



Health Services Safety
Investigations Body

Investigation report

Sepsis: investigating under the Patient Safety Incident Response Framework (PSIRF)

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Theme:

Delayed diagnosis, Hospital care, Patient safety themes

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About this report

HSSIB has modelled an approach to investigating patient safety events under the Patient Safety Incident Response Framework (PSIRF). This is to support NHS organisations and investigation staff to increase their learning about how to investigate under this framework and provide examples of how PSIRF tools and guidance can be used to improve investigations. This report differs from the usual HSSIB report template as it uses the PSIRF patient safety incident investigation template.

The report also contains learning relevant to healthcare organisations and staff on how sepsis may be identified and defined when reporting patient safety events and investigating incidents where sepsis may be suspected.

Introduction

HSSIB engaged with a wide range of stakeholders, including clinicians and national leads, to learn more about the issues surrounding recognition of sepsis and to identify areas where an investigation could focus to help improve patient safety.

Although sepsis has been the focus of extensive national work, it has persisted as a safety risk. The themes from incidents and complaints have remained the same over time. Evidence from the intelligence gathered suggests that greater insight into the challenges faced at an organisational level in recognising sepsis would be helpful.

To support NHS organisations and local investigation staff, HSSIB identified an opportunity to model approaches to patient safety incidents investigations (PSIIs) under the NHS Patient Safety Incident Response Framework (PSIRF). Stakeholders told HSSIB that this would help to

increase local learning and provide examples of how PSIRF tools can be used to improve investigations. HSSIB has also used this opportunity to identify learning that may help to improve how PSIRF can support staff in carrying out incident investigations.

This investigation has used the PSII report template and PSIRF tools to investigate the recognition of sepsis in a patient with diabetes and a foot infection. Findings and areas for improvement are listed for the organisations that were involved in this incident. However, the learning may be relevant to other organisations.

Patient safety incident investigation (PSII) report

Recognition of sepsis: in a patient with diabetes and a foot infection

Incident ID number:	I-031570 (HSSIB)
Date incident occurred:	7 to 12 June 2024
Report approved date:	8 January 2025
Approved by:	HSSIB

Terms used in this report

This patient safety incident investigation involves two hospitals, which are referred to as Hospital A and Hospital B to protect their anonymity. Hospital A provides general hospital services. Hospital B is a major trauma centre and provides a range of specialist services including vascular surgery (which deals with conditions that affect the flow of blood through veins and arteries).

In September 2024, the Department of Health and Social Care and the British Medical Association agreed to change the title of 'junior doctor' to 'resident doctor'. To reflect this change, the term 'resident doctor' is used in this report.

Distribution list

Barbara – the patient
Ian – the patient's son
Diabetic foot co-ordinator, Hospital A
Quality governance – patient safety investigations and compliance, Hospital B

Consultant learning response lead, Hospital B
Patient safety investigation lead, Hospital A
Head of patient safety, Hospital A
Associate medical director for emergency medicine and rehabilitation services division, Hospital A
Resident doctor, emergency department, Hospital A
Consultant clinical lead, emergency department, Hospital A
Resident doctor, medical team, Hospital A
Consultant deteriorating patient lead, Hospital A
Consultant endocrinologist, Hospital A
Staff nurse, ward, Hospital A
Consultant microbiologist, Hospital A
Clinical site manager, Hospital A
Head of quality and safety, integrated care board
Consultant clinical lead for vascular surgery, Hospital B
Resident doctors (x 5) vascular team, Hospital B
Staff nurses (x 2) Hospital B
Healthcare assistant, Hospital B
Consultant, vascular team, Hospital B
Consultant, Intensive Therapy Unit, Hospital B
Sepsis subject matter advisor

About patient safety incident investigations

Patient safety incident investigations (PSIIs) are undertaken to identify new opportunities for learning and improvement. PSIIs focus on improving healthcare systems; they do not look to blame individuals. Other organisations and investigation types consider issues such as criminality, culpability or cause of death. Including blame or trying to determine whether an incident was preventable within an investigation designed for learning can lead to a culture of fear, resulting in missed opportunities for improvement.

The key aim of a PSII is to provide a clear explanation of how an organisation's systems and processes contributed to a patient safety incident. Recognising that mistakes are human, PSIIIs examine 'system factors' such as the tools, technologies, environments, tasks and work processes involved. Findings from a PSII are then used to identify actions that will lead to improvements in the safety of the care patients receive.

PSIIIs begin as soon as possible after the incident and are normally completed within 3 months. This timeframe may be extended with the agreement of those affected, including patients, families, carers and staff. HSSIB started this investigation in August 2024 and it was completed in November 2024. The draft report was shared with all those affected for comments and feedback before being finalised.

If a PSII finds significant risks that require immediate action to improve patient safety, this action will be taken as soon as possible. Some safety actions for system improvement may not follow until later, according to a safety improvement plan that is based on the findings from several investigations or other learning responses.

An NHS organisation's investigation team follow the Duty of Candour and the [Engaging and involving patients, families and staff after a patient safety guidance](#) in their collaboration with those affected, to help them identify what happened and how this resulted in a patient safety incident. Investigators encourage human resources teams to follow the [Being fair tool](#) in the minority of cases when staff may be referred to them.

PSIIIs within NHS organisations are led by a senior lead investigator who is trained to conduct investigations for learning. The investigators follow the guidance set out in the [Patient Safety Incident Response Framework](#) and in the national [patient safety incident response standards](#).

A note of acknowledgement

We would like to thank Barbara whose experience is the focus of this investigation. Barbara and her son, Ian, gave generously of their time to help the investigation understand what happened and the impact of events on their lives. Information shared by them helped inform the investigation and identify areas of improvement.

In accordance with their wishes, Barbara and Ian are referred to by name throughout this report.

We also thank the healthcare staff who were keen to participate in the investigation and to discuss and support any improvements that might help make care for patients like Barbara safer in future.

About Barbara

The following words are written about Barbara to give the readers of this report a sense of her life, and the person she was.

Barbara has clever hands, and they are always busy. Sometimes those hands are growing things to eat – strawberries, bell peppers, spring onions and celery; other times they are sewing, knitting, crocheting or embroidering. But they will always be doing something, and the fruits of her labour are shared with those around her – friends, family and neighbours. You'll often find Barbara laughing – she is known to 'like a bit of a joke' – and she is also fiercely independent. Family is really important to Barbara, and Barbara, in turn, is really important to her family. Ian, Barbara's son, lives with his mum so he can care for her (and cook amazing meals!), which has been especially needed since she has struggled with health problems affecting her heart and kidneys, not to mention having diabetes.

Barbara hopes that sharing her experience will make people more aware of the risks of having a severe foot infection when you have diabetes, and the importance of being transferred quickly to a hospital with specialist knowledge and skill.

Executive summary

Incident summary

Barbara was advised to go to the emergency department at Hospital A after being seen for a routine follow-up outpatient appointment for her diabetes on Friday 7 June 2024. In the emergency department, Barbara was diagnosed with a severe infection of her right foot and antibiotics were started. The vascular team at Hospital B (the specialist hospital for vascular services) were contacted for advice as Barbara had a black middle toe and poor blood supply to her right foot. Barbara was already known to the vascular team because of problems with her feet and had been seen two weeks earlier, on 24 May, as an outpatient. On 7 June, the vascular team told the doctor in the emergency department to keep Barbara in Hospital A for antibiotic treatment and asked for two specialist scans to be carried out to provide additional information about the blood supply to her foot and the extent of the infection.

Barbara went from the emergency department to the acute care unit, and then on Saturday lunchtime was moved to a ward specialising in the care of people with diabetes. Over the weekend Barbara continued her antibiotics and routine monitoring did not indicate any cause for concern.

On Monday 10 June the diabetic foot co-ordinator saw Barbara. They were concerned about the appearance of Barbara's foot, particularly given her poor blood supply. The co-ordinator contacted the vascular team at Hospital B to inform them of the situation and, in their opinion, the need for Barbara to be transferred there. Later that day there was another conversation with the vascular team, and it was agreed Barbara could be transferred once a bed on a ward became available. During that day, routine monitoring showed that Barbara had become more unwell and needed oxygen therapy.

On Tuesday 11 June the diabetic foot co-ordinator saw Barbara and again contacted the vascular team to reiterate concern about Barbara's worsening infection. It was agreed that Barbara could be transferred that day to Hospital B's emergency department as there was still no ward bed available.

Barbara arrived at Hospital B at 17:10 hours. She was seen by one of the vascular team and the plan was for urgent surgery. Blood results showed that Barbara was at high risk of bleeding, so her surgery was delayed until the next day to allow time for medication to reduce the risk.

At approximately 07:00 hours on the morning of Wednesday 12 June Barbara was found unresponsive and the emergency medical team were called to help. Barbara was taken to the intensive care unit and blood results and other clinical details showed she had sepsis. Despite treatment, Barbara became more unwell, and an emergency below-knee amputation of her right leg was carried out that evening to gain control of the infection.

An incident report was submitted raising concerns about Barbara's care. Specifically, the concerns were around whether Barbara should have been transferred to Hospital B earlier, and whether this would have avoided her developing sepsis, and the need for such an extensive amputation.

Barbara's recovery from her amputation was complicated by health problems including pneumonia and issues with her heart and kidney function. Barbara was finally well enough to be discharged home on 11 October 2024.

Summary of key findings

The investigation found that:

- Blood tests and other clinical markers taken when Barbara was found unresponsive at Hospital B met the criteria for a diagnosis of sepsis.
- Clinicians had differing opinions about whether Barbara had sepsis in the period of time before she was found unresponsive. This difference in opinion reflected the various definitions of sepsis used by these clinicians. Based on the internationally agreed definition of sepsis, before Barbara was found unresponsive, her blood results and other clinical

markers indicated that her body was responding to an infection but did not meet the criteria of sepsis.

- The care and treatment Barbara received at Hospital A was in line with national and local guidance. There were signs that Barbara was becoming more unwell at Hospital A, likely due to worsening foot infection. However, this situation could only be resolved by her infection being brought under control by surgery at Hospital B and staff were proactively trying to achieve this.
- Barbara's experience demonstrates the complexities and risks of specialist services being centralised in a limited number of hospitals ('hubs') with surrounding hospitals ('spokes') referring patients to the hub for specialist care. The risks in relation to vascular services are greater for patients like Barbara who had a severe foot infection, compounded by a poor blood supply, against a background of significant, long-term health problems including diabetes.
- The expertise provided by the diabetic foot co-ordinator at Hospital A helps mitigate the risks involved. However, currently this expertise sits with one person, is restricted to Monday to Friday, and is not available out of hours. Also, the consultants with expertise in diabetes, and knowledge of diabetic foot problems, are not in the hospital out of hours.
- Hospital A does not have a formal agreement with Hospital B which sets out the details of its vascular service provision.
- The mismatch between capacity and demand for vascular services is compounded by a lack of capacity in general at Hospital B. The shortage of beds for the number of patients who need them means that transfers for all but the most urgent cases may be delayed.
- As is usual at specialist hospitals, the vascular doctors receiving patient referrals to Hospital B have different levels of knowledge, experience and expertise. This means there is the potential for variation in advice and/or transfer decisions. The patient safety risks inherent in this are compounded by there being variation in consultant oversight of decision making.
- There is no formalised referral process for patient referrals to Hospital B. This means documentation about referrals and decisions made may vary, both in content and in where the information is stored.
- Hospital A and Hospital B have separate patient information systems which cannot be accessed by each other. This meant Hospital B only had access to limited clinical information about Barbara while she was at Hospital A.
- Conversations about referrals take place in busy, pressured environments. The vascular doctor receiving referrals may be involved in other complex tasks and their attention divided between competing priorities.
- The action taken at Barbara's vascular outpatient appointment on 24 May was appropriate given there was no evidence of infection at that time.

Summary of areas for improvement and safety actions

The investigation identified two areas of improvement which Hospital A and Hospital B could develop safety actions to address.

Area of improvement 1

Review and update the requirements of vascular service provision between Hospital A and Hospital B.

Area of improvement 2

Out of hours expertise in diabetes and foot problems at Hospital A.

Background and context

What is sepsis?

Sepsis is a life-threatening condition that happens when the body's response to an infection injures its own tissues and organs (Singer et al, 2016). The clinical term for this is 'organ dysfunction'.

Sepsis is the main cause of death from infection, especially if it is not recognised and treated promptly (Singer et al, 2016). There are varying estimates of the number of deaths from sepsis. The UK Sepsis Trust states that there are up to 48,000 sepsis-related deaths in the UK each year (The UK Sepsis Trust, n.d.). The Office for National Statistics, which collects data from death certificates, recorded 26,203 sepsis related deaths in England and Wales in 2023 (Office for National Statistics, 2024). Most people who die from sepsis in the UK are over 75 years old, frail and/or have significant co-existing health conditions. Some people can potentially survive sepsis if they had the right treatment in a timely manner (Academy of Medical Royal Colleges, 2022; Singer et al, 2019).

There have been initiatives to improve the recognition and timely treatment of sepsis over the last 20 years, yet it has persisted as a safety risk. Furthermore, the themes from incidents and complaints involving sepsis have remained largely the same over time (Parliamentary and Health Service Ombudsman, 2023).

How is sepsis diagnosed?

Sepsis is not a specific illness. The diagnosis is based on a number of signs and symptoms in a patient with suspected infection (Singer et al, 2016). Sepsis can be difficult to diagnose even for experienced clinicians because:

- the signs of sepsis can be vague and can mimic other illnesses, particularly in the earlier stages of the condition
 - there is no single sign that uniquely points to sepsis
 - there is no single diagnostic test to confirm or rule out sepsis
 - there is no one predictive tool or set of clinical decision rules that has been evidenced to reliably determine who has sepsis
 - symptoms can show differently in different people, depending on their age, immune system, underlying health conditions, medications they take and the source of their infection.
- (National Institute for Health and Care Excellence, 2024)

Are some people more at risk of sepsis?

Yes. People in the following groups are at more risk of developing sepsis:

- the very young (under 1 year old)
- older people over 75 years or who are frail
- people with diabetes
- people with a weakened immune system such as those having chemotherapy treatment
- people with a genetic disorder that affects their immune system, such as people with Down's syndrome or sickle cell disease
- people who have recently had surgery or a serious illness
- people who have given birth, had a miscarriage or termination of pregnancy in the past 6 weeks. (National Institute for Health and Care Excellence, 2024; NHS, 2022)

Of note, people from a South Asian, African or African Caribbean background are more at risk of diabetes (Diabetes UK, n.d.). It is not known exactly why this is. Barbara, whose experience is documented in this report, is of Jamaican heritage and has diabetes. She is, therefore, at a higher risk of sepsis.

Are guidance and tools available to support clinicians to recognise, diagnose and treat sepsis?

Yes. The National Institute for Health and Care Excellence (NICE) published guidance on the recognition, diagnosis and early management of suspected sepsis in 2016 and this was updated in 2024. The Academy of Medical Royal Colleges (AoMRC) published a statement on the initial antibiotic treatment of sepsis in 2022. The UK Sepsis Trust has also published resources and tools to help with the recognition of, and response to, suspected sepsis.

NICE (2024) and AoMRC (2022) guidance highlights the importance of finding the source of any infection and taking action to control it. Sometimes control is achieved by antibiotic treatment; other times a surgical or drainage procedure may be needed in addition. Both NICE and AoMRC recommend the use of a tool called the 'national early warning score' (NEWS2) to assess the risk of severe illness or death from sepsis. NICE guidance makes clear that NEWS2 should be used to support clinical decision making, not to replace clinical judgement. This means that a patient's history, the findings from any physical examination, and any other reasons for concern must also be taken into account.

NEWS2 is a scoring tool developed by the Royal College of Physicians (RCP) to improve the detection of, and response to, patients who are becoming more unwell (Royal College of Physicians, 2017). Using the tool involves giving a number to vital signs that are routinely monitored when a patient is in hospital. The six vital signs are:

- respiratory (breathing) rate
- oxygen saturation (the amount of oxygen in a person's blood)
- temperature
- blood pressure
- pulse rate
- level of alertness or new confusion.

The number given to each vital sign is based on how far outside the expected range it is; the higher the number the more the vital sign varies from the norm. The numbers are then added up to give an overall score. Two points are added to the score for people who need oxygen to maintain their recommended oxygen saturation (see figure 1). The total score is used to indicate the person's risk of severe illness or death (see figure 2), prompt any actions to be taken, and decide the frequency of monitoring.

Figure 1: The NEWS2 scoring system (Royal College of Physicians, 2017)

Chart 1: The NEWS scoring system

Physiological parameter	Score						
	3	2	1	0	1	2	3
Respiration rate (per minute)	≤8		9–11	12–20		21–24	≥25
SpO ₂ Scale 1 (%)	≤91	92–93	94–95	≥96			
SpO ₂ Scale 2 (%)	≤83	84–85	86–87	88–92 ≥93 on air	93–94 on oxygen	95–96 on oxygen	≥97 on oxygen
Air or oxygen?		Oxygen		Air			
Systolic blood pressure (mmHg)	≤90	91–100	101–110	111–219			≥220
Pulse (per minute)	≤40		41–50	51–90	91–110	111–130	≥131
Consciousness				Alert			CVPU
Temperature (°C)	≤35.0		35.1–36.0	36.1–38.0	38.1–39.0	≥39.1	

Figure 2: NEWS2 scores and risk of severe illness and death (Royal College of Physicians, 2017)

Chart 2: NEWS thresholds and triggers

NEWS score	Clinical risk	Response
Aggregate score 0–4	Low	Ward-based response
Red score Score of 3 in any individual parameter	Low–medium	Urgent ward-based response*
Aggregate score 5–6	Medium	Key threshold for urgent response*
Aggregate score 7 or more	High	Urgent or emergency response**

* Response by a clinician or team with competence in the assessment and treatment of acutely ill patients and in recognising when the escalation of care to a critical care team is appropriate.

**The response team must also include staff with critical care skills, including airway management.

Hospital trusts are expected to use this scoring system to support their recognition of, and response to, patients who are becoming more unwell. Hospital A and Hospital B, which were involved in Barbara's care, use NEWS2 and their policies for monitoring and escalation of adult patients who are becoming more unwell reflect NICE (2024) guidance.

NICE guidance (2024) points out that NEWS2 was not developed specifically for sepsis, but rather to help improve the recognition of and response to patients who are becoming more unwell in general, whatever the cause. Although there is evidence to support the use of NEWS2 in the context of sepsis (Inada-Kim, 2022), NICE states that further research is needed.

In its statement on the initial antibiotic treatment of sepsis, AoMRC included a framework to help clinicians in their decision making and initial evaluation of sepsis. The framework linked NEWS2 scores to timeframes for actions to be taken and antibiotics given (see figure 3). AoMRC also recommended that research be carried out to evaluate the use of NEWS2 to guide the initial evaluation of sepsis.

Figure 3: Decision support framework to help clinicians with their initial evaluation of sepsis in adults 16 years or older (Academy of Medical Royal Colleges, 2022)

Vital signs	Vital signs: NEWS-2 'Physiology first'	0	1-4	5-6	≥7
Initial assessment	History, examination, lab results	<i>If clinical or carer concern, continuing deterioration, surgically remediable sepsis, neutropaenia, or blood gas / lab evidence of organ dysfunction, including elevated serum lactate, upgrade actions at least to next NEWS-2 level →</i>			
	Comorbid disease, frailty, patient preferences?	<i>Consider influence of comorbid disease, frailty and ethnicity on NEWS-2, and patient preferences for treatment intensity, limits, end-of-life care</i>			
Initial (generic) actions	Monitoring and escalation plan	Standard observations	- Registered nurse review <1 h - Obs 4-6 hrly if stable. - Escalate if no improvement	- Obs hourly. - Review <1 hr by clinician competent in acute illness assessment - Escalate if no improvement	- Obs every 30 mins. - Review <30 min by clinician competent in acute illness assessment. - Senior doctor review <1 hr if no improvement: refer to Outreach or ICU
	Initial treatment of precipitating condition	Standard care	<6 hr	<3 hr	<1 hr
Likelihood of infection & specific actions	Unlikely	Standard care	Review daily and reconsider infection if diagnosis remains uncertain		
	Possible	Review at least daily	< 6 h Source identification & control plan documented.	< 3 h: - Microbiology tests - Antimicrobials: administer or revise	< 1 h: - Microbiology tests - Antimicrobials: administer or revise (broad-spectrum if causative organism uncertain).
	Probable or definite	< 6 h Diagnostic tests & R plan	< 6 h - Microbiology tests - Antimicrobials: administer or revise - Source identification & control plan. - D/w ID/micro if uncertain, & review	< 6h - Source identification & control plan documented. 48 – 72 h - Source control initiated - Review antimicrobials with ID/micro/senior clinician	< 3 h - Source identification 3-6 h - Source control initiated according to clinical urgency 48 – 72 h: - Review antimicrobials with ID/micro/senior clinician

There is another scoring tool called the sequential [sepsis-related] organ failure assessment score (SOFA) that can be used to assess whether a person has sepsis. This tool is mostly used in critical care settings as it requires access to blood results and other clinical measurements (see figure 4). The tool is not intended to be used to guide patient care but as a way of characterising, or defining, a patient with sepsis (Singer et al, 2016). The investigation, with the support of a subject matter advisor, used this tool to consider whether Barbara met the criteria for sepsis before becoming unexpectedly and severely unwell the night before her surgery.

Figure 4: Sequential [sepsis-related] organ failure assessment score (Singer et al, 2016)

System	Score				
	0	1	2	3	4
Respiration					
Pao ₂ /Fio ₂ , mm Hg (kPa)	≥400 (53.3)	<400 (53.3)	<300 (40)	<200 (26.7) with respiratory support	<100 (13.3) with respiratory support
Coagulation					
Platelets, ×10 ³ /μL	≥150	<150	<100	<50	<20
Liver					
Bilirubin, mg/dL (μmol/L)	<1.2 (20)	1.2-1.9 (20-32)	2.0-5.9 (33-101)	6.0-11.9 (102-204)	>12.0 (204)
Cardiovascular	MAP ≥70 mm Hg	MAP <70 mm Hg	Dopamine <5 or dobutamine (any dose) ^b	Dopamine 5.1-15 or epinephrine ≤0.1 or norepinephrine ≤0.1 ^b	Dopamine >15 or epinephrine >0.1 or norepinephrine >0.1 ^b
Central nervous system					
Glasgow Coma Scale score ^c	15	13-14	10-12	6-9	<6
Renal					
Creatinine, mg/dL (μmol/L)	<1.2 (110)	1.2-1.9 (110-170)	2.0-3.4 (171-299)	3.5-4.9 (300-440)	>5.0 (440)
Urine output, mL/d				<500	<200

Most NHS hospitals have electronic patient records. Sepsis alerting tools have been developed that can be incorporated into these records to produce an automated alert in response to set triggers. Most sepsis alerts in NHS hospitals are based on NEWS2 (Honeyford et al, 2023). There is not yet enough evidence to confirm whether they help improve care for patients with possible sepsis (Academy of Medical Royal Colleges, 2022). Hospital A does not have electronic sepsis alerts: Hospital B does.

Is there a link between foot infections in people with diabetes and sepsis?

Yes, there is a link. Foot problems are common in people with diabetes largely because of nerve damage or poor blood supply caused by diseased blood vessels in the leg. It is estimated that 10% of people with diabetes will have a diabetic foot ulcer (localised injury to the skin and/or underlying tissue) at some point in their lives (National Institute for Health and Care Excellence, 2019). The nerve damage and poor blood supply caused by diabetes means that foot ulcers do not heal well and while present they are at risk of becoming infected. If a foot ulcer becomes infected, it can be life threatening because of the risk of sepsis, as well as limb threatening because of the risk of needing an amputation to control the infection. Foot ulcers precede more than 80% of amputations in people with diabetes (National Institute for Health and Care Excellence, 2019).

National guidance describes how to prevent and manage foot problems in people with diabetes. As recommended by that guidance, Hospital A had a standard operating procedure for when a patient needed to stay in hospital for treatment. The procedure detailed the actions to be taken in the emergency department, and the care pathway to be followed.

Barbara's experience

The dates and times below are from the clinical records and staff interviews. There is one difference between these dates and Barbara and Ian's recollection of events. They told the investigation that transfer from Hospital A to Hospital B took place on Monday 10 June not Tuesday 11 June 2024. The investigation has not been able to resolve this difference. Importantly, the difference in dates does not impact on the safety learning from this event.

Friday 7 June 2024

Barbara went to Hospital A for a routine follow-up outpatient appointment for her diabetes. Barbara's son, Ian, went with his mum to the appointment as she was in a lot of pain from her right foot and could not walk without help. Ian told the nurse how worried he was about his mum's foot and shared a photo he had taken. The photo showed an ulcer on her right foot and also the middle toe which had turned black (this colour indicates that the tissue has died or, to use the medical term, 'necrosed'). Barbara's foot had been reviewed two weeks earlier on 24 May 2024 by a vascular consultant in an outpatient clinic at Hospital B. The nurse contacted the diabetic foot co-ordinator, who is the expert within Hospital A on foot problems related to diabetes. The co-ordinator's advice was for Barbara to go to Hospital A's emergency department for further assessment and possibly treatment in hospital. Ian went with his mum to the emergency department, and they arrived at 14:07 hours.

Barbara was first seen by a nurse and then assessed by a resident doctor who wrote in the clinical records at 16:12 hours. The doctor documented that Barbara had ulcers on her right ankle, calf and 'second toe'. It was noted that the area on the second toe had begun as a blister that had burst. The doctor prescribed antibiotics for a severe foot infection and had a phone conversation with the vascular team at Hospital B. Barbara was known to the team and had been seen at an outpatient appointment with them 2 weeks earlier. The vascular doctor advised the resident doctor to request a specialist scan (called an angiogram) to provide more detailed information about the blood supply to Barbara's foot. This information would help inform treatment decisions, including regarding any surgery. The scan took place at 17:17 hours and the findings were reported at 17:24 hours. They showed that Barbara had a very poor blood supply to her feet, especially her right foot. When Barbara returned from her scan, she was given the two antibiotics prescribed by the resident doctor at 18:09 hours and 18:20 hours respectively. It was thought she may be transferred to Hospital B that evening, and possibly have surgery. At 22:35 hours it was documented that Barbara should not have any more to eat or drink in preparation for possible surgery if she was transferred.

The scan results, along with blood results and other details, were discussed with the vascular team at Hospital B later that evening at 23:32 hours. The advice given was that Barbara should have antibiotics in Hospital A, rather than be transferred to Hospital B. A magnetic resonance

imaging (MRI) scan was requested, to see if infection was present in the bones of Barbara's right foot as well as the surrounding tissues. The vascular doctor also asked for photos of Barbara's foot to be sent to the vascular team to help with their understanding of the situation. Barbara was transferred to the acute care unit just after midnight (00:17 hours) under the medical team.

Saturday 8 June 2024

Barbara was seen by a doctor at 01:38 hours on Saturday morning. The doctor carried out a detailed assessment of Barbara's foot and documented their impression which was that she had a severe diabetic foot infection and ulcer. Their plan included Barbara continuing on the antibiotics prescribed which were in accordance with local guidance for the severity of her infection and extremely poor blood supply to her foot. They also noted that she would need to have surgery and their documented plan included discussing this again with the vascular team, as well as the need for the diabetic foot co-ordinator to see Barbara on Monday 10 June (which was the co-ordinator's next working day).

Later that morning, Barbara was reviewed by a different doctor who documented that Barbara was sitting up in bed and alert. Their record included that Barbara was unable to put any weight on her right foot due to pain. The medical plan made earlier that day was reiterated. Barbara's temperature was raised at 38.4 Celsius that morning and the nurse informed the doctor of this while they were on the ward seeing patients. The doctor discussed the situation with the microbiology team. The team's advice was to continue with the current antibiotics and to send a blood sample and swabs to try and identify the particular germs causing infection. Later that day, Barbara's temperature had returned to within the expected range.

At lunchtime, Barbara was moved from the acute care unit to a ward. The care of patients on this ward is led by consultants with specialist knowledge of diabetes and the doctors and nurses on the ward are familiar with the associated health problems such as foot problems.

Sunday 9 June 2024

There was no obvious change or worsening in Barbara's general health; her NEWS2 score was mostly 0 (see 'Background and context' section).

Monday 10 June 2024

Barbara was seen by a resident doctor and the diabetic foot co-ordinator. The co-ordinator examined Barbara's right foot and reviewed the blood results and other clinical details. Specifically, they noted the strong odour and 'tracking discolouration' under Barbara's foot which they suspected to be an abscess. Overall, their opinion was that there were signs of worsening infection, in the context of a very poor blood supply. The co-ordinator spoke with the

vascular team at Hospital B to inform them of their concern. The vascular team asked to be sent the results of the second scan (MRI) they had requested on Friday evening which they wanted to review before making any decision. The co-ordinator spoke to the resident doctor and documented that they would 'strongly recommend' Barbara be transferred to Hospital B as they suspected her 'limb is at risk'. In addition, the co-ordinator spoke with the consultant responsible for Barbara's care, to make them aware of the situation and to ask if they could help facilitate the scan report being available as soon as possible.

The MRI scan took place at 11:05 hours and the findings were reported at 12:11 hours. The consultant responsible for Barbara's care discussed the findings with the radiologist who wrote the scan report, and then spoke with the diabetic foot co-ordinator. The consultant then documented that Barbara needed urgent transfer to Hospital B. The co-ordinator contacted the vascular team and updated them on the scan findings, which included the possibility of 'gas gangrene' – a particularly severe form of infection in which gas is released into surrounding tissues. The co-ordinator reiterated their concern that Barbara was at risk of losing her limb because of infection and her poor blood supply. The vascular doctor agreed to call back with a plan for transfer after they had reviewed the scan and photos of Barbara's foot that the co-ordinator had sent.

In addition to the communication about Barbara's foot, there was a discussion that lunchtime about Barbara's blood results which showed that she was at risk of bleeding. Barbara was prescribed a medication (vitamin K) to correct the situation and her usual dose of warfarin (a medication which alters blood clotting and that Barbara was taking for an unrelated health condition) was not given.

At 15:11 hours a conversation took place between a resident doctor from the medical team and the vascular team. The vascular doctor said that the main concern was the abscess under Barbara's foot which needed to be drained. They asked about Barbara's blood results and other details such as her NEWS2. The vascular doctor said that Barbara could be transferred when there was a ward bed available for her. They said that they did not think there was one available currently and suggested that the bed manager at Hospital A liaise with the bed manager at Hospital B about Barbara's need for transfer. At 15:51 hours the bed manager documented that they had spoken with their counterpart at Hospital B about the need for a bed and told the nurse caring for Barbara about the plan for transfer. Barbara was also made aware and told that this was likely to be 'today or tomorrow'.

Routine monitoring by the nursing team had also identified that the oxygen saturation of Barbara's blood was lower than expected (see 'Background and context' section). Barbara's oxygen saturation had dropped below expected levels on two occasions before Monday, but that day was the first one where they were consistently outside the expected range. The nursing team made the doctors aware of the situation and Barbara was given oxygen therapy.

Barbara's need for oxygen meant her NEWS2 rose during the course of the day from 1 that morning to 4 by midnight. In response to this score, the nursing team requested a doctor review. The resident doctor who saw Barbara documented that she was not experiencing any new symptoms. The doctor thought that Barbara's need for oxygen may be due to a new respiratory infection and requested a chest X-ray and swabs for COVID-19 and flu.

Tuesday 11 June 2024

In the early hours of Tuesday morning, the nursing team spoke with the bed manager to get an update on Barbara's planned transfer. The bed manager said that there was still no bed available at Hospital B. At 10:22 hours that morning, after reviewing Barbara, the diabetic foot co-ordinator contacted the vascular team again. They spoke with a different vascular doctor to the previous day and reiterated their concerns about Barbara. The co-ordinator told the vascular doctor that they thought Barbara's foot infection was getting worse with an abscess having developed, and that Barbara was more unwell despite antibiotic treatment. The vascular doctor agreed that Barbara needed to be transferred that day and said she could be transferred to the emergency department if there was no ward bed available. The co-ordinator checked whether a bed was available and, as there was not, at 10:54 hours they documented the decision for Barbara to be transferred to the emergency department at Hospital B. The hospital transport service was contacted, and Barbara was added to their existing booked patient journeys for that day.

The consultant responsible for Barbara's care saw her that morning. They reviewed her blood and other clinical results and noted her continuing need for oxygen therapy. The consultant knew Barbara was waiting to go to Hospital B and the plan was to continue the current monitoring in place until she left. Barbara's NEWS2 was consistently 3 that day.

Barbara arrived at the emergency department of Hospital B at 17:10 hours and was assessed by a doctor from the vascular team at about 18:30 hours. They documented their impression that Barbara had a 'severe diabetic foot infection requiring urgent amputation and debridement [removal of dead and infected tissue]'. Blood tests taken on Barbara's arrival at Hospital B showed that she was still at risk of bleeding; a further dose of vitamin K was given to correct this. Surgery was planned for the next day to give the medication time to take effect. The doctor discussed Barbara with their consultant, and they reviewed her together at about 23:00 hours. The plan for surgery the next day was confirmed, on the condition that blood tests showed Barbara's risk of bleeding had been reduced to a safer level.

Wednesday 12 June 2024

At 02:00 hours, a nurse completed a pre-surgery checklist with Barbara after which she settled to sleep. Nursing staff recall checking on Barbara several times during the night as is usual practice. At about 07:00 hours a healthcare assistant went to Barbara to carry out routine

monitoring tasks. Barbara was unresponsive and not breathing normally so the healthcare assistant pressed the emergency bell to summon the help of nursing staff. The medical emergency team were called to attend at 07:06 hours.

Following treatment, Barbara became more alert again although blood test results showed that she was extremely unwell. After further tests and scans, Barbara was taken to the intensive care unit at midday and the documented impression was that she had sepsis. Throughout that day, and despite treatment to help her kidneys, lungs and heart work normally, Barbara's health deteriorated. There was concern that unless Barbara's infection was brought under control by surgery she would not survive. However, there was also concern that she may not be well enough for surgery. After discussions between the teams involved, Barbara was taken for an emergency below-knee amputation at 18:34 hours.

An incident report was submitted raising concerns about Barbara's care. Specifically, the concerns were around whether Barbara should have been transferred to Hospital B earlier, and whether this would have avoided her developing sepsis, and the need for such an extensive amputation.

Barbara's recovery from surgery was complicated by health issues which meant she needed to stay in hospital for longer than expected. She developed pneumonia after her amputation and then had problems with her heart and kidney function. As well as the challenges of her physical health, Barbara had to adjust to her amputation and to using a wheelchair. In addition, a new home had to be found as Barbara's previous one was not suitable for wheelchair use.

Barbara was finally well enough to be discharged to her new home on 11 October 2024.

Investigation approach

Investigation team

Role	Initials	Job title	Dept/directorate and organisation
Investigation commissioner/convenor:	This investigation is one of three PSII exemplars about sepsis		HSSIB
Investigation lead:	The report is led by, and a publication of, HSSIB rather than any individual		HSSIB

Summary of investigation process

An incident report was submitted via Hospital B's electronic reporting system raising concerns about Barbara's care. The lead consultant for the vascular service carried out an initial review of events. They found that a vascular consultant had not been involved in the decisions made about Barbara while she was at Hospital A and they were concerned that the urgency of transfer had not been 'fully appreciated' until the diabetic foot co-ordinator became involved on Monday 10 June. In the lead consultant's opinion, Barbara's need for intensive care due to sepsis and such extensive amputation may have been avoided if she had been transferred to Hospital B earlier.

The incident report and review by the lead consultant was discussed at the hospital's weekly multidisciplinary Patient Safety Incident Review meeting. Senior staff (such as the medical director, associate director for nursing, and leads for patient safety) attend this meeting to discuss incidents and decide the most appropriate way to respond to them. Those at the meeting agreed that a patient safety incident investigation (PSII) should be carried out for further learning. One of Hospital B's agreed priorities for investigation is incidents where a delay in diagnosis may have affected the outcome for a patient.

The medical director and the associate director of improvement at Hospital B shared the anonymised incident with HSSIB. A meeting took place, and it was agreed that Barbara's experience would be the focus of one of three HSSIB investigations exploring the recognition of sepsis. Nominated investigation leads from Hospital A and Hospital B worked with the HSSIB team during the investigation.

The draft report was shared for comments with all those affected by the incident including Barbara, her son, and staff involved either directly or indirectly with Barbara's care. These people will also receive a final copy of the report once it has been approved by HSSIB. Progress on safety actions to address the areas of improvement included will be monitored by the relevant safety leads in Hospital A and Hospital B.

Terms of reference

The terms of reference for this investigation were informed by Barbara and her son, and the concerns they shared during the investigation's first meeting with them. Key staff involved in Barbara's care, either directly or indirectly, also informed and helped to shape the areas of focus.

This investigation will:

- explore whether Barbara had signs or symptoms of sepsis before she became unexpectedly and severely unwell the night before surgery

- explore the factors that influenced the timing of Barbara's transfer from Hospital A to Hospital B
- identify opportunities for improvement in the care of patients with diabetes and a severe foot infection in a non-specialist hospital.

In addition, the investigation will explore the actions and decision made at Barbara's outpatient appointment with the vascular team on 24 May 2024. The outcome of this appointment was raised as a concern by Barbara and her son and is included in this report to avoid them being involved in an additional complaint process.

Further details about the terms of reference, and how the investigation addressed these, can be found in appendix 1.

Information gathering

The investigation gathered information from multiple sources and sought different perspectives on events. The investigation considered how factors such as the environment, equipment, tasks, policies and organisational culture influenced the decisions and actions of staff.

Information sources included:

- Barbara and her son, Ian
- staff directly or indirectly involved in Barbara's care
- Barbara's clinical records
- national and local guidelines about sepsis
- articles and research about sepsis
- an international sepsis subject matter advisor.

The investigation used a number of different methods to help organise, understand and analyse the information gathered. Methods included:

- developing a timeline to help make sense and create a narrative understanding of events
- creating a map of all the relevant organisations, at different levels of the healthcare system, from government to hospital, to illustrate how these related to the activities of staff
- using a framework (called the Systems Engineering Initiative for Patient Safety (SEIPS)) to inform information gathering and help examine the data gathered. The framework prompts investigators to consider how work factors such as the environment, equipment, organisational policies and procedures interact to influence the actions and decisions of staff (see appendix 2)

- developing themes from analysis of the information gathered to help understand and explain why things happened in the way they did
- application of NHS England's '[Safety action development guide](#)' to inform thinking about the development of areas of improvement and safety actions
- use of an evidence log to document the information sources used to inform the investigation.

Findings

This section sets out the findings from the investigation's analysis of the information gathered. The findings are presented under the following headings:

- Hub and spoke model of vascular services
- Barbara's care at Hospital A
- Barbara's care at Hospital B
- Different definitions and uses of the term 'sepsis'
- Concern raised by Barbara about her outpatient appointment at Hospital B.

Hub and spoke model of vascular services

There are no vascular services on site at Hospital A. Patients are referred to Hospital B, which is the specialist centre for the region, for vascular expertise. Sometimes a patient can stay at Hospital A for their care with the vascular team providing advice and guidance remotely; other times a patient will need to be transferred to Hospital B. For example, patients will be transferred if they need surgery or a procedure that can only be carried out by a doctor with specialist vascular knowledge and skills. This 'hub and spoke' model of care is typical of how specialist services are provided in the NHS, with one hospital (in this case, Hospital B) being the specialist 'hub' and surrounding non-specialist 'spoke' hospitals (in this case, Hospital A) referring patients to the hub as and when needed.

Hospital A does not have a formal agreement with Hospital B which sets out the details of service provision (for example, the timescale within which a patient should be transferred once it has been agreed they need to go to Hospital B). The investigation found that the nature of services provided by Hospital B had changed over time and new roles had been created in response to emerging need. For example, a diabetic foot co-ordinator was employed to work at Hospital A in 2015 to provide expert assessment and advice for the growing number of patients with diabetes and foot problems, such as infected and/or non-healing ulcers. Staff interviewed told the investigation how much they valued the knowledge and expertise that this role brought.

A vascular consultant at Hospital B said that the co-ordinator is “our eyes and ears at [Hospital A]” who “supports us bringing over the patients that need to be here”. A consultant with expertise in diabetes at Hospital A said the co-ordinator “has the most experience of all of us with diabetic foot problems”. The co-ordinator works Monday to Friday, 06:45 hours to 14:45 hours. Outside of these hours, and if they are on leave or unwell, there is no one with equivalent expertise in the hospital.

The investigation found there were factors that hindered the timely transfer of patients from Hospital A to Hospital B. These included:

- Insufficient capacity at Hospital B to meet the demand for vascular services. This was the most consistent and significant factor raised by staff when discussing the transfer of patients. The mismatch between capacity and demand means that patients are prioritised and transferred in order of assessed clinical urgency.
- The problem created by the mismatch between capacity and demand for vascular services is compounded by the lack of capacity in general at Hospital B. Comments heard repeatedly during interviews were summed up by one consultant who said: “We are in a complete mess with beds”. This situation means there are patients waiting in the emergency department for a ward bed. The perception among doctors who spoke with the investigation was that bed managers at Hospital B gave priority to patients waiting in their emergency department for a ward bed over patients waiting to be transferred from other hospitals. A view heard at both Hospital A and Hospital B was that bed managers “think a patient is ‘safe’ because they’re in a hospital bed” despite that hospital not having the expertise to manage the patient’s problem effectively. It was not within the scope of the investigation to gather information to test this perception.
- Patients deemed by the vascular team to need urgent treatment (often because their condition is life threatening) are brought by ambulance to the emergency department at Hospital B. This bypasses the wait for a ward bed and so is a relatively quick process. The investigation was told that unless there was a clear need for urgent treatment, transfer to the emergency department was “frowned upon” by bed managers and met with “a lot of resistance”. This was because there were not enough ward beds for existing patients in the emergency department, and because of the risks inherent in transferring a patient to an often-overcrowded department. Furthermore, staff interviewed pointed out that it was a very poor patient experience to go from receiving care in a ward bed to waiting for assessment on a trolley in an emergency department. Staff at Hospital A acknowledged these reasons but highlighted the impact of this: “It’s frustrating ... there are patients that we are really worried about ... we think they need to go over that day and it gets blocked ... we’re told no, they can’t come, they have to wait for a bed”.
- Hospital A and Hospital B have separate patient information systems which cannot be accessed by each other. This meant Hospital B only had access to limited clinical

information about Barbara while she was at Hospital A. Treatment decisions are made by the vascular team without seeing or knowing the patient, and with a reliance on the referring clinician at Hospital A providing relevant, accurate information. A vascular doctor with 12 years' experience of receiving referrals said that "the picture given on the phone isn't always accurate". The investigation heard similar comments from other vascular doctors it met with. In addition, the current process relies on the information given by the referrer being understood as intended by the receiving doctor. There are multiple risks inherent in this mode of information exchange including language barriers, communication styles, distraction and noise, to name a few. Furthermore, this conversation may be taking place when the receiving vascular doctor is engaged in other complex activities and responding to many other competing demands on their attention. For example, the vascular doctor who spoke to the diabetic foot co-ordinator on Monday said that at the time of the call they were busy dealing with an emergency patient. The vascular doctor who spoke to the co-ordinator on Tuesday was in the middle of a review of all the patients on the vascular ward.

- As is usual at specialist hospitals, the vascular doctors at Hospital B who take referrals for advice on treatment, and/or make decisions about transfer, have different levels of knowledge, experience and expertise. This means there is the potential for variation in advice and/or transfer decisions depending on the vascular doctor that is spoken to. Comparing their conversation with the vascular doctor on Monday and another vascular doctor on Tuesday, the diabetic foot co-ordinator said: "It was a very different conversation with a different outcome ... rather than it being like, a process, it felt like it was because it was a different person I was speaking to".
- Although there is a consultant available to discuss referrals, there is no requirement for consultant input to, or oversight of, referral decisions. It appeared there was a reliance on the vascular doctors who received referrals discussing them with the consultant on duty that day. If a patient was accepted for transfer it seemed this would be discussed with the consultant as they needed to know the patient was arriving. However, if a patient was not accepted for transfer, a discussion with the consultant was dependent on the doctor who took the referral choosing to discuss it and/or remembering to do so among many other competing demands on their time and attention.
- The investigation found there was no formalised or consistent process for documenting referrals received and treatment decisions made. The electronic information system at Hospital B had an entry for the telephone conversation on Friday evening and nothing else until Barbara arrived the following Tuesday.
- The investigation was told about an online referral system (in the form of an app) used by some specialist teams at Hospital B to formalise the process, including senior oversight of referrals. The vascular doctors interviewed thought the app was already in use at Hospital A for vascular referrals. Staff interviewed at Hospital A were aware of the app and were already using it for referrals to some specialist teams. However, none were aware that there

was an expectation for them to use it for patient referrals to the vascular team and they said they had not been asked to do so.

- The investigation found that the vascular doctors taking referrals may be “fielding calls from multiple hospitals” at the same time as they are dealing with other situations and involved in other tasks. One of the vascular doctors, reflecting on their experience of taking referrals alongside their other duties, said it was “usually very stressful and overwhelming”. The negative impact of high workload and competing demands while trying to make clinical decisions has been highlighted in previous national investigation reports (Healthcare Safety Investigation Branch, 2019).

In summary, Hospital A has no vascular services on site and there is limited access to expertise for patients with diabetes and foot problems out of hours. In addition, there are multiple factors, many outside the control of staff, that make it difficult to transfer patients like Barbara in a timely way to Hospital B.

Area of improvement 1

Review and update the requirements of vascular service provision between Hospital A and Hospital B.

Area of improvement 2

Out of hours expertise in diabetes and foot problems at Hospital A.

Barbara’s care at Hospital A

Barbara was assessed by a doctor, referred to the vascular team, had a specialist scan, and received the first dose of antibiotics for her severe foot infection within approximately 4 hours of arriving at the emergency department at Hospital A on Friday 7 June. Barbara’s NEWS2 score was 0 at the time of her assessment by the doctor (16:12 hours). Consultant clinical leads reviewing Barbara’s care in response to the incident report submitted agreed that her treatment in the emergency department was timely and appropriate. Specifically, Barbara’s care was in line with the Academy of Medical Royal Colleges guidance (see ‘Background and context’ section) and Hospital A’s standard operating procedure for patients with diabetes in the emergency department with foot complications.

The antibiotics prescribed for Barbara were those recommended by hospital policy to treat either a severe foot infection in a patient with diabetes, or suspected sepsis. Documentation in Barbara's clinical records suggest the focus (and choice of antibiotic) was to treat severe foot infection rather than suspected sepsis. Barbara's NEWS2, reason for coming to the emergency department, and recent medical history supported this focus, albeit that she was at increased risk of sepsis because of her diabetes.

Barbara stayed at Hospital A for antibiotic treatment and scans on the advice of the vascular team. As is usual practice, she was initially cared for on the acute care unit by the medical team and then moved to a ward at lunchtime on Saturday. Again, those reviewing Barbara's care said that the move was timely and appropriate as this ward specialises in the care of patients with diabetes.

Consultant review of patients on this ward takes place on a Tuesday and Friday. On other days of the week, doctors with varying levels of knowledge and experience of diabetes – and associated problems like foot infections – are responsible for the care of patients on the ward. They can seek help and advice from senior colleagues as and when needed. Importantly, the diabetic foot co-ordinator also sees and advises on the care of patients with foot problems during the week and liaises with the vascular team at Hospital B. At the weekend, there is not a consultant with expertise in diabetes present in Hospital A and the diabetic foot co-ordinator does not work at weekends.

Although the doctors seeing Barbara over the weekend did not have expertise in diabetes and foot problems, they – along with nursing staff – had knowledge and experience of recognising and responding to patients who are getting more unwell. As discussed in the 'Background and context' section of this report, NEWS2 is the national tool used to support staff in recognising that a patient is becoming more unwell, sepsis being one of the causes of this. Barbara's NEWS2 indicated that she was at low risk of severe illness and death when she was at Hospital A. That said, her NEWS2 did rise while she was there and at its highest was 4. This NEWS2 of 4 was on one occasion (Monday evening), and expected actions were taken by the nursing team. The main reason for Barbara's NEWS2 being above 0 was that her oxygen saturation was below the expected range. Barbara was given oxygen therapy from Monday evening onwards to correct this. The need for oxygen therapy indicated that Barbara was more unwell, but clinicians explained there could be many reasons for this, such as a respiratory infection (a possibility explored by the doctor who saw her on Monday night).

With the benefit of hindsight, clinicians reflecting on Barbara's care thought her need for oxygen therapy may have been a signal that her severe foot infection was now affecting other areas of her body, causing damage which meant her organs were not functioning normally. In essence, her requirement for oxygen could be seen as evidence of her developing sepsis. It is impossible to know for certain, and organ dysfunction caused by sepsis may not be accompanied by any

obvious signs (Singer et al, 2016). Furthermore, if Barbara's rise in NEWS2 was the result of worsening foot infection, this could only be resolved by the infection being brought under control through surgery at Hospital B; staff were already trying to transfer Barbara for this purpose.

Barbara's care at Hospital B

Barbara's NEWS2 score at Hospital B was 2 or 3 in the first 5 hours of her arrival. At 23:22 hours her NEWS2 had improved and was 0 as the oxygen saturation of her blood was within the expected range without the need for oxygen therapy. This was the last time the NEWS2 was calculated before Barbara was found unresponsive. Barbara's NEWS2, therefore, did not indicate any increase in her risk of becoming severely unwell after her transfer from Hospital A. The vascular doctors involved with Barbara's care before she was found unresponsive described her as "alert" and said there were no signs to suggest Barbara was severely unwell or had sepsis (see section below). The staff nurse who cared for Barbara when she arrived on the ward recalled feeling that something was "not quite right" and stated that Barbara was "a bit wheezy" but as they had just met her, they said it was hard to know what was 'normal' for her. The NEWS2 did not give cause for concern. A healthcare assistant spoke with Barbara while completing paperwork and monitoring her vital signs in the first hour or so after she arrived on the ward; they described Barbara as engaging normally.

Although there were no objective signs to cause clinical staff to be concerned, Barbara's son, Ian, left his mum that evening very worried about her. Ian said his mum told him to "make sure to take care" of himself, which seemed out of character and not something she would usually say. In addition, Ian said his mum's breathing did not seem normal for her. He told the investigation that he grew increasingly worried about his mum during the night. He telephoned the ward on two occasions (at about 03:00 hours and 05:00 hours) to ask about his mum and was told she was sleeping. Although it was not documented in the nursing records, the staff nurse who cared for Barbara that night remembered that Ian had telephoned. Ian came to see his mum early that morning, before going to work, arriving at about 07:00 hours to find lots of clinical staff and machines around his mum's bed as she had been found unresponsive. The importance of giving particular attention to family concerns is included in national guidance for sepsis (National Institute for Health and Care Excellence, 2024). In addition, a national initiative known as 'Martha's Rule' now provides patients and families with a way to seek an urgent clinical review if their concerns are not being responded to (NHS England, n.d.).

It is not certain why Barbara became so unwell, so quickly, that night. A small amount of vomit was seen on Barbara's pillow and in her mouth when she was found unresponsive at about 07:00 hours, and the possibility of Barbara having aspirated (that is, food or liquid having got into her airway) was documented by the emergency medical team. Other possibilities recorded at the time included Barbara having a seizure, or stroke, or a blood clot in one of the blood vessels in her lungs, or a heart problem, or sepsis due to her severe foot infection. Scans

showed that Barbara had not had a stroke and did not have a blood clot in her lungs. A heart problem was also thought unlikely to be the cause of her deterioration as it did not fit with the overall clinical picture.

Different definitions and uses of the term ‘sepsis’

Blood tests and other clinical markers at the time Barbara was found unresponsive met the criteria for a diagnosis of sepsis (Singer et al, 2016). Clinicians had differing opinions about whether Barbara had sepsis – or any objective signs to suggest sepsis – before this point. The investigation found that this difference in opinion resulted from there being no consistent definition of sepsis among clinicians and, therefore, no consistent use of the term. This lack of consistency was found across different specialties and among clinicians within the same specialty. Vascular doctors participating in the investigation described Barbara as having “diabetic foot sepsis” and said this was “a recognised term”. While this term may be used colloquially, it is not nationally recognised. A search of published medical abstracts over the last 5 years using the term ‘diabetic foot sepsis’ identified two, both from South Africa, suggesting it may be an accepted term there. Other papers refer to diabetic foot infection or diabetic gangrenous foot, and there were many reports of infected feet leading to systemic (affecting the whole body) sepsis, but the term ‘diabetic foot sepsis’ was not found.

From interviews it seemed that the vascular doctors were using the term ‘foot sepsis’ instead of ‘severe foot infection’ to emphasise the seriousness of, and risks associated with, patients with diabetes having a severe foot infection, specifically:

- the risk of these patients becoming very unwell because of the infection causing tissue and organ damage - that is, developing sepsis in line with the international definition (see ‘Background and context’ section)
- the risk of these patients needing an amputation if there is poor blood supply to the feet.

Comments by the consultant clinical lead for vascular surgery reflected these points: “[Barbara] ended up with sepsis because we did things slowly ... if we wait for these patients to be ill, and they can get ill very quickly, we’ve lost our opportunity for less extensive surgery ... it doesn’t make sense to not bring them here”.

The consultant clinical lead explained that it is not possible to know if Barbara’s leg would have been saved if she had been transferred earlier because there are so many factors which could have affected this. Doctors involved with, or commenting on, Barbara’s care at Hospital A debated whether there were signs of Barbara having sepsis while she was there. In particular, they discussed her reduced blood oxygen saturation and need for oxygen therapy on Monday and Tuesday and whether other actions were warranted. However, these reflections were with the benefit of hindsight, knowing what happened to Barbara and her subsequent diagnosis of

sepsis. At the time, the response to her NEWS2 was in line with national and local guidance, she was on the appropriate antibiotics for her infection, and there were no other readily discernible signs to indicate that Barbara was on the verge of being severely unwell.

Again, the investigation found there were different definitions of sepsis among the doctors interviewed at Hospital A, and uncertainty about the line between sepsis and infection. Comments such as “I would not consider [Barbara] had sepsis ... well, maybe a degree of sepsis ... it depends on how you look at it”, and “this lady had infection but the difference between that and sepsis is cloudy” were typical of those the investigation heard. Such comments reflect the well-recognised challenges of defining sepsis and the multiple definitions and terminologies currently in use at a national level (Singer et al, 2016; Tidswell et al, 2020). Before being found unresponsive on Wednesday morning, Barbara’s blood results and other clinical information indicated that her body was responding to an infection but did not meet the criteria of sepsis (Singer et al, 2016).

The investigation found that consultants with specialist expertise were “not surprised” by the outcome for Barbara. The consultant clinical lead for vascular services knew it was imperative for things to move quickly for the chance of less extensive surgery. The consultant lead for intensive care at Hospital B knew it was imperative for things to move quickly for the chance to avoid the risk of Barbara becoming very unwell given her foot infection and significant chronic illnesses. But the hub and spoke model means patients are looked after by non-specialists, in a healthcare system where hospitals often have a shortage of beds to meet demand, meaning transfers for all but the most urgent of patients are unlikely to be quick.

Concern raised by Barbara about her outpatient appointment at Hospital B

Barbara had an outpatient appointment with the vascular team at Hospital B on 24 May 2024, 2 weeks before she was kept in Hospital A for treatment. At that appointment, Barbara’s foot was looked at by a vascular consultant and a specialist test was requested. Barbara was told that she would be sent an appointment for a few weeks’ time to discuss the test results. Given subsequent events, Barbara and Ian wondered whether it was appropriate for her to be allowed home or whether actions should have been taken that might have prevented Barbara getting so unwell just a few weeks later. The investigation met with the consultant who saw Barbara in the outpatient clinic and also discussed the matter with the consultant clinical lead for vascular services.

The letter to Barbara’s GP, written by the vascular consultant who saw her in clinic, included details of the swelling, skin changes and ‘small, clean active ... ulcer’ on Barbara’s right ankle bone and right calf. The letter also mentioned that Barbara had a wound which was ‘healing well’ on her right second toe, and which Barbara said arose from a burst blister. Barbara’s feet

were described as 'warm'. The consultant suggested a number of further tests to provide more detailed information about the blood supply to Barbara's feet and in order to 'plan appropriate intervention'. This consultant was involved in Barbara's care when she was in Hospital B, after her transfer from Hospital A. They explained that patients with foot problems like Barbara's are not kept in hospital, as there is no immediate treatment needed and the wound on Barbara's toe did not look infected and was healing and dry. The consultant added that sometimes patients with foot ulcers and a poor blood supply can be well for many years, while others can deteriorate quickly, saying "it is very difficult to predict".

The consultant clinical lead for vascular services agreed with the actions taken at Barbara's outpatient appointment given there was no evidence of infection at that time. They confirmed that the specialist test that had been requested was appropriate and would have informed decisions about how best to treat Barbara's ulcers.

Summary of findings and areas for improvement

This section brings together the main findings of the investigation which are detailed below.

- Blood tests and other clinical markers taken when Barbara was found unresponsive at Hospital B met the criteria for a diagnosis of sepsis.
- Clinicians had differing opinions about whether Barbara had sepsis in the period of time before she was found unresponsive. This difference in opinion reflected the various definitions of sepsis used by these clinicians. Based on the internationally agreed definition of sepsis, before Barbara was found unresponsive, her blood results and other clinical markers indicated that her body was responding to an infection but did not meet the criteria of sepsis.
- The care and treatment Barbara received at Hospital A was in line with national and local guidance. Barbara's NEWS2 score increased while she was there, indicating that she was becoming more unwell, likely due to worsening foot infection. This situation could only be resolved by her infection being brought under control by surgery at Hospital B and staff were proactively trying to achieve this.
- Barbara's experience demonstrates the complexities and risks inherent in a hub and spoke model of care. The risks in relation to vascular care are greater for patients like Barbara who had a severe foot infection, compounded by a poor blood supply, against a background of significant long-term health problems including diabetes.
- The expertise provided by the diabetic foot co-ordinator at Hospital A helps mediate the risks involved, but currently this expertise sits with one person, is restricted to Monday to Friday, and is not available out of hours. Added to this, the consultants with expertise in diabetes, and knowledge of diabetic foot problems, are not in the hospital out of hours.

- Hospital A does not have a formal agreement with Hospital B which sets out the details of its vascular service provision.
- The mismatch between capacity and demand for vascular services is compounded by the lack of capacity in general at Hospital B. The shortage of beds for the number of patients who need them means that transfers for all but the most urgent of patients is unlikely to be quick.
- As is usual at specialist hospitals, the vascular doctors receiving patient referrals to Hospital B have different levels of knowledge, experience and expertise. This means there is the potential for variation in advice and/or transfer decisions. The patient safety risks inherent in this are compounded by there being variation in consultant oversight of decision making.
- There is no formalised referral process for patient referrals to Hospital B. This means documentation about referrals and decisions made may vary, both in content and in where the information is stored.
- Hospital A and Hospital B have separate patient information systems which cannot be accessed by each other. This meant Hospital B only had access to limited clinical information about Barbara while she was at Hospital A.
- Conversations about referrals take place in busy, pressured environments and the vascular doctor receiving referrals may be involved in other complex tasks and their attention divided between competing priorities.
- The actions and decision taken at Barbara's vascular outpatient appointment on 24 May were appropriate given there was no evidence of infection at that time.

The investigation identified two areas of improvement which Hospital A and Hospital B could develop safety actions to address:

Area of improvement 1

Review and update the requirements of vascular service provision between Hospital A and Hospital B.

Area of improvement 2

Out of hours expertise in diabetes and foot problems at Hospital A.

Appendices

Appendix 1: Terms of reference (ToR)

Incident/incident reference	I-031570 (HSSIB)
Date agreed/version no.	17 October 2024
Date investigation is to be completed by	31 January 2025
Learning response lead	HSSIB
Staff engaged in the development of ToR (names/roles)	Patient safety investigations and compliance, Hospital B Patient safety investigation lead, Hospital A Staff interviewed informed the ToR but they were not directly developed with them (and the ToR changed during the course of the investigation in response to emerging findings) HSSIB
Patient/family/carers engaged in the development of ToR (names/relationship)	If declined please state briefly why?
Name	Barbara
Relationship	Patient
Name	Ian
Relationship	Barbara's son

The investigation will:

ToR 1	Explore whether Barbara had signs or symptoms of sepsis before she became unexpectedly and severely unwell the night before surgery.
Key questions	List of questions to be asked to support the aim of the ToR: 1. Did Barbara's temperature, heart rate, blood pressure, respiratory rate, oxygen saturation or NEWS2 indicate her condition was worsening? 2. Did Barbara's blood results or other tests suggest sepsis (rather than a normal response to infection)? 3. Did Barbara's mental state change or were there any other objective signs of

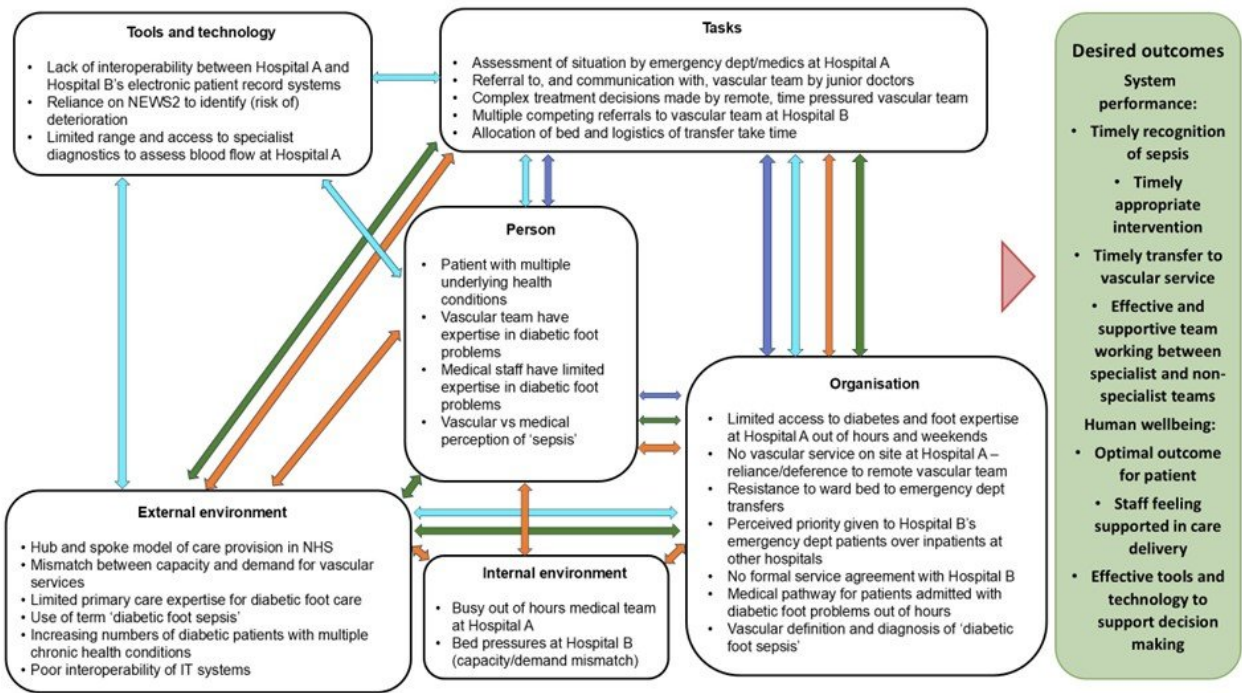
	organ dysfunction? 4. Are there any electronic alerts or prompts in place to support staff in recognising sepsis? 5. What was staffs' understanding about Barbara's risk of sepsis? What influenced that?
Healthcare settings	Key areas considered relevant to observe/interact with during the investigation: • Possibly emergency department and/or ward area (depending on information gathered at interviews).
Healthcare processes	Known processes that appear significant to consider within the investigation: • Assessment of patients – specifically, monitoring/NEWS2 and escalation. • Pathway for patients with diabetes and foot infection. • Ward allocation for patients.

ToR 2	Explore the factors that influenced the timing of Barbara's transfer from Hospital A to Hospital B.
Key questions	List of questions to be asked to support the aim of the ToR: 1. Is there a service level agreement or expected practice about the timeframes for transfer? If so, what are they? What factors affect timing of transfer? 2. Who makes the final decision regarding timing of transfer? Is there consultant input to, or oversight of, decisions? If not, what knowledge and experience do those making the decisions have? Is there variation? 3. How does the diabetic foot co-ordinator feed into the process of transfer decisions?
Healthcare settings	Key areas considered relevant to observe/interact with during the investigation: • No specific settings to observe.
Healthcare processes	Known processes that appear significant to consider within the investigation: • National and local guidance regarding sepsis and foot infections in patients with diabetes. • Transfer processes, guidelines or service level agreements.

	• Vascular referral processes.
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ToR 3	Identify opportunities for improvement in the care of patients with diabetes and a severe foot infection in a non-specialist hospital.
Key questions	List of questions to be asked to support the aim of the ToR: 1. Is there a pathway for patients with diabetes and foot infections? Was Barbara cared for in line with this? 2. What mitigations exist to ensure ongoing specialist input while a patient is awaiting transfer from the district general hospital to the specialist hospital? 3. What is the normal process for ongoing monitoring of a patient with diabetes and a severe foot infection once admitted (that is, who with specialist knowledge sees the patient)? 4. What safety risks are there in the current pathway? 5. Are there opportunities to re-design the current pathway to reduce risks to diabetic patients with severe foot infections? What might the unintended consequences be?
Healthcare settings	Key areas considered relevant to observe/interact with during the investigation: • Possibly emergency department and/or ward area (depending on information gathered at interviews).
Healthcare processes	Known processes that appear significant to consider within the investigation: • Referral processes between Hospital A and Hospital B. • Pathway for patients with diabetes and foot problems. • Ward allocation for patients with diabetes and severe foot infections.

Appendix 2: Systems Engineering Initiative for Patient Safety (SEIPS) framework



Appendix 2 key interactions

	The hub and spoke model of care provision in the NHS means that Hospital A has no vascular service on site. There is limited access to expertise in foot problems in patients with diabetes out of hours.
	The mismatch between capacity and demand for vascular services meant that Barbara stayed at Hospital A rather than being transferred to Hospital B with her severe foot infection.
	The lack of interoperability of clinical systems, limited range of specialist diagnostics, and care by non-specialists in 'spoke' hospitals, hampers assessment of risk for patients like Barbara.
	The term 'sepsis' is understood and used differently by clinicians and clinical teams.

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