for example, gastrointestinal conditions or urinary tract infection' (NICE, 2019a).

4.1.10 NICE guidelines are supplemented with clinical knowledge summaries, which are summaries of the current evidence base and practical guidance on best practice in respect of over 330 common presentations. Although not a factor in Abby's care, the investigation found there was no obvious cross-referencing to ectopic pregnancy in the NICE clinical knowledge summary for women experiencing symptoms of a UTI (NICE, 2019b).

The clinical knowledge summary for UTI does not alert clinicians to the similarities between the symptoms of UTI and those of ectopic pregnancy. Where reference is made to pregnant and non-pregnant women in the UTI guidelines, it is generally with reference to prescribing anti-microbials for treatment.



Process factors that may have influenced the delay in recognising and diagnosing ectopic pregnancy 2

HSIB makes the following safety recommendation

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'.

4.2 Assessment and diagnosis in the emergency department

4.2.1 NICE guidance for ectopic pregnancy recommends that ‘clinicians exclude the possibility of ectopic pregnancy, even in the absence of risk factors (such as previous ectopic pregnancy), because about a third of women with an ectopic pregnancy will have no known risk factors’ (NICE, 2019a).

4.2.2 Risk factors which increase the chance of ectopic pregnancy include: previous ectopic pregnancy, prior pelvic inflammatory disease or damage to the Fallopian tubes from infection or surgery, a history of infertility, therapy for in vitro fertilisation (IVF), increased maternal age and smoking (BMJ Best Practice, 2019).

4.2.3 The investigation found that Abby had given a detailed medical history when she had attended the MIU, which included a history of pelvic inflammatory disease and her method of contraception. This history was not known to ED clinical staff at the time of Abby’s attendance.

4.2.4 The ED doctor who reviewed Abby following her triage assessment was regularly employed as a junior grade locum by the Trust, mostly at weekends. They had four years’ experience working in emergency departments in this and other hospitals. Prior to that, the doctor had worked on medical wards in another NHS trust.

They told the investigation that they had frequently assessed women in early pregnancy who were experiencing pain and bleeding and had referred these women to the EPU, in accordance with guidance. However, they informed the investigation that they had never received feedback from these referrals. This meant that differential diagnoses were never confirmed, and potential learning opportunities were not realised.

4.2.5 The ED doctor explained to the investigation their decision-making process with regard to Abby, referring to Abby’s medical notes to assist with their recollections. They said that as well as taking a routine medical history and conducting a physical examination, they told Abby that it was possible “the pregnancy might be in the wrong place” – something a scan would clarify in due course. The doctor told the investigation that saying this was part of their normal practice when speaking with a woman in early pregnancy with pain.

4.2.6 The doctor reported they considered Abby’s early pregnancy as one with complications because of the pain she was experiencing. This was why further blood tests were ordered as part of Abby’s assessment.

4.2.7 One of the blood tests was a venous blood gas test(15), which is used to determine the acidity of the blood. Increased acidity can be an indicator of acute internal bleeding and may show as a rise in lactate levels due to the presence of lactic acid. The test showed Abby’s levels were within the normal range.

4.2.8 Another blood test assessed Abby's haemoglobin (Hb)(16) level. A low level of Hb in the blood is termed anaemia. Reasons for a low Hb level can include internal bleeding. Abby's haemoglobin levels were also within the normal range.

4.2.9 The ED SMA told the investigation that immediately following a large internal bleed, the concentration of Hb in a blood sample will generally stay the same, meaning that Hb count is not always a reliable indicator of a large internal bleed.

4.2.10 The doctor's assessment of Abby's medical history noted:

- a constant non-radiating(17) pain localised in the lower abdomen/vagina since 20:00 hours the previous night
- no fever, dizziness or vomiting but patient felt generally unwell with pain
- no vaginal bleeding but some dark brown spotting seen recently on toilet paper
- an erratic menstrual cycle with the last menstrual period, of unknown duration, occurring 5.4 weeks previously
- no pain during sex or on passing urine
- the use of Depo-Provera contraceptive injection
- that Abby was normally fit and well and smoked 10 cigarettes a day.

4.2.11 A physical examination noted:

- a soft abdomen with tenderness to the right side of the lower abdomen with no rebound or guarding(18)
- a heart rate of 110 beats per minute – this was noted as high (tachycardic), but the doctor was aware that Abby had recently been given the news she was pregnant and considered this may have resulted in the tachycardia
- Abby looked pale.

4.2.12 The doctor told the investigation that they believed the blood tests would assist them in understanding whether Abby was having a significant internal bleed, such as might occur with a ruptured ectopic pregnancy. When considering the possibility of the pregnancy being "**in the wrong place**", the doctor said that they had included ruptured ectopic pregnancy in their differential diagnosis. They told the investigation that they were reassured by Abby's stable blood pressure and the blood test results; specifically, normal haemoglobin, lactate levels and the absence of acidosis (raised acidity in the blood). On that basis, they discounted a large internal bleed associated with a ruptured ectopic pregnancy

(15) A venous blood gas test measures the amount of oxygen and carbon dioxide in the sample. It is quicker and easier to obtain than an arterial blood sample.

(16) The protein in red cells that carries oxygen in the blood.

(17) A radiating pain is one that starts in one area and spreads to a larger area. Conversely, non-radiating pain is localised to a specific area.

(18) Rebound and guarding are potential patient reactions to pressure on the body, observed during a physical examination completed as part of the differential diagnosis. A lack of rebound or guarding can exclude inflammation of the abdomen (peritoneum) and appendicitis.

4.2.13 Having ruled out a ruptured ectopic pregnancy, the ED doctor reflected during interview that a diagnosis of ectopic pregnancy was also no longer considered. Instead they had a working diagnosis of ‘threatened miscarriage’.

4.2.14 Miscarriage is the spontaneous loss of a pregnancy before 24 weeks of gestation. There are various classifications of miscarriage. A threatened miscarriage is when a pregnant woman has vaginal bleeding in the first 24 weeks. The NICE clinical knowledge summary (NICE, 2018) describes the symptoms as:

- ‘Bleeding is typically scanty, varying from a brownish discharge to bright red bleeding, and may recur over several days.
- Lower abdominal cramping pain or lower backache, when it occurs, usually develops after the onset of bleeding.’

4.2.15 Miscarriage is a common complication of pregnancy with about 125,000 occurring in the UK every year. The best way to diagnose a miscarriage is by a transvaginal ultrasound scan (TVUS) (Jurkovic et al, 2013).

4.2.16 The investigation confirmed that the only reliable method of diagnosing an ectopic pregnancy or miscarriage was through a TVUS, which the doctor referred Abby for at the end of their assessment.

4.3 Decision not to refer to the on-call specialist registrar

4.3.1 According to Trust policy, under certain circumstances ED clinicians were required to seek a review of the patient by the on-call obstetrician or gynaecologist.

4.3.2 Trust policy stated that ‘in the case of an unexpected positive pregnancy test, or when the presenting complaint could be pregnancy related, there should be a low threshold for discussion with the on call Obstetric or Gynaecology teams’. The flowchart in the Trust’s policy

set the threshold for escalation at early warning score (EWS) 4 and above, and/or clinical signs such as a swelling or inflammation of the abdomen. Elsewhere in the body of the policy an EWS threshold of 3 and above was stated.

4.3.3 The ED doctor described an environment in which they worked regularly as a junior doctor and were known to the team. They felt able to escalate to more senior colleagues and did so regularly.

4.3.4 Abby was given an EWS of 4 at triage. At the time of the ED doctor's review, Abby's EWS had improved from 4 to 1; referral to a gynaecologist was therefore not mandated by the Trust's policy. 4.3.5 The next set of observations were completed approximately 80 minutes after the ED doctor's review. These gave Abby an EWS of 4, owing to falling blood pressure. The nurse gave Abby a glass of water and re-checked her blood pressure minutes later. Her blood pressure had risen, and her EWS was recorded as 3.

4.3.6 The nursing notes recorded 'patient appears agitated' and 'Doctor informed' but gave no indication of which doctor or the outcome of any conversation. The ED doctor who had completed the original assessment was in another part of the ED and was unaware of the deterioration in Abby's EWS from 1 to 4 with signs of low blood pressure and high respiratory and pulse rate. This should have warranted escalation to the gynaecology registrar for review within 30 minutes according to Trust policy.

4.3.7 NICE clinical guideline 50, Acutely ill adults in hospital: recognising and responding to deterioration (NICE, 2007), recommends that patients in emergency departments should have physiological observations recorded at the time of their admission or initial assessment. It goes on to recommend that these physiological observations then form the basis of a 'track and trigger system' to identify a patient whose clinical condition is deteriorating or at risk of deterioration.

4.3.8 In 2012, the Royal College of Physicians reported on the benefits of standardising reporting systems and published a National Early Warning Score (NEWS) (Royal College of Physicians, 2012). This was superseded in 2017 by the publication of NEWS2 (Royal College of Physicians, 2017).

4.3.9 The ED SMA explained to the investigation that it was common for patients in the ED to have elevated EWS owing to the nature of presentations. The investigation considered that, had the early warning score been used to monitor overall trends, it may have alerted ED staff to a propensity for deterioration. The Trust policy encouraged the use of early warning scores at decision points between areas on the pathway. This may have encouraged the use of scores in isolation to make decisions about a patient's state of health at a certain point in time and not as part of a trend.

4.4 The decision to refer Abby for further investigation

4.4.1 The analysis of this event considered what factors may have influenced decision making:

- The investigation found that clinical information gathered during the assessment process was not presented in a way that assisted ED clinicians' understanding of Abby's condition. Information collected at triage was on a separate sheet to observations taken at the time of the medical assessment.
- The information that had been captured at the MIU, including Abby's baseline observations, a subjective pain score of 9/10, that she had a history of pelvic inflammatory disease and was a patient at the genitourinary clinic, was not available to ED staff during their assessment.
- During triage assessment, Abby's pain was recorded (as it had been in the MIU) as abdominal pain radiating into the back. The ED doctor noted for the first time during their assessment that Abby reported a non-radiating pain in the lower abdomen and vagina. In the MIU Abby had rated her pain as 9/10, during triage it was recorded as 8/10. A further set of observations at 10:25 hours recorded pain at 4/10. Neither change would have been obvious to ED staff, so the significance of Abby's pain may not have been remarkable.
- The ED doctor explained that they did not have much previous experience in gynaecology as their background was as a medical registrar, but they described seeing one to two women per shift in the ED with bleeding or pain in early pregnancy.
- During interview, the ED doctor was asked how many times they had previously diagnosed ectopic pregnancy. The doctor said that having referred patients on to other specialties they never got feedback on their diagnosis, which would have helped inform their practice – "that's the nature of the ED".
- The care pathway the ED doctor was expected to follow was contained in a written policy that had been published five months previously. The ED doctor told the investigation they relied largely on word of mouth from colleagues to keep up to date with new policies. ED managers at the Trust described a system that was reliant on locums to maintain staffing levels, and there was an acceptance that locum doctors sat outside the normal supervision and education cycle. In addition to this, the ED was reported as "busy" with patients being nursed in the corridor at the time Abby attended.

4.4.2 The investigation sought the opinion of a human factors specialist to consider why and how decisions and actions taken in the ED would have made sense at the time.

4.4.3 The specialist explained that where a decision requires engagement between several people and systems, safety scientists consider ‘distributed cognition’ important to a successful decision (Hutchins, 1995). Distributed cognition considers how the involvement of different people, workplaces and tools or equipment may help or hinder the transfer and interpretation of information for the purpose of decision making.

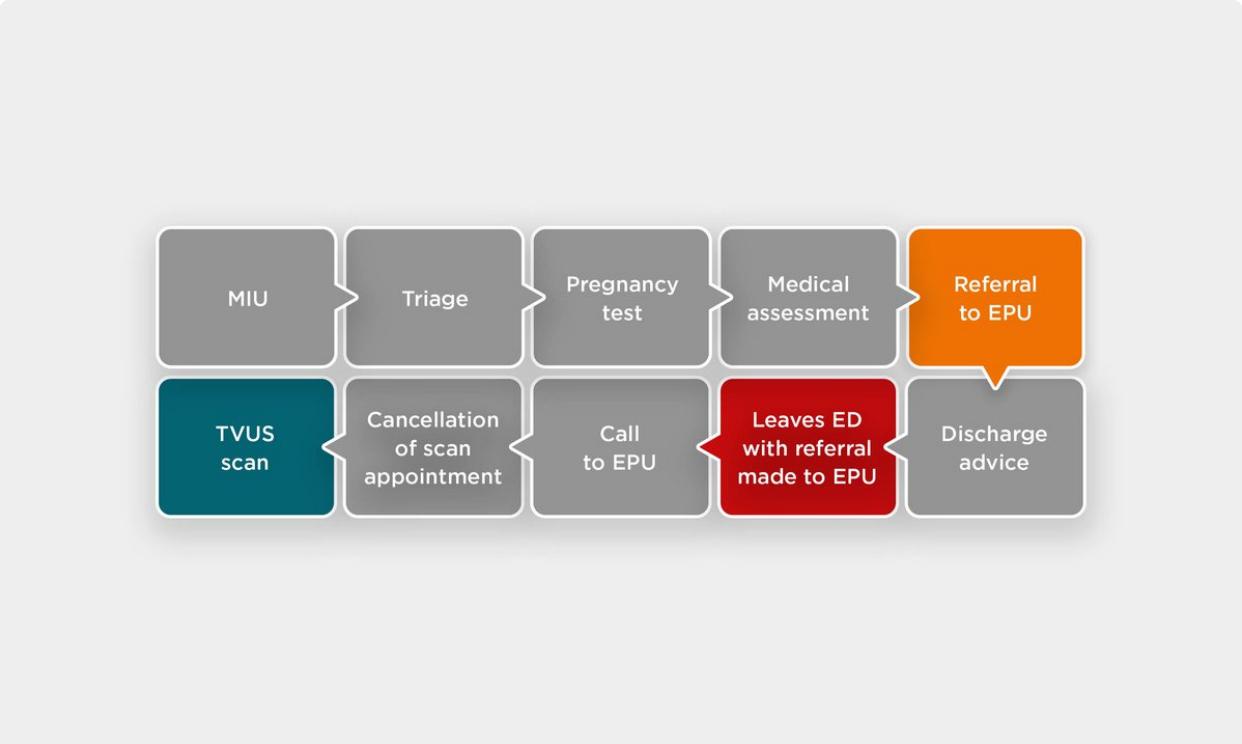
4.4.4 Decision making is more likely to go well if the information relied upon is clear, confirmed, available and presented in a meaningful and obvious form. Decision making in the ‘real world’ rarely provides such ideal circumstances. Naturalistic decision making (Klein et al, 2007) refers to when information sources are presented less than ideally, are uncertain, complicated and considered under time pressure. Human behaviour has adapted to these conditions by developing mental shortcuts known as heuristics (Kahneman and Klein, 2009).

4.4.5 Evidence shows how people typically make sense of a situation by drawing on their experiences, intuition and evaluating potential options through mental simulation, or ‘what-if’ scenarios (Klein et al, 2007). This is unlike an analytical approach to decision making, which is likely to be adopted where more time and complete information is available. The analytical approach allows us to consider every piece of information, compare different potential causes and provide the most probable explanation.

4.4.6 The Healthcare Safety Investigation Branch (HSIB) investigation report, Recognising and responding to critically unwell patients (2019), addresses in detail many themes in common with this investigation, such as:

- Information about the patient was dispersed across a variety of documentation and several clinical staff. The design and presentation of information did not support staff in making a complete and accurate assessment of the patient’s health.
- Staff may rely on tools such as EWS, especially when working in a busy and complex environment. There tended to be a focus on the latest physiological observations and staff could have been falsely reassured when EWS indicated the patient’s condition may be improving.
- There are numerous factors that can influence situation awareness, and thus decision making, in the ED. Improving decision making and situation awareness is not simple and requires emphasis on designing the system to support information and awareness getting to the places where it is needed.
- Escalation protocols place a high demand on medical staff and may not be achievable, owing to a task versus resource mismatch.

4.4.7 Although the information about Abby's case was not presented to the ED doctor involved in her care in a way that supported robust decision making, the investigation found that following a medical review the ED doctor suspected Abby might be experiencing a threatened miscarriage. The doctor decided that Abby's clinical condition warranted a referral to the early pregnancy unit for further assessment and a TVUS scan.



Process factors that may have influenced the delay in recognising and diagnosing ectopic pregnancy 3

4.5 Referral to the early pregnancy unit from the emergency department

4.5.1 The investigation considered that the interaction between the ED and the EPU relating to Abby's referral was a key opportunity for a specialist in early pregnancy to be involved in Abby's care. The Trust policy included six flow charts intended to enable clinicians working in ED to 'promptly manage and determine the most appropriate route of care for pregnant women'. The policy stated the decision to refer a woman with an EWS of 0 to 3 to the early pregnancy unit was to be made jointly by the accepting and referring team.

4.5.2 The accepting team – early pregnancy unit – was located at two hospitals within the Trust. Clinical nurse specialists (CNSs) ran TVUS clinics for women who had been pregnant for less than 16 weeks. They were assisted by general nurses and the service was augmented by additional clinics run by trained sonographers. Clinics consisted of elective TVUS appointments for women known to the service with a non-urgent need, with additional capacity to respond to

short notice, urgent referrals. The investigation was told that at the last audit, the service was conducting approximately 1,000 urgent scans per month with a 30:70 ratio between the two hospital sites.

4.5.3 A CNS explained that from Monday to Friday, when the EPUs were staffed, a CNS was available at both hospitals to assist with clinical decision-making regarding women with an early pregnancy complication. This might result in a decision to refer a woman straight to the EPU for an urgent scan. For women whose symptoms were not considered to warrant an urgent scan, the CNS would allocate the next available elective scan appointment. The ED clinician could discharge the woman with a referral accepted and a treatment plan in place. A discharge summary would be sent to the woman's GP detailing the period of care in ED.

4.5.4 Managers of the early pregnancy service told the investigation that at weekends the referral process changed. The EPU service at the hospital Abby attended (EPU 1) was closed at weekends (see Figure 2), but referral advice for ED staff was available from the EPU at the other hospital site (EPU 2). From interviews with managers and clinicians, it appeared that there was an assumption that ED doctors referred directly to this unit.

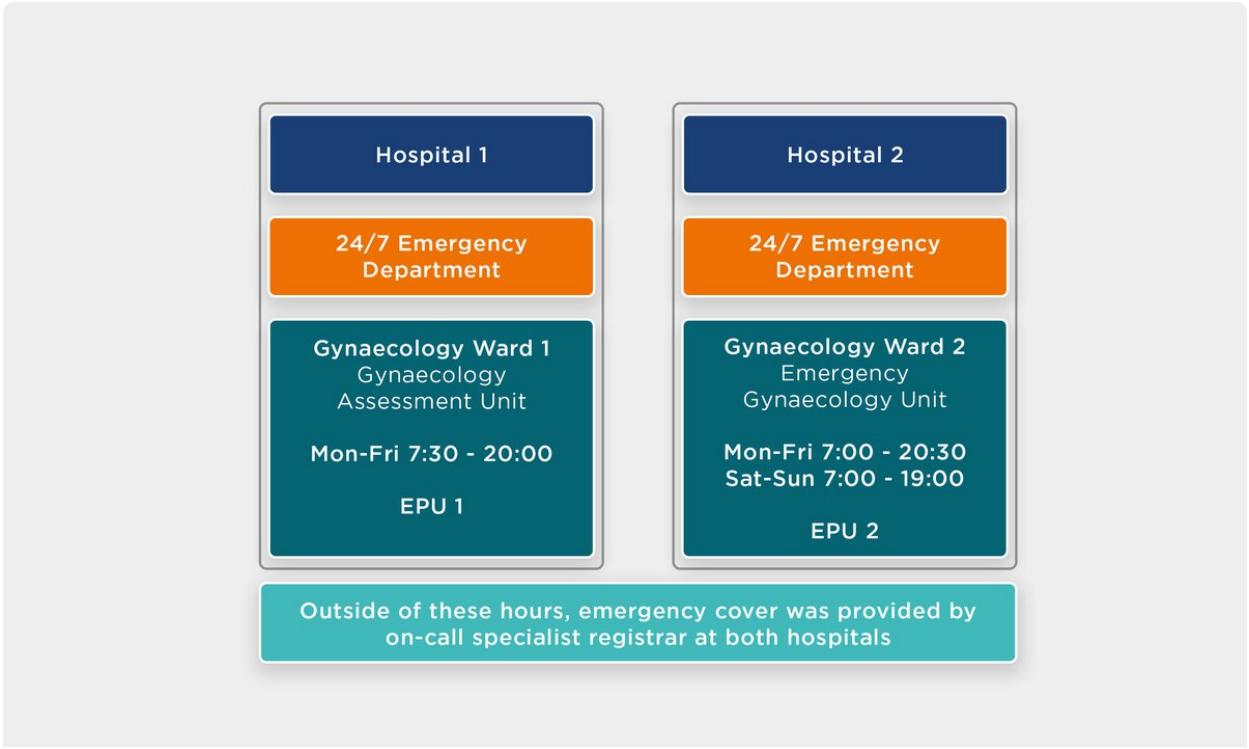


Fig 2 Trust organisation of seven-day early pregnancy services

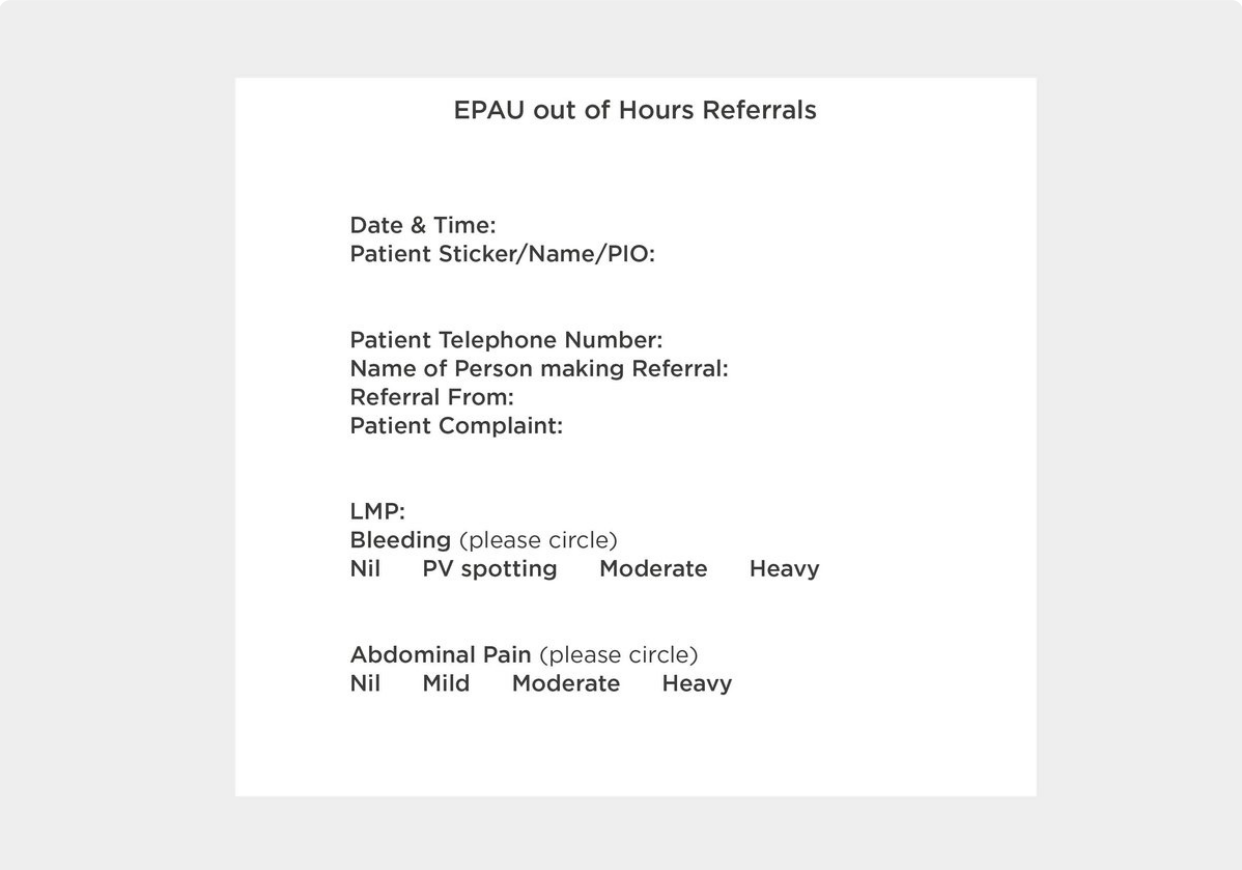
4.5.5 Weekend referral to the early pregnancy unit from the hospital Abby attended was by means of an out-of-hours (OOH) referral form. The expected process was that the ED clinician would forward a completed form to a central EPU email address or by fax to EPU 2. When received, the CNS would review patient notes made in the ED and then telephone the woman and conduct a triage assessment before deciding on the most appropriate treatment.

4.5.6 This process was not captured in the Trust policy flow chart but was explained at the foot of the OOH referral form. The clinical lead for gynaecology explained it would be appropriate for the ED doctor to discharge a patient who was clinically stable, on the understanding that a referral had been made to the EPU and a CNS would triage the patient as soon as possible.

4.5.7 In the reference event the ED doctor, having decided to refer, telephoned the gynaecology ward where EPU 1 was situated and reported talking to someone they assumed to be a midwife. The investigation was not able to ascertain who had received the phone call from the ED. It was presumed by those interviewed during the investigation that the call was answered by a general nurse on the gynaecology ward in hospital 1. The doctor's recall of the discussion focused on confirmation that Abby was less than 16 weeks pregnant. The investigation noted that 16 weeks was the point at which, as per the Trust's policy, responsibility for pregnant women transferred from gynaecology to obstetric services.

4.5.8 At the end of the referral conversation, the ED doctor understood that Abby would receive a call later that day from the EPU to book a scan appointment within 24 hours. Abby's medical notes were annotated: 'Discussed with gynae Ward EPU – who have taken the referral and will contact px [patient] for scan appt.' The doctor did not complete an OOH referral form.

4.5.9 The OOH referral form was the intended means of capturing patient and clinical data in the referral process. It was locally designed and is reproduced in Figure 3. In Abby's care a completed form recorded her personal details, the ED doctor's first name, mention of symptoms including abdominal pain, blood in the urine, positive pregnancy test and use of contraception. It included the date of Abby's last menstrual period and highlighted 'no bleeding' and 'moderate pain'.



EPAU out of Hours Referrals

Date & Time:
Patient Sticker/Name/PIO:

Patient Telephone Number:
Name of Person making Referral:
Referral From:
Patient Complaint:

LMP:
Bleeding (please circle)
Nil PV spotting Moderate Heavy

Abdominal Pain (please circle)
Nil Mild Moderate Heavy

Fig 3 Trust out-of-hours referral form

4.5.10 When analysing Abby's care, the investigation found that an OOH referral form had been completed on the gynaecology ward at hospital 1 and faxed to EPU 2, at the other hospital site, for review by the CNS.

4.5.11 The referral process did not provide acknowledgement of the referral or confirmation that a CNS had undertaken a review. The investigation was advised that the single CNS on duty would review, prioritise and follow up faxed referrals between other appointments or on completion of the clinic. On Monday morning a CNS at EPU 2 would normally check received OOH referral forms to ensure there was a corresponding scan appointment in the booking system.

4.5.12 The investigation found no evidence that ED staff were routinely completing the OOH referral form. During interviews it became apparent that a telephone call from the ED to the EPU was the normal basis for referral. At weekends, nurses working on the gynaecology ward in hospital 1 would complete OOH referral forms based on information given by the ED and then fax the form to EPU 2. The CNS would then call the woman, who had already been discharged from the ED.

4.5.13 The referral processes described by managers and clinicians during the investigation are shown in Figure 4.

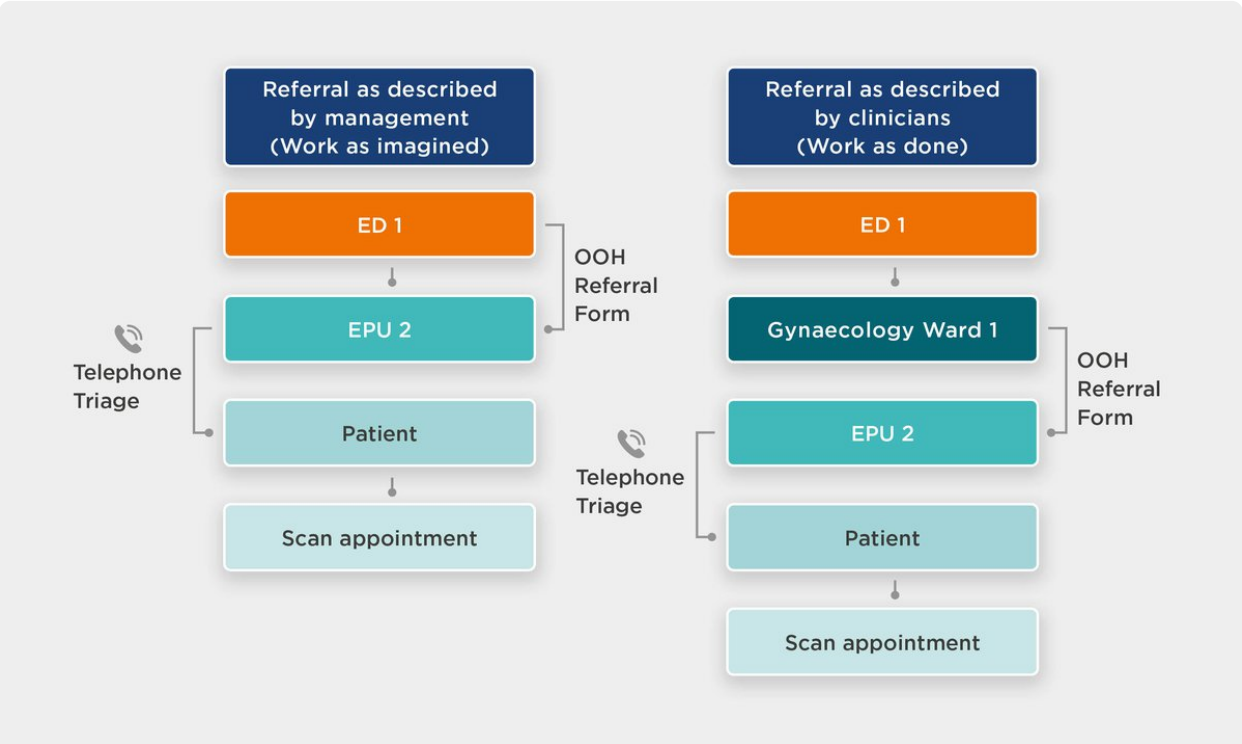
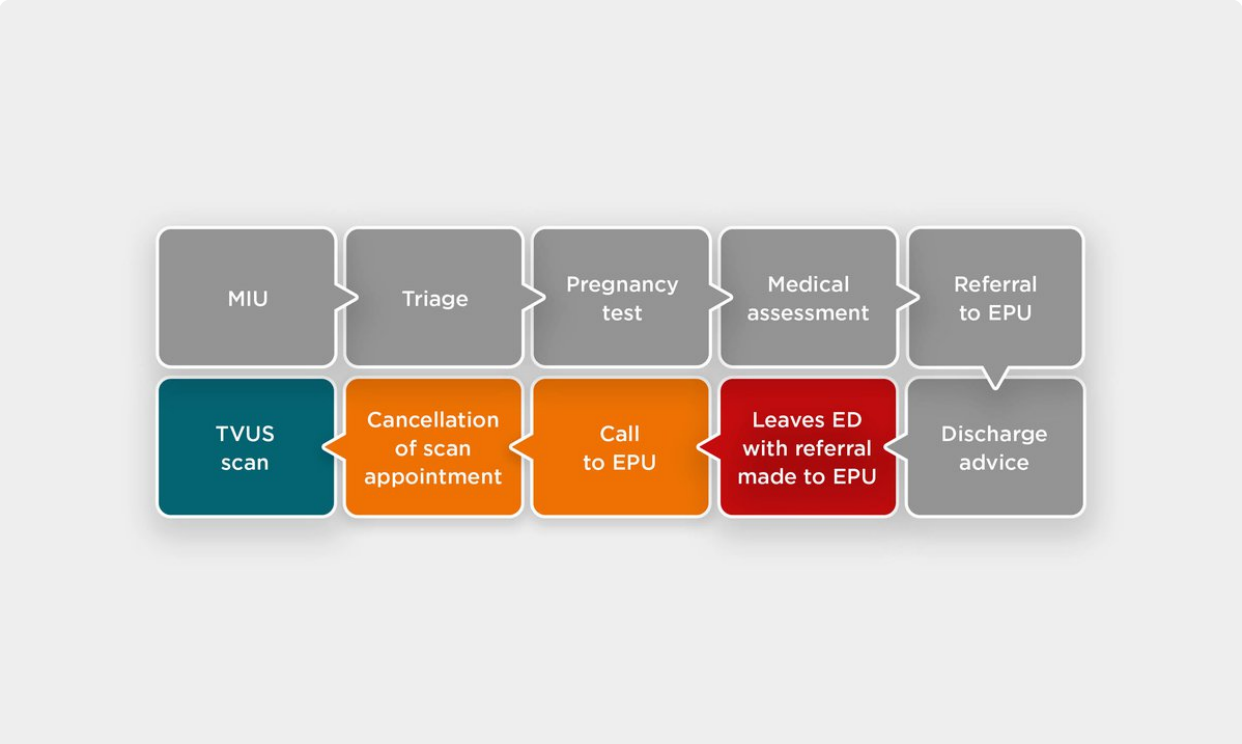


Fig 4 Diagram showing high-level task analysis of ‘work as imagined’ compared to ‘work as done’

4.5.14 The investigation identified the following systemic factors operating between ED and the EPU service that may have contributed to the delay in diagnosing Abby’s ectopic pregnancy:

- The ED doctor had no direct conversation with a CNS. They followed their usual practice of referral, which was via a phone call to a given number at hospital 1. In line with Trust policy, there was no CNS at this site at weekends. The opening times of the EPU service were not clear in Trust policy. Without a structured conversation between the ED doctor and a CNS with the appropriate knowledge and experience to determine potential risk to Abby, the ED doctor’s working diagnosis of threatened miscarriage remained unchallenged.
- The investigation found that access to TVUS for women referred from the ED was based on clinical priority. The ED doctor understood that the referral would result in a scan within 24 hours. This was not correct as a scan within 24 hours was not available for all women, but only for those prioritised by a CNS as requiring one.
- The OOH referral form did not have structured questions to guide and standardise clinical information flow about early pregnancy complications. A more structured form may have provided an opportunity for the CNS to prioritise Abby’s scan appointment based on more detailed referral information and the presence of risk factors.

- The referral process at weekends and out of hours was complex and involved transfer of information between multiple people. The complexity of the process, combined with the unstructured referral form, increased the risk that women may not be prioritised for a scan in an optimal timeframe.



Process factors that may have influenced the delay in recognising and diagnosing ectopic pregnancy 4

4.6 Communication between Abby and the EPU service

4.6.1 The investigation considered that the communication between Abby and the EPU service was a fresh opportunity for her symptoms and the timing of her scan to be considered by an early pregnancy specialist.

4.6.2 Having arrived home from hospital on Saturday and still in pain, Abby telephoned the number in her discharge advice leaflet for the EPU. This connected her with EPU 2. Abby recalled explaining to the member of staff that she had attended the ED with symptoms of severe abdominal pain, had felt dizzy and had a high temperature. She was offered a scan appointment on Wednesday at EPU 1 but said that she could not wait that long, so instead was offered a scan appointment at EPU 2 on Monday. Abby thought she was talking to a receptionist, rather than a nurse or doctor, because they ‘just listened to what I had to say’.

4.6.3 The investigation was unable to establish if, or to what extent, the ED doctor’s working diagnosis of threatened miscarriage was discussed during the phone call.

4.6.4 The investigation was shown an early pregnancy telephone triage form that the CNS would normally use to record patient information. The investigation was advised by the manager of the EPU service that their expectation was that this form would be completed for all patient communications. The form included text boxes for answers about medical and obstetric history, reason for referral, an assessment/provisional clinical diagnosis and options for action in the form of:

- see immediately
- see within 48 hours
- see within seven days
- telephone advice given, no need for attendance at EPU
- appointment declined.

4.6.5 The investigation was advised that a completed triage form could not be found in relation to the conversation with Abby. It was not possible to identify who had received the call from Abby or the clinical rationale for booking a scan appointment on Monday. The investigation was told that at weekends there was only one CNS on duty. On the Saturday when Abby called, the CNS had a full list of scan appointments. At some point an entry was made on the EPU electronic appointment diary with Abby's details and a short note, 'PV [vaginal] bleed'.

4.6.6 As Abby's call to the EPU was unplanned, it is possible the form was not completed as it would be for a planned triage by a CNS. Had the triage form been completed, as per the expected process, it would have provided a better opportunity to make a clinical assessment of Abby's condition.

4.6.7 The investigation was unable to ascertain whether staff at EPU 2 linked Abby's incoming call with the previously faxed OOH referral form. The only record of any response to the form was a hand-written note, 'voicemail left', next to Saturday's date. The telephone number was correct, but Abby did not remember receiving a voicemail from the CNS on Saturday.

4.6.8 The investigation heard from CNSs on the unit that they would not hesitate to "bring women in" for an urgent appointment at the weekend if they had concerns, even if all the elective appointments were booked. When discussing what symptoms might suggest a same-day scan was required, the investigation heard unanimous opinion from early pregnancy professionals that acute abdominal pain would be a "red flag" symptom that met the threshold. On the weekend Abby attended the ED, four urgent scans were conducted in addition to 19 scans on the elective list. 4.6.9 The clinical lead for gynaecology told the investigation that it seemed Abby's symptoms were not deemed to warrant an urgent scan on Saturday or Sunday, and she was instead given an appointment on an elective list on Monday. They considered this was consistent with a suspected miscarriage.

4.6.10 The investigation noted that in the process described by clinicians (‘work as disclosed’) the OOH referral form was intended to initiate a sequence of events. This would result in a phone call between the CNS and the patient and a decision on clinical priority and treatment. Abby’s scan appointment was actually booked following her call to the EPU which bypassed this process. How the referral system was able to respond to this difference in ‘work as disclosed’ and ‘work as done’ (see Figure 5) was key to understanding why Abby’s report of abdominal pain did not result in her being offered an urgent scan over the weekend.

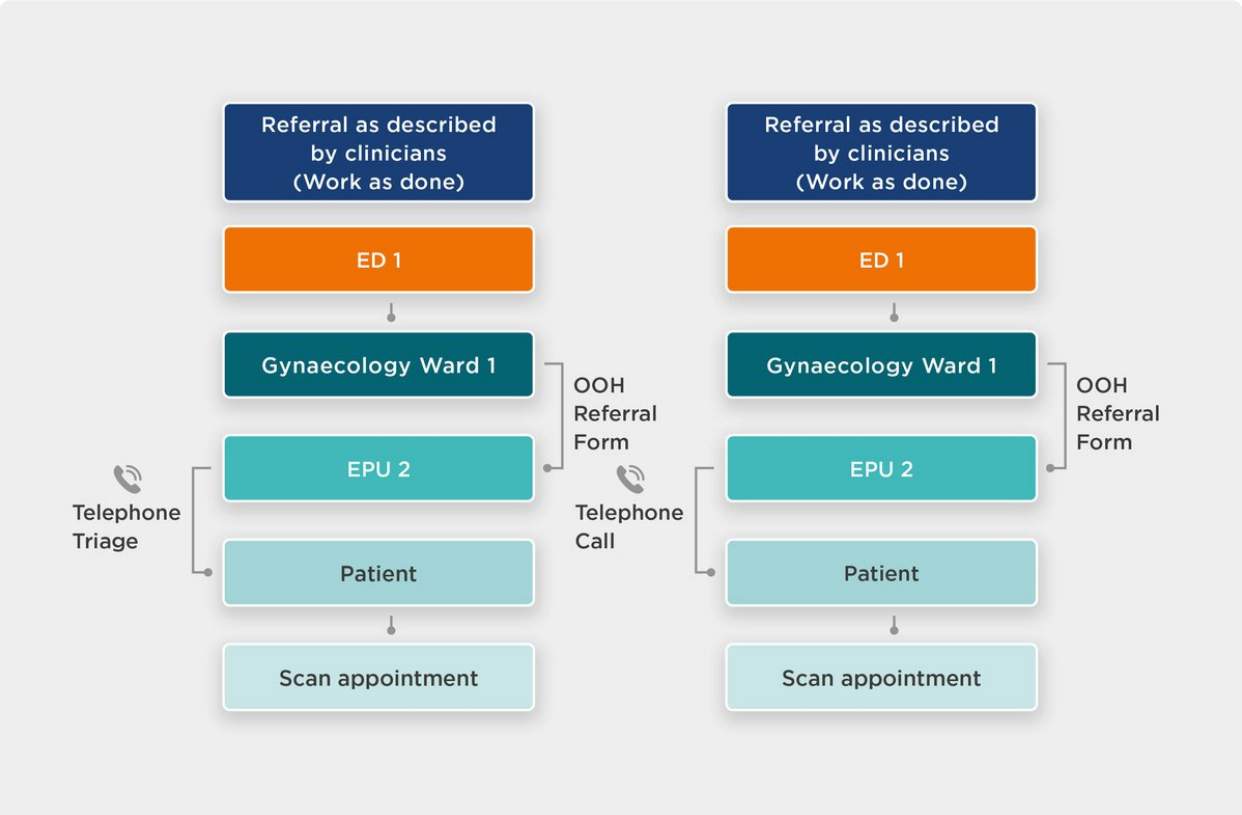


Fig 5 Diagram showing high-level task analysis of ‘work as disclosed’ compared to ‘work as done’

4.6.11 The second communication between Abby and the EPU occurred when the EPU contacted Abby to rearrange her booked Monday scan. Owing to staff sickness a decision had been made to reduce the number of elective scan appointments that day from 18 to 10.

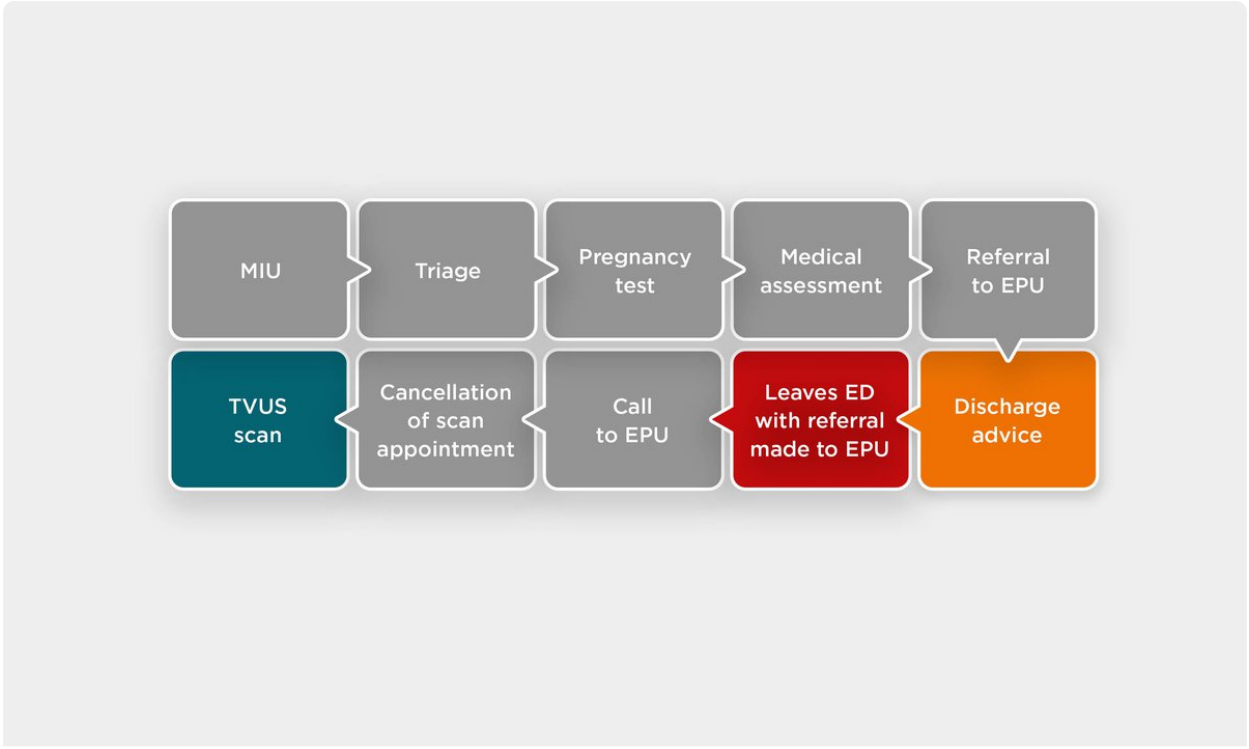
4.6.12 When Abby received the call to reschedule her appointment, she remembered being told the reason for the delay but did not recall being asked any questions about her symptoms. Her impression was that she had been talking to a “receptionist”. The investigation was told the ward administrative clerk had made the call.

4.6.13 Abby was offered, and accepted, an appointment at EPU 2 the following day at 14:00 hours – three days after being discharged from the ED.

4.6.14 The investigation heard the reallocation of appointments would normally involve a review of information to prioritise urgent cases and reallocate others for later in the week. There was limited recorded information about Abby's case; she was noted as experiencing vaginal bleeding, but there was no explicit rationale to support the decision to cancel her scan. There was also no evidence of a completed telephone triage form.

4.6.15 The telephone call was an opportunity to confirm and update the existing information. Although Abby's symptoms had improved and she had gone to work, she told the investigation she had still been experiencing pain. It is unclear whether Abby reported her pain during the phone call.

4.6.16 The investigation considered that this phone call was another opportunity to review Abby's condition. Without consideration of new information about Abby, any decision to reschedule was unlikely to challenge the decision made on Saturday, which classified Abby as a non-urgent referral.



Process factors that may have influenced the delay in recognising and diagnosing ectopic pregnancy 5

4.7 Decision to discharge from the emergency department

4.7.1 Typically, on weekdays TVUS appointments would be organised before women left the ED, either for the same day or at a later date depending on their clinical symptoms. At weekends and out of hours, patients considered clinically stable were discharged from the ED,

with a referral to EPU but no appointment scheduled. The investigation analysed the discharge process to understand what precautions were taken to mitigate the risks to Abby while she waited for a scan.

4.7.2 The ED doctor said that their decision to discharge Abby was made on the basis of her improved pain and improved physiological markers. The ED doctor also noted that Abby wished to go home and that she was going to be with her mother after discharge. In addition, their understanding was that Abby would receive a TVUS within 24 hours.

4.7.3 Abby was prescribed co-codamol to take at home for her pain and the ED doctor advised her to rest until the scan and to return to the ED if the bleeding or pain increased or if she was concerned – termed “safety netting advice” by the ED doctor. In interview, Abby could not remember being given safety netting advice. She did recall being given a ‘Bleeding in early pregnancy’ leaflet which included the phone number for the EPU.

4.7.4 The ED doctor explained to the investigation that this leaflet was chosen because it included the telephone number for the EPU, not because of the relevance of the specific content about bleeding and miscarriage.

4.7.5 Abby reported “collapsing” twice at home later that day and being in considerable pain. Abby decided not to go back to the ED because she had already sought medical advice from two hospitals that day and felt she would be “stupid to go back again”.

4.7.6 The investigation reviewed the discharge advice leaflet given to Abby. It focused on bleeding and miscarriage and did not contain information about the warning signs for ectopic pregnancy.

4.7.7 A discharge leaflet that focuses on a specific diagnosis excludes the opportunity for a patient to consider a deterioration in a wider range of symptoms. The investigation considered that more generic advice about early pregnancy complications and signs of deterioration would be beneficial for women awaiting diagnosis by TVUS.

4.8 Advice for early pregnancy patients discharged from the ED

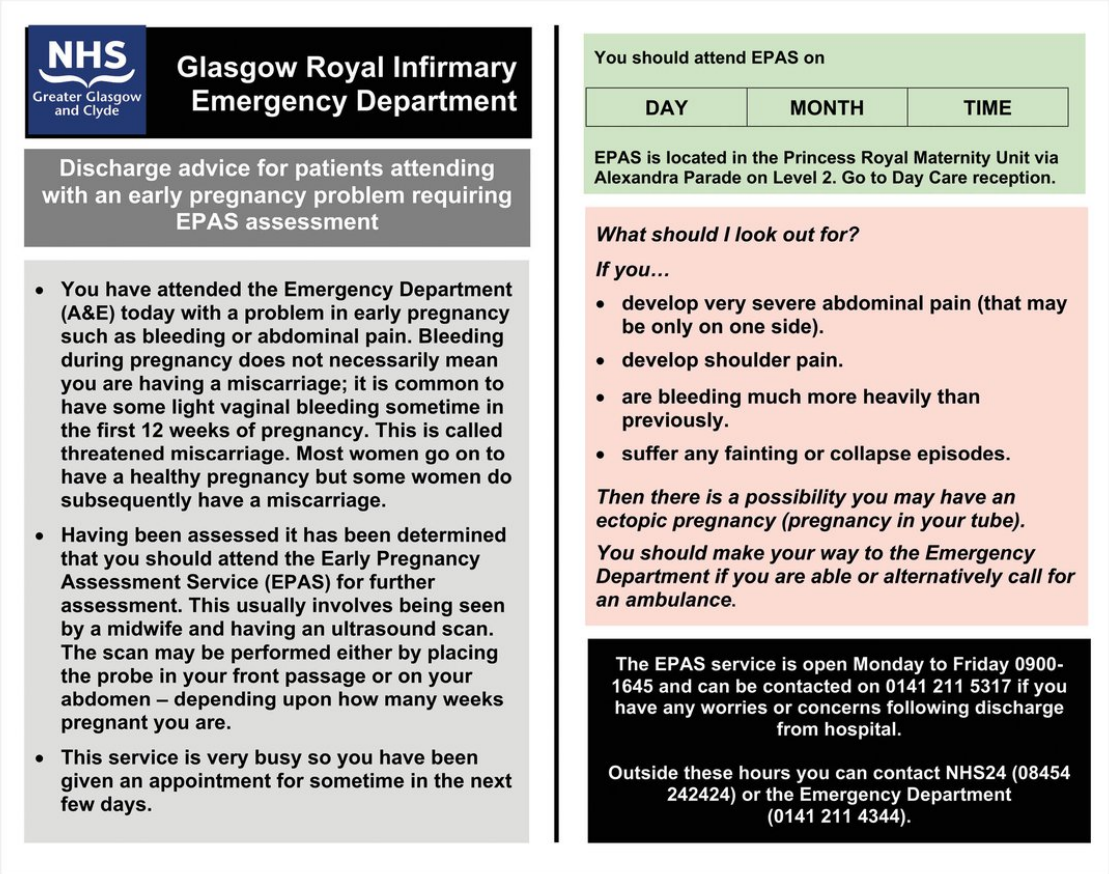
4.8.1 Discharge advice is a way ED clinicians can mitigate, or reduce, the risk of future harm when discharging a patient pending further review by a specialist service. Research shows that successful communication of discharge information is critical to help mitigate this risk. During the wider investigation, discharge leaflets of varying content and style were encountered – some EDs had no printed discharge advice about early pregnancy problems. The investigation was keen to understand how a patient might be supported to recognise when their condition was deteriorating and to take the correct action.

4.8.2 A study that rated patients' understanding of their diagnosis and medication in the ED, along with their post-ED care and return instructions, concluded that the majority (79%) of patients discharged demonstrated a flawed understanding of discharge instructions (Engel et al, 2009). Barriers to effective communication in the ED setting included time demands, lack of continuity of care, noise, lack of privacy, and the frequently stressful nature of the visit. Communication at discharge was recognised as part of delivering high-quality ED care.

4.8.3 In 2017, following concerns about the variability in practice across emergency departments in the NHS, the Royal College of Emergency Medicine (RCEM) issued guidance entitled Giving Information to Patients in the Emergency Department (Royal College of Emergency Medicine, 2017a). The guidance acknowledged that patients' recall of medical information provided to them is fallible and advocated generic discharge information.

4.8.4 The RCEM guidance went on to suggest the simplest method of providing advice was probably with the provision of information leaflets. Written materials provided at discharge have generally been associated with improved recall of information in most situations. There was evidence that some leaflets produced at trust level may have been written in language that lacked clarity and was inappropriate for the target audience.

4.8.5 As it does with a number of conditions, the RCEM provides on its website an exemplar for early pregnancy discharge advice already in use in a trust (see Figure 6). The exemplar advice entitled, Discharge advice for patients attending with an early pregnancy problem requiring [EPU] assessment (Royal College of Emergency Medicine, 2011), does not identify with a specific diagnosis. It provides in very general terms the information required to recognise deterioration of a complication in early pregnancy. The advice bridges the gap between departure from the ED and arrival at the EPU where the location of a pregnancy can be further investigated.



NHS Greater Glasgow and Clyde

Glasgow Royal Infirmary Emergency Department

Discharge advice for patients attending with an early pregnancy problem requiring EPAS assessment

- You have attended the Emergency Department (A&E) today with a problem in early pregnancy such as bleeding or abdominal pain. Bleeding during pregnancy does not necessarily mean you are having a miscarriage; it is common to have some light vaginal bleeding sometime in the first 12 weeks of pregnancy. This is called threatened miscarriage. Most women go on to have a healthy pregnancy but some women do subsequently have a miscarriage.
- Having been assessed it has been determined that you should attend the Early Pregnancy Assessment Service (EPAS) for further assessment. This usually involves being seen by a midwife and having an ultrasound scan. The scan may be performed either by placing the probe in your front passage or on your abdomen – depending upon how many weeks pregnant you are.
- This service is very busy so you have been given an appointment for sometime in the next few days.

You should attend EPAS on

DAY	MONTH	TIME

EPAS is located in the Princess Royal Maternity Unit via Alexandra Parade on Level 2. Go to Day Care reception.

What should I look out for?

If you…

- develop very severe abdominal pain (that may be only on one side).
- develop shoulder pain.
- are bleeding much more heavily than previously.
- suffer any fainting or collapse episodes.

Then there is a possibility you may have an ectopic pregnancy (pregnancy in your tube).

You should make your way to the Emergency Department if you are able or alternatively call for an ambulance.

The EPAS service is open Monday to Friday 0900-1645 and can be contacted on 0141 211 5317 if you have any worries or concerns following discharge from hospital.

Outside these hours you can contact NHS24 (08454 242424) or the Emergency Department (0141 211 4344).

Fig 6 Example of an early pregnancy discharge advice leaflet offered on the RCEM website

4.8.6 It was apparent from the sites visited during the investigation that there was still national variation in the advice leaflets offered to women with complications in early pregnancy who were being discharged from the ED. Like the one given to Abby, leaflets seen by the investigation were associated with a diagnosis aligned to either bleeding and miscarriage or ectopic pregnancy. Trusts had written and printed leaflets specific to their own organisation. These leaflets all included similar facts presented in varying degrees of detail with trust-specific contact details. The investigation was told that some trusts were using readily available literature provided by third parties, such as The Ectopic Pregnancy Trust or the Miscarriage Association, along with generic contact information.

4.8.7 While there may be a requirement to include trust-specific information on discharge advice, the investigation observed that there was no single, standardised library of discharge information leaflets. As a result, individual trusts may be investing considerable time, effort and money compiling local discharge leaflets from national sources with resulting variation.

4.8.8 The investigation concluded that it would be beneficial to standardise the content of information included in an early pregnancy advice leaflet for EDs to give to women who are awaiting assessment by an EPU. Such standardisation could draw on clinical expertise and non-technical advice on effective communication. Such a document would provide clinicians with the reassurance that the information they have delivered verbally will be effectively reinforced in the aftercare setting.

HSIB makes the following safety recommendation

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.

4.9 Models of early pregnancy services

The investigation visited five other trusts and their associated EPUs and spoke with clinical experts in early pregnancy to understand service provision and how it might influence the timely diagnosis of ectopic pregnancy.

Although only a small proportion of the estimated 200 EPUs in the UK were included, visits were intended to be representative of different service models:

- 24/7 emergency gynaecology unit • two large hospital trusts with multiple sites
- a trust with responsibility for urban and large rural catchment
- EPU based in a community health centre.

4.9.1 The investigation found that early pregnancy services had evolved in various ways to meet national guidelines:

‘Regional services should be organised so that an early pregnancy assessment service is available 7 days a week for women with early pregnancy complications, where scanning can be carried out and decisions about management made.'

- An early pregnancy assessment service should: be a dedicated service provided by healthcare professionals competent to diagnose and care for women with pain and/ or bleeding in early pregnancy and
- offer ultrasound and assessment of serum human chorionic gonadotrophin (hCG) levels and
- be staffed by healthcare professionals with training in sensitive communication and breaking bad news’ (NICE, 2019a). The guideline states that when their symptoms indicate it is necessary, women should be able to have a scan within 24 hours. NICE recommends that women who have had recurrent miscarriage(19), a previous ectopic pregnancy or a molar pregnancy(20) should be allowed direct access via self‐referral. All other women with pain and/ or bleeding in early pregnancy ‘should be assessed by a healthcare professional (such as a GP, accident and emergency [A&E] doctor, midwife or nurse) before referral to an early pregnancy assessment service’.

(19) Recurrent miscarriage in early pregnancy is defined as three consecutive miscarriages in the first 24 weeks of pregnancy (NICE, 2018).

(20) Molar pregnancy is an abnormal form of pregnancy in which a non-viable fertilised egg implants in the womb and will fail to come to term.

4.9.2 In 2016, the NHS Health Research Authority commissioned a research study entitled, Variations in the organisation of Early Pregnancy Assessment Units in the UK and their effects on clinical, service and patient‐centred outcomes (VESPA).

The study recognised that while most NHS hospitals in the UK have an EPU, there was considerable variation between them in terms of the level of care they provide and their accessibility to women. In addition, staffing levels varied considerably between the units. The most cost-effective organisational model for an EPU is unknown. The results of the VESPA study are yet to be published.

4.9.3 The investigation noted a variation in service provision in the sites visited and different risks associated with each operational model. Not all models had undertaken comprehensive identification and mitigation of risks.

4.9.4 In other safety-critical industries systematic risk analysis is used to inform a risk management process to reduce the ways in which harm can occur.

4.9.5 Safety science differentiates between ‘hazard’ and ‘risk’. A hazard denotes a situation that may lead to harm. Risk is a description of the likelihood of occurrence of the hazard and the severity of the consequences if a hazard occurs. A systemic risk analysis is a method of dissecting a process to identify potential hazards and put in place risk controls. The outcome of a successful risk analysis is the implementation of risk reduction measures or controls (Health and Safety Executive, 2001).

4.9.6 The second phase of the Safer Clinical Systems programme, a five-year patient safety improvement programme funded by the Health Foundation (Dixon-Woods et al, 2014), sought to move organisations on from looking back at errors and incidents to looking forward and focusing on risk. It drew attention to systems factors such as task design, physical environments, communication and team structure, and their role in patient safety.

Phase two ran from 2011 to 2014 and used a structured approach with four sequential steps to identify hazards and introduce risk controls in care pathways at different test sites. The first two steps involved defining the pathway and context and undertaking a systems diagnosis; these steps were reportedly well valued by participating organisations. Work undertaken by the test sites identified a large number of hazards and risks along patient pathways.

These included:

- poor reliability of systems
- poorly designed or poorly articulated systems
- inadequate communication and co-ordination
- staff shortages and deficits in competence.

4.9.7 When considering the pathway from the ED to the EPU, the hazards around information presentation and communication observed in Abby’s care were seen in other models. During three of the site visits, the investigation undertook a more detailed observation of EPUs at work. Of particular note was the volume of telephone calls nurses took, from the ED, GPs and women calling for advice. The most consistent recording of information was observed when there was a nurse dedicated to call handling.

4.9.8 Differences in weekday and weekend services posed additional latent, systemic risk. The investigation learnt of a woman being directed from the ED to a closed EPU on a Sunday and collapsing on arrival. The investigation also saw examples of risk mitigation in place. To avoid women being admitted to hospital unnecessarily or discharged from the ED without a scan appointment out of hours, one hospital allocated four emergency scan appointments on the list for the following day. These appointments could be allocated during the night by ED doctors and women could be discharged with a care plan in place. Unused appointments would be re-allocated the next morning.

4.9.9 An EPU that relocated into a community setting had to address systemic risk presented by being situated outside an acute trust. The trust identified concerns about information transfer, testing, and emergency transfer to the acute hospital. These were mitigated by, for example, the use of electronic patient records, protocols with the local ambulance service and point-of-care hCG testing.

4.9.10 Triage was of particular importance in enabling services to manage demand and allocation of resource to clinical need.

4.9.11 Two of the sites visited allowed women to self-refer to the EPU, which enabled clinicians with specialist skills to assess women's cases for risk factors and decide on the appropriate treatment. Where self-referral or direct streaming from the ED was not an option, the investigation observed a variety of referral processes intended to identify risk factors for ectopic pregnancy and mitigate the risk of delayed diagnosis. One of the systems observed by the investigation involved allocating an objective score to the risk assessment of early pregnancy complications.

4.9.12 During a review of literature, the investigation found considerable reference to the conduct of handover but less about referral. The General Medical Council (GMC) explains to clinicians that referral is 'when you arrange for another practitioner to provide a service that falls outside your professional competence' (General Medical Council, 2013). The GMC definition places the responsibility on the referrer to pass on relevant information about the patient's condition and history, along with the reason for transferring care of the patient. In much of the literature reviewed, situations that fell within the GMC description of referral were synonymous with handover or hand-off (World Health Organization, 2007).

4.9.13 A study entitled, Clinical handover within the emergency care pathway and the potential risks of clinical handover failure (Sujan et al, 2014), included thematic and conversation analysis of 130 audio recordings of patient referrals from the ED to acute medicine. It made many observations including:

- Referrals provided an opportunity to seek specialist advice and to reach a joint decision about what the best course of action should be for the patient.
- During handover, verbal communication relied on memory and the sender may filter information depending on perceived importance. The communication may be unstructured and confusing. Sender and receiver may have different goals and information needs. Interruptions, noise and lack of privacy may negatively affect verbal communication.
- The referral of patients from the ED to other departments may lead to situations where allocation of responsibility is unclear.

4.9.14 The study also described an approach that recognised participants in handover (or referral) exchanging a mental model of what they understood the process to be, what they wanted out of it and what they needed to do to ensure that their own needs and priorities were achieved. The study noted that handovers involved multiple mental models. The study found that ill-formed mental models, often used by inexperienced practitioners, may not achieve the necessary outcomes but the deficiency may not be recognised. It suggested that making these mental models more explicit to the various participants could increase the chance of the handover accommodating participants' differing needs.

4.9.15 The study concluded that the ED should agree with the specialities formal systems for the handover of cases. It suggested consideration of structured communication protocols, possibly supported by checklists. It acknowledged the benefits and limitations of standardisation, adding that the adoption of such communication protocols needed to provide flexibility for clinicians.

4.9.16 Both the Royal College of Emergency Medicine (RCEM, 2017b) and the Royal College of Obstetricians and Gynaecologists (RCOG, 2016b) recommend protocols between the ED and EPU to enable appropriate access to early pregnancy services. The investigation considered that the hazards around communication of symptoms would be reduced by an agreed format when assessing risk to patients during referral when they may have to wait for a scan. The use of such a tool by EPUs and referrers would promote a standard dialogue and serve to raise awareness of risk factors for ectopic pregnancy.

HSIB makes the following safety recommendation

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.

HSIB makes the following safety observation

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.

4.10 Workforce capacity

4.10.1 All EPUs visited by the investigation offered a scanning service from Monday to Friday, normally over a 12 to 13-hour period during the working day. Weekend service provision was less consistent. The delivery of a seven-day service had cost implications for trusts but the investigation heard that availability of qualified sonographers was also a limiting factor.

4.10.2 Examples of the challenges of providing ultrasound practitioners to conduct scans were observed by the investigation. In Abby’s case there was no appropriately qualified professional to undertake an ultrasound scan when a CNS was absent due to sickness. The appointment list was reduced, and appointments were postponed as a consequence. The investigation visited another trust which suspended a Saturday scanning clinic while a CNS was on maternity leave and was not replaced during that period.

4.10.3 Initially, ultrasound scanning was largely conducted by healthcare professionals with a background as registered radiographers(21). The investigation was told by the British Medical Ultrasound Society that there is increased pressure on radiographers as the use of sonography has broadened as a diagnostic tool and become an established part of an increasing number of patient care pathways – early pregnancy and obstetric scanning are two examples. As in early pregnancy, sonography is now conducted by a wide range of non-radiographers. With specialist training, ultrasound practitioners use ultrasound as a ‘tool’ to aid and assist their wider examination and treatment.

4.10.4 In 2015, the Migration Advisory Committee (MAC) identified sonography as a shortage occupation (Migration Advisory Committee, 2015) with the Society and College of Radiographers (SCoR) workforce survey analysis estimating the vacancy rate to be at least 12.6% (Society and College of Radiographers, 2019). In addition, SCoR found that a third of sonographers who responded to the survey were over 50 years of age. This comes at a time when nursing is also a MAC shortage category.

4.10.5 In response to the sonography workforce challenge, Health Education England supported a programme of direct entry qualification at both undergraduate and postgraduate level on CASE-accredited(22) university courses. A report by the Centre for Workforce Intelligence in 2017 (Centre for workforce intelligence, 2017), recognised that as sonography is

not a regulated profession in the UK, it makes it difficult to ensure consistent professional standards, training and accreditation and that this was a challenge to workforce planning. At present, statutory registration of sonography practitioners is largely achieved by professional background as a radiographer, midwife or nurse and not as a sonographer. The investigation was told that many direct entrant sonographers joining the workforce were unlikely to have a previous healthcare registration and would have no statutory professional registration. They would, however, be eligible for optional voluntary registration on the Public Voluntary Register of Sonographers.

4.10.6 Four of the trusts visited had developed their CNSs or advanced nurse practitioners as nurse-sonographers. One trust acknowledged this was to increase capacity to deliver sonography. Two trusts used sonographers on a roster from the radiology department, while two used a mix of sonographers and nurse-sonographers.

All trusts visited had consultant-led clinics at least twice weekly. When considering skill mix and staffing levels for EPUs, the investigation could find no consensus.

(21) Radiographers are regulated professionals. Radiographers, Diagnostic Radiographers or Therapeutic Radiographers undertake a broad portfolio of either diagnostic examinations or radiotherapy procedures.

(22) Accredited by the Consortium for the Accreditation of Sonographic Education.

HSIB makes the following safety observation

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.

4.11 Assurance of early pregnancy services

4.11.1 The Care Quality Commission (CQC) has a statutory obligation to provide assurance for the standards of care delivered in acute hospitals. It uses an inspection framework to guide this process. Gynaecology services are inspected against the CQC's Gynaecology and Termination of Pregnancy service framework (Care Quality Commission, 2018). Gynaecology had previously been inspected alongside maternity services but since the introduction of new policy in June 2017, gynaecology services have been inspected separately. By November 2019, eight such inspections had been completed

4.11.2 Early pregnancy services are assessed as part of the CQC gynaecology framework. However, NICE guideline 126, which addresses a large proportion of work in relation to early pregnancy and potential complications, such as ectopic pregnancy, is not considered in the assessment regime.

4.11.3 CQC assurance includes data collection. The data currently used by the CQC is largely focused around obstetric (childbirth □related) service outcomes. This investigation has identified variability in models of early pregnancy service provision with each model presenting different risks. HSIB considers the CQC has an important role in driving standardisation of safety in this sector of gynaecology. Its assurance of early pregnancy care may benefit from a more complete review of pathways within the service.

HSIB makes the following safety recommendation Safety recommendation

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

5 Summary of findings, safety recommendations, and safety observations

5.1 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.
- 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.

6 Appendix 1: Strategic Executive Information System and National Reporting and Learning System search criteria

The investigation reviewed incidents relating to ectopic pregnancy reported to the national Strategic Executive Information System (StEIS), following identification of a potential risk around diagnosis of this condition during routine review of the StEIS database. The search criteria used for this detailed review can be found below:

System	StEIS	
Dates	Date database searched	20 August 2018
	Date incident reported	01 April 2017 to 20 August 2018
Search criteria	Field	Search terms
	All incident categories	‘ectopic’
Results	Containing ‘ectopic’	59 reports
	Reported as a missed diagnosis of ectopic pregnancy resulting in serious harm	30 reports
	Reported as occurring in ED	13 reports

A search of the National Reporting and Learning System (NRLS) was undertaken to further understand incidents reported, including location of diagnosis. The search criteria can be seen below:

System	NRLS	
Dates	Date database searched	15 November 2019
Date incident reported	1 April 2017 to 31 March 2019	
Search criteria	Field	Search terms
All incident categories	‘ectopic’ AND ‘pregnancy’	
Results	Containing ‘ectopic’ AND ‘pregnancy’	28,604 reports
	Excluding Wales	27,790 reports
	Incident categories ‘Access, admission, transfer, discharge’ ‘Clinical assessment’ ‘Documentation’ ‘Treatment/procedure’	18,523 reports
		569 reports

	Level of harm ‘Moderate’ ‘Severe’ ‘Death’	
	Excluding ‘Obstetrics and Gynaecology’ specialty	93 results

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