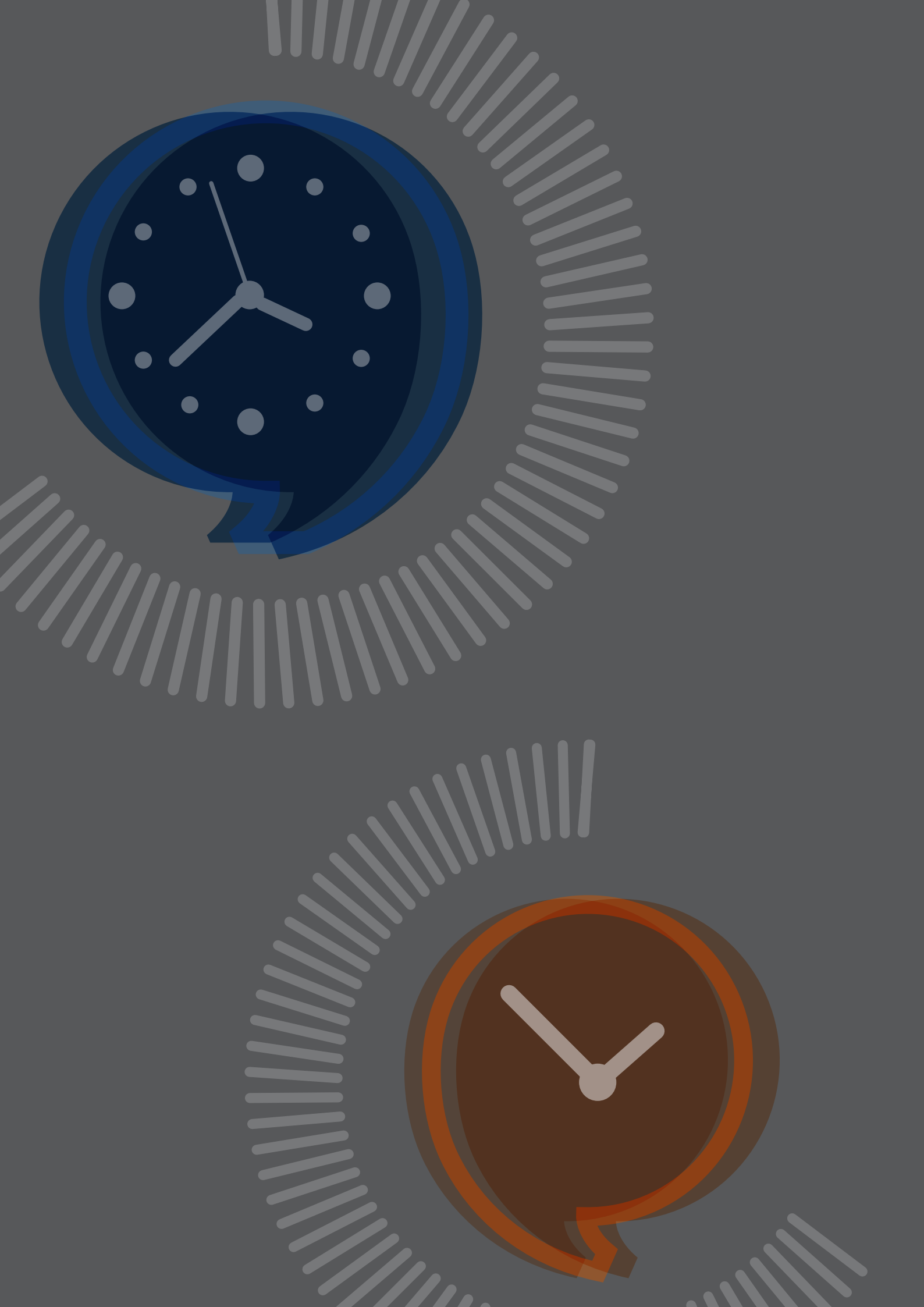
Parliamentary and Health Service Ombudsman

TIME TO ACT

Severe sepsis: rapid diagnosis and treatment saves lives



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Foreword from the Ombudsman

This is our first clinical report. It focuses on ten cases we investigated where patients did not receive the treatment they urgently needed. In every case, tragically, the patient died.

Sepsis is a significant cause of death and disability in the UK.

We want complaining to make a difference and so we are publishing our first clinical report. It focuses on ten complaints we investigated about patients with severe sepsis who did not receive the treatment they urgently needed. In every case, tragically the patient died. In some cases, with better care and treatment, they may have survived.

The Ombudsman can support the drive for a patient-centred NHS by shining a light on issues raised with us by patients and their families. We would like to thank the families in this report who have allowed us to tell their stories.

The crucial lessons to be learnt from this report all derive from concerned people raising complaints about the care received by their loved ones, and pursuing that complaint with us when they do not receive a satisfactory outcome. In doing so they are performing a valuable public service. We know that many do not complain because they feel it will make no difference. Our job is to make sure it does.

We have worked closely with NHS England, NICE, UK Sepsis Trust, the Royal College of Physicians, the Royal College of Surgeons, and the College of Emergency Medicine to find solutions to the issues identified in our report.

We are now looking to these organisations and others to make the necessary changes to improve NHS care.

We know it is not easy to spot the early signs of sepsis, but if we learn from these complaints and work to improve diagnosis and provide rapid treatment, then lives can be saved.

Dame Julie Mellor, DBE
Health Service Ombudsman for England
September 2013

Signs of sepsis

S lurred speech

E xtreme muscle pain

P assing no urine

S evere breathlessness

I *feel I might die*

S kin mottled or discoloured

Executive summary

Tragic consequences

This report highlights the death of patients in the NHS after failure to diagnose and rapidly treat severe sepsis. It focuses on ten cases we investigated where patients did not receive the treatment they urgently needed. In every case, tragically, the patient died.

The case stories in this report cover an age range from the first to the eighth decades of life, showing how severe sepsis can strike at any time. They highlight shortcomings in initial assessment and delay in emergency treatment which led to missed opportunities to save lives. They include the tragedy of an active and generally healthy eight-year-old girl whose sepsis was not diagnosed or treated in time, leaving her family with *'the unbearable pain of losing her'*. We also tell the story of a man whose minor operation was complicated by necrotising fasciitis, leading to leg amputation and hospital stay for 15 months, and who never fully recovered after early signs of sepsis were not treated.

From our casebook we have avoided choosing very complex cases. We have anonymised the cases to focus on the wider learning from them. They have in common shortcomings in the care of their illness (at home, in hospital emergency departments, and in hospital wards), and the fact that they have all sadly died. We could have selected many other cases, from different parts of the country.

About sepsis

Bacterial infection is very common, and usually responsive to antibiotics, but in a small proportion of cases infection can overcome the body's defence mechanisms and progress rapidly to critical illness – known as severe sepsis. Such a situation can be highly challenging to the clinical team providing care. According to the UK Sepsis Trust, 37,000 people are estimated to die of sepsis each year. The most common causes of severe sepsis are pneumonia, bowel perforation, urinary infection, and severe skin infections. Infection complicating childbirth, although less common overall, is the leading cause of direct maternal death.

A complex environment

Existing care standards and protocols are not being followed. Emergency departments are busy and sometimes chaotic places. Staff must often prioritise in difficult circumstances and decide which of several important and urgent tasks they need to do next. This is complicated substantially by the facts that only a small proportion of patients with infection become

so critically ill, and people with severe sepsis can be significantly more unwell than they appear.

The standards applied by the Ombudsman in determining whether the care of patients with severe sepsis is reasonable are based on current published guidance by the Surviving Sepsis Campaign, the National Institute for Health and Care Excellence (NICE), and other expert organisations including the General Medical Council (GMC). There is no doubt about the evidence of the need for good initial assessment and immediate basic resuscitation. The readily available Surviving Sepsis Campaign Care Bundles (sepsis care bundles) are evidence-based and robust.

What we found

Care failings seem to occur mainly in the first few hours when rapid diagnosis and simple treatment can be critical to the chances of survival.

The shortcomings we identified cover both the delivery of clinical care and the way it is organised.

Clinical issues included failure to:

- take a timely history and make a timely examination
- do the necessary tests to quickly identify the source of infection
- monitor regularly
- start important treatment quickly.

Organisational issues include:

- adequate staff education and training
- ensuring appropriate and timely senior input
- timely referral to critical care
- making and documenting a management plan
- effective handover protocols.

National audits show that clinical standards are not being achieved. For example, in 2012 the College of Emergency Medicine found that their standards for severe sepsis were often not met. None of this is new. These failings have been identified before in previous national reports and various pieces of national guidance and standards.

Saving lives, saving money

Taking action to address these shortcomings does not necessarily require more NHS resource – that is not what we are recommending. Indeed, better care could lead to savings in

'Sepsis is a more common reason for hospital admission than heart attack – and has a higher mortality.'

The UK Sepsis Trust

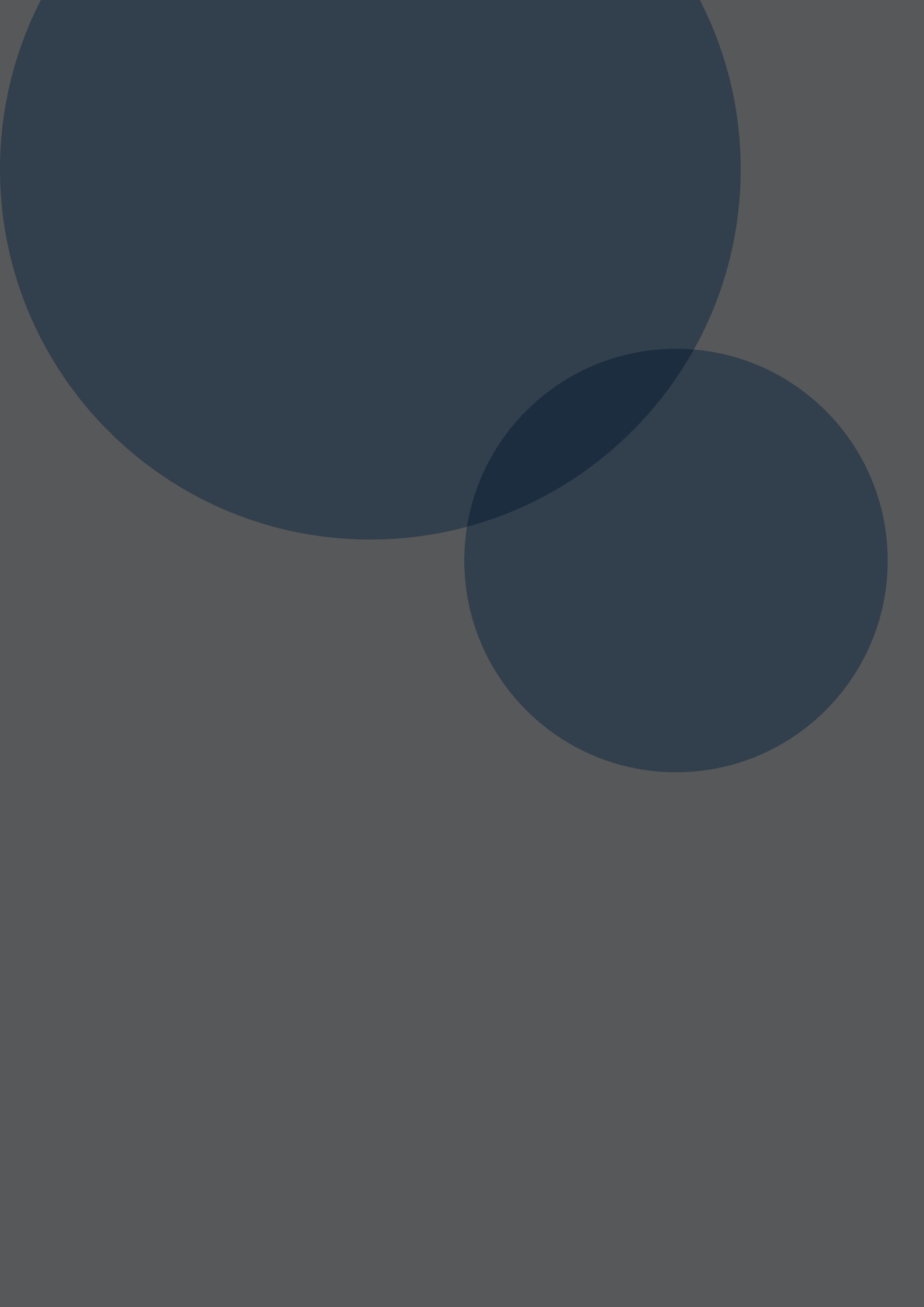
terms of reduced length of hospital stay and less intensive care and renal dialysis. The UK Sepsis Trust estimates that there are some 100,000 hospital admissions for sepsis each year, with an average cost of about £20,000. Just following basic principles could save £4,000 per episode, and the potential cost saving even after taking account of the increased costs related to improved survival amount to £196 million per year.

Action

We have worked together with NHS England, NICE, the Royal Colleges of Physicians and Surgeons, the College of Emergency Medicine and the UK Sepsis Trust to identify our call to action. We are most grateful for their input.

Our role

The Ombudsman can support the drive for a patient-centred NHS by shining a light on issues raised with us by patients and their families. One of our key roles is to ensure that complaints make a difference. When we identify concerns about patient safety relating to individual clinicians or organisations, we raise them with regulators. The crucial lessons to be learnt from this report all derive from concerned people raising complaints about the care received by their loved ones, and pursuing that complaint with us when they do not receive a satisfactory outcome. In doing so they are performing a valuable public service. We know that many do not complain because they feel it will make no difference. Our job is to make sure it does.



Case stories

Ten examples from our casebook of stories where failure to rapidly diagnose and treat severe sepsis has had tragic consequences.

Mr F's story

Mr F was 37 and married with two young children. When he was admitted to hospital with fever, aches, pains, sickness and other symptoms, staff initially failed to realise just how ill he was. He died the next day.

What happened

Mr F had become increasingly unwell over a five-day period, with fever, aches and pains, diarrhoea and vomiting, dizziness, and breathlessness. His GP referred him to hospital.

When he arrived at hospital, he had a very rapid pulse, although his temperature was then normal; his blood pressure was low; and he was breathing quickly. The nurse told the doctor about the observations, and he asked for an ECG test before seeing him. Mr F was not seen by the doctor until one and a half hours later. The doctor noted that Mr F was not passing urine, had poor circulation, a rash, and swollen glands. Routine blood tests indicated that Mr F had an infection and advanced acute kidney failure. Intravenous fluids began and the emergency department consultant requested that Mr F was treated as an urgent medical and critical care case.

More than three hours after he had arrived at hospital, Mr F was seen by a middle grade doctor and half an hour later by the medical consultant. It was only at this point that Mr F was diagnosed with severe sepsis, and he was given antibiotics and more fluids.

More than eight hours after admission, Mr F was moved to intensive care. By then, he was desperately ill. He was given drugs to stimulate his circulation, and two hours later was anaesthetised and put on a ventilator. He collapsed, but staff were able to resuscitate him. However, he became increasingly unstable and tragically died that night.

The post mortem examination showed that Mr F had died of overwhelming sepsis.

What we found

We found that during Mr F's first two hours in hospital, the severity of his condition was not recognised. Hospital staff failed to act on his severely abnormal vital signs and there was a delay in carrying out all necessary tests and in starting fluids and administering antibiotics. These failings fell substantially short of National Institute for Health and Care Excellence guidance on responding to acute illness in adults in hospital, and guidelines from the Surviving Sepsis Campaign. Although the care given to Mr F improved during the next six hours, he was not monitored frequently enough and there was uncertainty about which consultant was in charge.

Mr F's wife felt that her husband's care and treatment had reduced his chances of survival. She told us that '*However slim a chance* [he] *had of recovery I would have liked that 10% to have been safe and secure. Did he have this 10% chance as he walked through the door?*'

Mr F was extremely ill by the time he got to hospital and his condition deteriorated so rapidly that it is unlikely that he would have survived, even with ideal treatment. However, we concluded that the hospital's delays in treatment reduced whatever small chance of recovery Mr F may have had.

What happened next

Following our involvement, the Trust apologised to Mr F's wife and paid her compensation in line with our recommendations.

Mr F's wife said that she did not want her husband's life to have been a waste. The Trust took steps to learn from this case. Among other actions, they introduced the modified early warning score system (based on vital sign observations) and revised their care pathway for patients presumed to have sepsis. More staff were recruited to the emergency department and the intensive care outreach team, and the deployment of on-call clinical staff was changed to ensure their best usage out-of-hours and for the care of acutely ill patients.

'In severe sepsis, fluid resuscitation is for right now, not later.'

The UK Sepsis Trust

Summary of failings against standards

Clinical care

✕	Timely history and examination on admission or referral.
	Investigations to determine:
✕	• Indices of perfusion
✕	• Indices of infection
✕	• Source of infection
✕	• Cultures of blood and other sites.
✕	Regular physiological monitoring using track and trigger systems.
✕	Accurate recognition of the severity of the illness.
	Basic resuscitation with:
✕	• Large-volume fluid therapy
✕	• Intravenous broad-spectrum antibiotics after taking cultures.

Child B's story

Child B was eight years old. Her family described her as a 'strong, well loved child, whose weekends were full of her activities, swimming, gymnastics, tap and ballet'. She was discharged from hospital but staff had missed signs that indicated she was seriously ill. She died at home the next day.

What happened

Child B was usually well, but had been poorly for eight days with a dry cough. On 6 March she developed abdominal pain and vomited eight times. She was taken to hospital that evening. She showed signs that she was generally unwell, and was increasingly tired and lethargic.

At A&E, triage staff took Child B's vital signs, noting she had a slight fever and a rapid pulse but was breathing normally and had normal blood pressure. She was seen half an hour later by the emergency department doctor, who noted that her breathing was laboured, but she was thought to be suffering from mesenteric adenitis (inflamed lymph glands in the abdomen, which causes pain) or possibly appendicitis or gastroenteritis.

Child B was transferred to the children's ward. Her temperature was high and her pulse had got quicker, and her blood pressure was raised. She was seen by the registrar, who diagnosed her as having a viral infection or tonsillitis. The plan was to give her paracetamol to lower her temperature, and to review her later and allow her home if she had settled. No blood tests were carried out. Later that night, her temperature came down, although her pulse was still very rapid. Her parents were told they could take Child B home with the assurance they could bring her back in if necessary.

Tragically, Child B collapsed at home the next morning and could not be resuscitated.

A post mortem examination showed that Child B had developed a bacterial infection that caused left-sided pneumonia, complicated by a collection of pus in her left chest cavity (pleural empyema).

In the words of Child B's family, '*Now we are left with the unbearable pain of losing her. Our home is too quiet, empty, and our happy lives together have been shattered*'.

What we found

The registrar missed two factors that should have alerted her to the possibility that Child B was seriously ill. First, the long duration of her illness was not typical of a simple viral illness. Secondly, although Child B's temperature had come down, her pulse remained very rapid. This suggested sepsis. The registrar should have paid more attention to these factors and carried out further investigations, which might reasonably have included blood tests. The registrar's assessment of Child B was inadequate, and her diagnosis did not explain all the clinical findings.

The reassurance from the fact that Child B's temperature fell after paracetamol was given, was also misplaced.

What happened next

At our recommendation, the Trust apologised to Child B's family, paid them compensation and explained how they would prevent a repeat of their failings. Specific measures put in place by the Trust include developing a paediatric early warning score system, and preparing local clinical guidelines on the clinical management of children with fever. We also recommended that the registrar reflected on our findings and worked with her local clinical tutor to agree and implement a plan to address the specific failings in her care of Child B.

The hospital has since admitted breaches in the duty of care provided to Child B.

'Now we are left with the unbearable pain of losing her. Our home is too quiet, empty, and our happy lives together have been shattered.'

The family of Child B

Summary of failings against standards

Clinical care

- ✕ Timely history and examination on admission or referral.

Investigations to determine:

- ✕ • Indices of perfusion
- ✕ • Indices of infection
- ✕ • Source of infection
- ✕ • Cultures of blood and other sites.

- ✕ Accurate recognition of the severity of the illness.

Organisation of care

- ✕ Appropriate and timely senior medical input.

37,000 people are estimated to die of sepsis each year in the UK

The UK Sepsis Trust

Mr H's story

Mr H, who was 67 years old, developed necrotising fasciitis while recovering from a hernia operation. Hospital staff failed to recognise the seriousness of his condition at an early stage, and he waited more than 16 hours for the emergency surgery he needed.

What happened

On 2 March Mr H had surgery for a large inguinal hernia descending into the scrotum. A drain was left in the wound to allow any fluid to pass out. This continued to discharge, delaying his return home. Mr H's family remarked on a foul smell from the wound, but this was not mentioned in his health records.

Mr H was finally discharged on 16 March, but the next day the GP was called because he was generally unwell. Mr H's son recalled that '*everywhere he sat in the house, he left a damp patch and foul smell*'. The GP sent Mr H to the emergency department, arriving late in the evening. The paramedic recorded low blood pressure. However, the nursing triage assessment was not recorded, and there was no indication that any account was taken of Mr H's low blood pressure and the urgency of the GP's concerns.

Around three hours later Mr H saw a doctor, who noted a large area of dead tissue over his lower abdomen. The doctor realised that Mr H was seriously ill – he had necrotising fasciitis. Mr H was given intravenous fluids and antibiotics, and was referred for emergency surgery to remove the dead tissue. However, surgery was delayed until more than 16 hours after Mr H's arrival.

Mr H had extensive surgery to remove the dead tissue, and his postoperative care was complicated and slow. In all, he was in hospital for 15 months and suffered numerous illnesses. One leg was also amputated. Mr H's son said that his father:

> '*had gone from being a relatively healthy man with a hernia to being unable to move far from his chair. He should have been playing with his grandchildren and enjoying his retirement now, but he can't.*'

He said that '*no amount of money can ever repay my father for his lack of dignity, mobility and pride*'.

Mr H never fully recovered and died a year later.

What we found

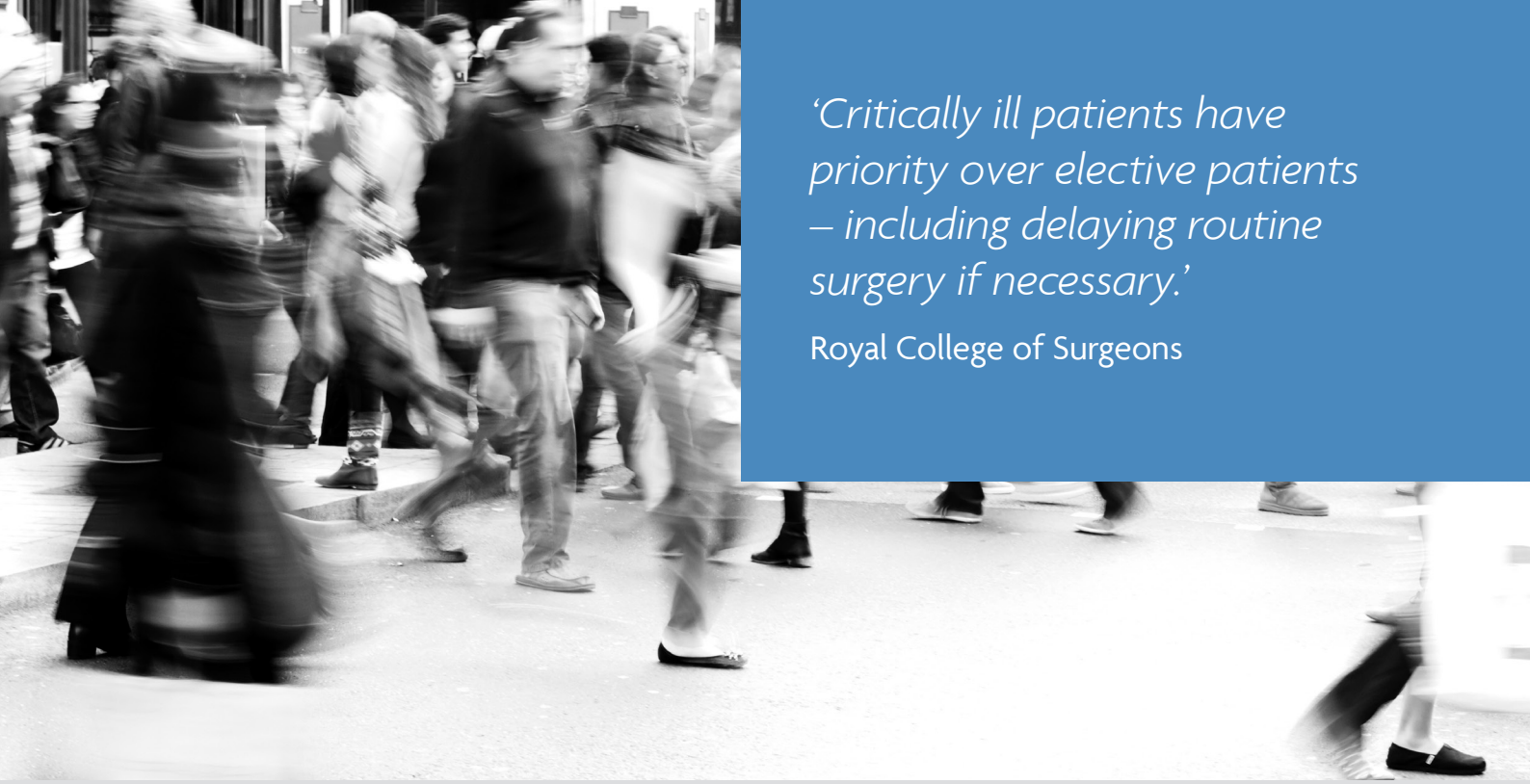
We found failings in the poor assessment of Mr H when he was readmitted to hospital, the delay in treating sepsis, and the delay in carrying out the emergency surgery. We also criticised the way the Trust dealt with the family's complaint about Mr H's care and treatment.

What happened next

In line with our recommendations, the Trust apologised to Mr H's family and paid compensation to his wife. The Trust also drew up plans to address their failings. Their action plan included implementing the Manchester triage system in the emergency department, and introducing the 'patient at risk' and pain-scoring systems to improve patient assessment on arrival. They also planned to revise their guidelines for managing sepsis.

'The consultant must be involved if critical care is needed but cannot be arranged.'

Royal College of Surgeons



'Critically ill patients have priority over elective patients – including delaying routine surgery if necessary.'

Royal College of Surgeons

Summary of failings against standards

Clinical care

- ✗ Timely history and examination on admission or referral.
- ✗ Regular physiological monitoring using track and trigger systems.

Basic resuscitation with:

- ✗ • Large volume fluid therapy
- ✗ • Intravenous broad-spectrum antibiotics after taking cultures
- ✗ • Vasopressor therapy if required to maintain adequate haemodynamics and tissue perfusion.
- ✗ Source control to be performed as soon as possible after initial resuscitation.

Organisation of care

- ✗ Appropriate and timely referral for source control.

Mr D's story

Mr D was a 46-year-old computer engineer, who taught mathematics, and liked making things for his daughter. His mother described him as a '*loving and helpful man, not only to the family, but to all who knew him*'. Two GPs failed to properly assess his condition. Within days he collapsed and died.

What happened

Mr D had had a sore throat for a week, but then became generally unwell and was shivering uncontrollably. He called the GP out-of-hours service at 11.19am on 14 February, and a nurse called back at 12.03pm. Mr D explained his symptoms, describing the pain as being the worst he had ever experienced and how he could not stop shivering. The nurse arranged for him to see a doctor at a health centre, which he attended within the hour.

The GP who saw Mr D noted his temperature was 39°C, and that he had a white coating on his tongue and palate. He was aware that Mr D had a history of asthma, and diagnosed oral thrush and prescribed lozenges. Overnight Mr D's face started to swell so that it was difficult to open his eyes and the glands in his neck were swollen. Mr D's partner called the out-of-hours service at 1.40pm, and a second GP called her back at 2.16pm. Mr D described his symptoms and said he had trouble breathing and had back pain. Mr D's breathing troubles can be heard clearly in the recording of this call. The GP asked about his eye problems, and if he could eat and drink. She told Mr D to continue taking paracetamol, and to see his own GP the next day.

The next morning Mr D collapsed and died at home while having a shower. The post mortem examination showed a large collection of pus in his chest cavity (pleural empyema).

What we found

Both GPs failed to adequately assess Mr D's condition and to act in line with the relevant professional standards. Although Mr D might not have survived even if he had been properly assessed, an opportunity to treat him was lost that might have led to his survival. All this caused unnecessary distress for Mr D's family, and was made worse by the way the GP out-of-hours service dealt with the family's complaint.

In the words of Mr D's mother: '*I feel that if he was treated properly and given the proper medication he would still be alive today to enjoy his life with his parents, his partner and his young daughter*'.

What happened next

We recommended that the out-of-hours service apologise to Mr D's mother and pay her compensation. We also asked them how they would ensure that they and the GPs had learnt lessons from Mr D's case, and how they would prevent a recurrence. The service complied

with our recommendations. The GPs reflected on the limitations of telephone consultations and how to get the best information available during a telephone consultation, the importance of repeating specific questions to assess the severity of a patient's condition, and the need to make it very clear when they feel that a face-to-face consultation is necessary, even when it is not convenient. The service made changes to their complaint handling process.

Summary of failings against standards

Clinical care

✗ Timely history and examination on admission or referral.

Investigations to determine:

✗ • Indices of perfusion

✗ • Indices of infection

✗ • Source of infection

✗ • Cultures of blood and other sites.

✗ Accurate recognition of the severity of the illness.

✗ All of this to commence immediately on recognition of severe sepsis and to be completed within six hours of presentation.

Just following **basic principles** could

save £4,000

per episode

The UK Sepsis Trust

Mr E's story

Mr E, a 75-year-old man, was in good health and worked part-time. His family described him as a loving husband, father and grandfather, '*full of life and vitality*'. He died ten days after being admitted to hospital, but with the right care and treatment he would probably have survived.

What happened

Mr E had been feeling increasingly unwell for a few days. On 18 January he was taken to hospital. He arrived at 2.17pm and was seen by a nurse. He had a very high temperature, very rapid pulse, and was breathing quickly. The nurse prioritised him to be seen by a doctor within one hour, but there was a delay of four hours. In the meantime, his condition was deteriorating, and blood tests showed he had a very low white blood cell count.

At 6.30pm Mr E saw a junior doctor for the first time, in the medical assessment unit. The doctor diagnosed pneumonia and neutropenic sepsis. Antibiotics and intravenous fluids were prescribed at 7.30pm, but were not administered to Mr E for another two hours. Nursing records show that Mr E was increasingly confused and agitated during the night, but no observations were written down.

At 10am the next morning Mr E had a cardiac arrest. He was resuscitated and moved to intensive care, where he received full life support and was put on a ventilator. He remained stable but it was not possible to take him off the ventilator. On 28 January the central vein intravenous line was replaced, and shortly afterwards Mr E collapsed again and this time could not be resuscitated.

Mr E's family described his death as '*unexpected, premature and devastating for the whole family ... Another family must never again experience what we have. This would be a fitting legacy*'.

What we found

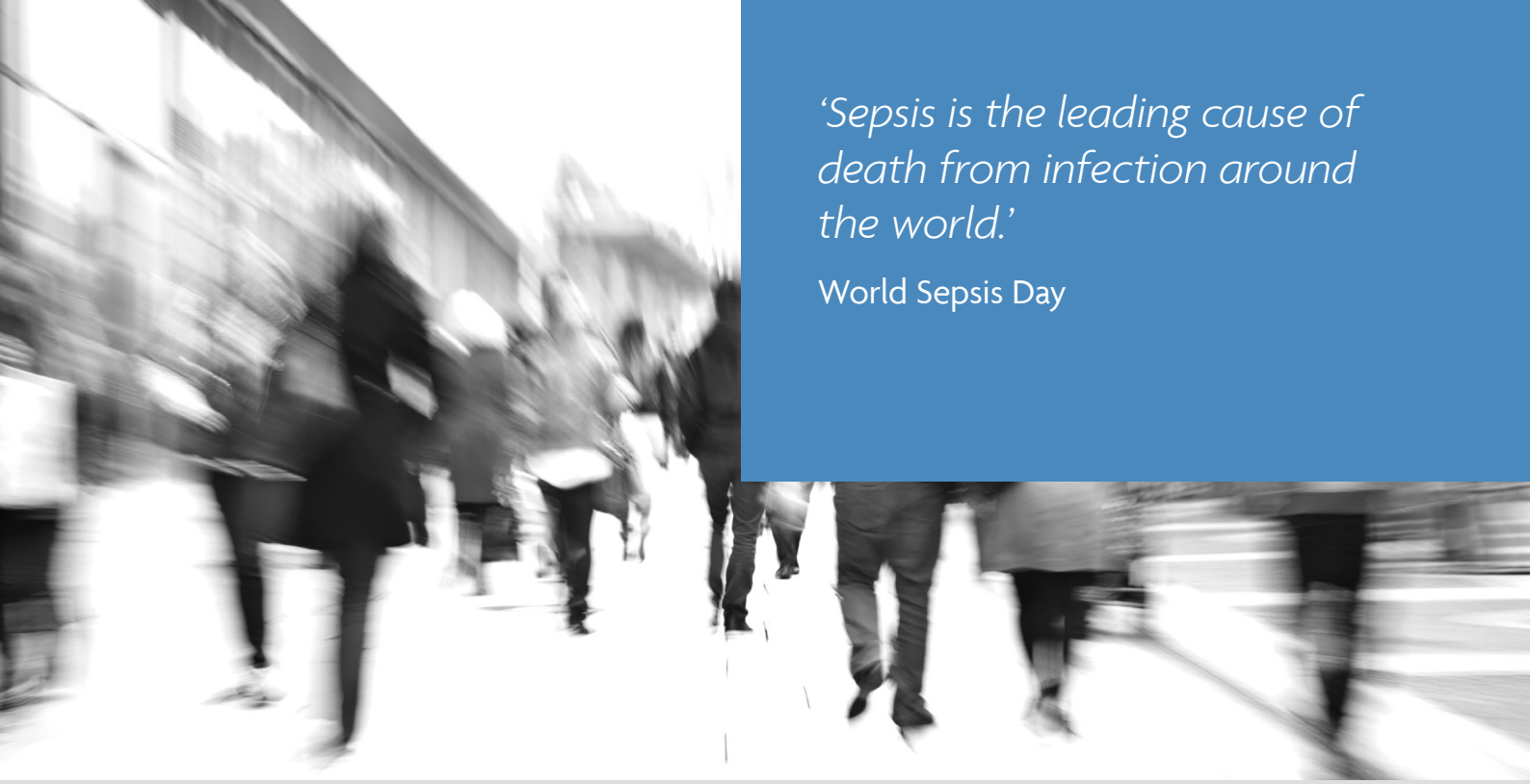
We found that it was more likely than not that Mr E would have survived if he had been given the proper treatment. Instead, he was not treated as an urgent enough case when he arrived at the hospital, in spite of his abnormal vital signs, and further checks were not frequent enough. He was not seen quickly enough by a doctor, and there were delays in him being given the prescribed fluids and antibiotics. We also found that it was possible that Mr E's final cardiac arrest was precipitated by the insertion of a new central line – a procedure which was poorly documented. As for the Trust's response to the family's complaint, they failed to acknowledge all of the failings in care, and took no specific actions to improve and learn from the case.

What happened next

Following our investigation, the Trust apologised to Mr E's family and paid them compensation. They also reported on the lessons learnt from Mr E's case, and the remedial actions they were taking. Key points included: improved staff training and supervision; changes to the early warning score system; a policy for medical review before patients leave the emergency department; increased staffing levels; and enhanced clinical leadership.

'In severe sepsis the doctor should not leave the patient until antibiotics have been administered.'

Royal College of Physicians



'Sepsis is the leading cause of death from infection around the world.'

World Sepsis Day

Summary of failings against standards

Clinical care

- ✗ Timely history and examination on admission or referral.

Investigations to determine:

- ✗ • Indices of perfusion
- ✗ • Indices of infection
- ✗ • Source of infection
- ✗ • Cultures of blood and other sites.

Basic resuscitation with:

- ✗ • Large volume fluid therapy
- ✗ • Intravenous broad-spectrum antibiotics after taking cultures
- ✗ • Vasopressor therapy if required to maintain adequate haemodynamics and tissue perfusion.

- ✗ All of this to commence immediately on recognition of severe sepsis and to be completed within six hours of presentation.

Organisation of care

- ✗ Appropriate and timely senior medical input.

- ✗ Timely referral to critical care.

Mrs G's story

Mrs G was 67 and in reasonable health. Her husband had retired and they were looking forward to their time together. Mrs G died of severe sepsis within 24 hours of being referred to hospital with flu-like symptoms. The outcome might have been different if staff had recognised the signs more quickly.

What happened

One Friday Mrs G came home from her job as a supermarket cashier feeling unwell. She took paracetamol and rested over the weekend. On Monday her work colleagues told Mrs G that she '*looked awful*', but she refused to go home early. Mr G said his wife '*did not like being fussed over*'. She saw a GP that evening and again the next morning, complaining of a swollen neck and flu-like symptoms. The GP referred Mrs G to hospital.

Mrs G arrived at the hospital at 11am. She saw a junior doctor from the ear, nose and throat department at 11.40am, who diagnosed a neck abscess and took advice from a registrar before deciding what should happen next. Mrs G was admitted for a full investigation, and so that the abscess could be drained. At 1.30pm an intravenous drip was inserted. Antibiotics were prescribed but they were not given to Mrs G until around 3.30pm.

By 3pm Mrs G's temperature was high. She was breathing rapidly, her oxygen levels were reduced, and blood tests showed evidence of infection and acute kidney failure. The junior doctor contacted another senior ear, nose and throat doctor, who advised continuing with the current treatment. The junior doctor was called back at 7.30pm because Mrs G's blood pressure had dropped significantly. There was uncertainty about whether she was suffering from severe sepsis or heart failure. Further tests were done and staff spoke to the medical registrar by telephone. The medical registrar advised them not to change Mrs G's treatment.

By 9.15pm Mrs G was increasingly breathless and the medical registrar was called again. She considered swine flu as a possible diagnosis and arranged yet more tests. The on-call junior doctor checked on Mrs G at midnight. Her temperature was normal but her blood pressure was critically low. At this point, staff considered moving Mrs G to intensive care, but the intensive care registrar said '*no*' to this. Mrs G was now so breathless that she could not speak and her blood oxygen levels fell, despite staff giving her added oxygen. At 2.20am Mrs G collapsed. Staff resuscitated her, but she collapsed again and sadly died at 3.30am. The cause of death was recorded as sepsis arising as a consequence of a neck abscess.

Reflecting on events, Mr G said that his wife's death had come '*completely out of the blue*' and had '*totally changed his life*'. By complaining about her care and treatment, Mr G hoped that lessons would be learnt and that others would not have to go through the same experience.

'When early warning scores indicate critical illness or deterioration, sepsis is a likely cause.'

The UK Sepsis Trust

What we found

The survival rate for patients with such rapidly progressive sepsis is low, even with good treatment. Nevertheless, opportunities to give Mrs G a chance of surviving were missed. The medical registrar's and the intensive care registrar's assessments and treatment fell far short of what was required. Other failings included the delay in diagnosing severe sepsis, delays in administering intravenous fluids, the prescription of inadequate amounts of fluids, delays in administering antibiotics, the lack of any consultant-level involvement and the inadequate supervision of the junior doctor.

What happened next

In line with our recommendations, the Trust apologised to Mr G and paid him compensation. They also accepted that Mrs G should have been looked after in intensive care. The Trust drew up plans to prevent the same failings happening again. They increased staffing for the critical care outreach team and established a 'hospital at night' team to provide better care out-of-hours. They also set out steps to improve the management of severe sepsis, including the introduction of a sepsis box to ensure that antibiotics are available immediately, and a pro forma to document sepsis treatment. Severe sepsis simulation sessions will also be included in an education programme for junior doctors and nurses.

'High risk patients should be discussed with the consultant within four hours if they are not responding as expected.'

Royal College of Surgeons

Summary of failings against standards

Clinical care

Investigations to determine:

- ✗ • Indices of perfusion.

- ✗ Accurate recognition of the severity of the illness.

Basic resuscitation with:

- ✗ Large volume fluid therapy
- ✗ Intravenous broad-spectrum antibiotics after taking cultures
- ✗ Vasopressor therapy if required to maintain adequate haemodynamics and tissue perfusion.

- ✗ All of this to commence immediately on recognition of severe sepsis and to be completed within six hours of presentation.

- ✗ Source control to be performed as soon as possible after initial resuscitation.

Organisation of care

- ✗ Appropriate and timely senior medical input.

- ✗ Timely referral to critical care.

Hospitalisation for sepsis has **more than doubled** over the last **10 years**

World Sepsis Day

Mr C's story

Mr C, aged 63, was having advanced lung cancer treatment, which put him at high risk of infection. Yet hospital staff paid too little attention to this, even when blood tests indicated that he had an infection.

What happened

Mr C began receiving palliative chemotherapy on 12 September. He was admitted to hospital on 16 September feeling generally unwell and breathless. He had no fever, but his blood pressure was low and he had a very rapid abnormal heart rhythm. Blood tests showed a low white blood cell count. He was given medical treatment to control his abnormal heart rhythm.

On 17 September Mr C saw a consultant, who thought the breathlessness was caused by his abnormal heart beat. The next day, blood tests showed evidence of infection. Mr C seemed a little better and it was decided to defer the next chemotherapy dose.

On 19 September he had no fever but his blood pressure remained low, so further treatment for his heart was considered, but not given. On 21 September Mr C's condition deteriorated, with low oxygen levels in the blood. He was seen by the intensive care outreach team, who suspected sepsis and planned to give him antibiotics if he developed a temperature. On 22 September Mr C's temperature was high, his white blood cell count was lower, and he had increased inflammation. He was diagnosed with neutropenic sepsis and was given antibiotics, but he continued to decline and sadly died later that day.

What we found

More consideration should have been given to the fact that Mr C was at greater risk of infection because of his cancer and its treatment, and more attention should have been paid to the abnormal blood test results. The Trust did not follow their own policy on neutropenic sepsis, which stated that patients in septic shock (unwell with low blood pressure) might not have fever but still need intravenous antibiotics.

There was also a delay in giving Mr C necessary antibiotics. While Mr C was gravely ill and might not have survived even with good treatment, an opportunity was lost that might have led him to live longer.

What happened next

The Trust complied with our recommendations. They apologised to Mr C's wife, paid her compensation, and drew up plans to ensure that their failings were not repeated. Their plans included implementing the sepsis care bundles, improving the recognition of sepsis and monitoring compliance with the sepsis care bundles, and appointing additional staff.

Summary of failings against standards

Clinical care

- ✗ Timely history and examination on admission or referral.

Investigations to determine:

- ✗ • Source of infection
- ✗ • Cultures of blood and other sites.

- ✗ Accurate recognition of the severity of the illness.

Basic resuscitation with:

- ✗ • Intravenous broad-spectrum antibiotics after taking cultures.

Organisation of care

- ✗ Timely referral to critical care.

'Septic patients must be managed as an urgent priority.'

The College of Emergency Medicine

Mrs K's story

Mrs K was referred to hospital by her GP after her leg had become swollen following a knee replacement operation. There were delays in diagnosing and treating the infection and sadly Mrs K died of sepsis the next day.

What happened

Mrs K was 71 years old. She had long-standing leukaemia, for which she received regular blood transfusions. Her right knee had been replaced four months earlier, and had then become infected. On 25 February her GP referred Mrs K to hospital because she was short of breath. Her right leg was also swollen and the knee was tender. Mrs K was also due to have a blood transfusion the next day and was very anaemic. She was on antibiotics because she had discomfort passing urine and her abdomen was tender.

Hospital blood tests showed high levels of inflammation, and urine tests indicated an infection. The provisional diagnosis was that Mrs K's knee joint was infected, and she was admitted under the care of the medical team. An orthopaedic junior doctor tried unsuccessfully to take a fluid sample from Mrs K's knee.

Although medical notes indicated plans to give her intravenous antibiotics, these were not given. The next day, Mrs K was seen by the medical consultant, who remained concerned that her knee joint might be infected, and passed her care to the orthopaedic team. The orthopaedic consultant noted the painful knee but suspected a urinary infection.

The medical consultant saw Mrs K again at 10am the next morning, and remained concerned about a knee infection and spoke to the orthopaedic team. Mrs K was given intravenous antibiotics and the orthopaedic doctor managed to obtain a sample of fluid from her knee, which showed infection. By 2.25pm Mrs K was acutely unwell. She was moved to intensive care at 5.30pm, given a blood transfusion, and put on a ventilator. Her husband visited her during the day and '*knew she had passed the point of no return*'. Sadly, he was proved right. Mrs K died late the same evening.

Mrs K's husband felt strongly that: '*I do not believe that another family should have to experience the great distress ... that we have experienced ... My hope is that the Trust can learn from this investigation, so that new procedures will be implemented to reduce the likelihood of such mistakes happening in the future.*'

What we found

The Trust's failure to properly assess Mrs K's medical needs delayed the diagnosis of her infected knee joint. They did not give her antibiotics, and a necessary blood transfusion was delayed. We also found shortcomings in communication between departments, in record keeping, general care, and in communication with Mrs K's family.

'Sepsis is time critical – risk of death rises with every hour treatment is delayed.'

The UK Sepsis Trust

What happened next

We asked the Trust to apologise to Mrs K's daughter, pay her compensation, and draw up plans to prevent a repeat of their failings. The Trust did so. They also undertook a serious incident enquiry, and a trauma services review, which led to a new policy for the clinical treatment of swollen painful knees, and for the appropriate use of antibiotics. Actions to address the shortcomings in general care included audits on observations and early warning score performance, and monitoring the standards of care.

Summary of failings against standards

Clinical care

Investigations to determine:

- ✗ • Source of infection.

- ✗ Accurate recognition of the severity of the illness.

Basic resuscitation with:

- ✗ • Large-volume fluid therapy
- ✗ • Intravenous broad-spectrum antibiotics after taking cultures.

- ✗ All of this to commence immediately on recognition of severe sepsis and to be completed within six hours of presentation.

- ✗ Source control to be performed as soon as possible after initial resuscitation.

Organisation of care

- ✗ Appropriate and timely senior medical input.

Mrs A's story

Mrs A died the day after she was admitted to hospital with kidney pain. Our investigation revealed delays in recognising that she had a kidney infection, and a lack of senior medical staff involvement at an early stage. Matters were not helped by a substantial delay in starting antibiotics.

What happened

Mrs A, aged 63, had a history of kidney stones and had recently been treated by her GP for a urinary infection. On 1 November she developed severe pain over her right kidney, and was admitted to hospital. A urine sample was taken and a urine analysis report was recorded. Mrs A was transferred to a second hospital later that afternoon, where the urine analysis report was presented to medical staff. Observations were satisfactory, and there were no findings apart from tenderness over the kidney. The surgical team planned a scan the following morning.

During the night Mrs A's condition deteriorated rapidly. Her temperature was high (39.8^{0}C) and her blood pressure was low. At 1.30am a junior doctor gave Mrs A 500ml of fluid intravenously. The 'patient at risk' nurse reviewed her at 2.55am. By 3.40am Mrs A's blood pressure had not improved, and she was given 750ml of fluid. Her blood pressure fell further to 73mmHg at 4.15am, and urine tests showed excess white blood cells.

The junior doctor recognised that Mrs A had septic shock and spoke to the laboratory about appropriate antibiotics, but these were not administered until 7.15am. At around 6am Mrs A was moved to intensive care. A central venous monitoring line proved difficult to insert.

Mrs A was put on mechanical ventilation and given increasing doses of drugs to support her circulation. Her husband did not learn of her deterioration until he called the ward at 10am, by which time Mrs A was unconscious. She continued to decline, and died at 8.45pm on 2 November. The post mortem showed that Mrs A's right kidney was infected and that there was generalised sepsis.

In the words of Mrs A's husband: '*We can never bring back my wife or the mother of my sons, but something positive must come from this very raw and personal tragedy. Efforts must be made to ensure that no other patient suffers the same consequences as* [she] *did.*'

What we found

While not all criteria for severe sepsis were present until 3.40am, there were delays in recognising Mrs A's kidney infection, and involving senior medical staff and intensive care. There was a substantial delay in starting antibiotics. All these shortcomings breached the severe sepsis guidance. However, it was not possible to say if Mrs A would have survived, had care been appropriate. We also criticised the failure to tell Mrs A's husband about her deterioration, which has affected his ability to come to terms with her death.

'When early warning scores indicate escalation of care, it is about both involving a senior doctor and critical care outreach.'

Royal College of Physicians

What happened next

The Trust agreed to apologise to Mr A, to draw up plans to prevent a repeat of their failings, and to update him on progress. Unfortunately, the Trust missed all the target dates for these steps, which added to Mr A's frustration. The Trust's plans included implementing a new sepsis care bundle protocol with a one-hour pathway, changing their observation charts, asking medical staff to record the time that medication is prescribed, and further training for junior doctors.

Summary of failings against standards

Clinical care

Basic resuscitation with:

- ✗ • Large-volume fluid therapy
- ✗ • Intravenous broad-spectrum antibiotics after taking cultures
- ✗ • Vasopressor therapy if required to maintain adequate haemodynamics and tissue perfusion.

✗ All of this to commence immediately on recognition of severe sepsis and to be completed within six hours of presentation.

✗ Source control to be performed as soon as possible after initial resuscitation.

Organisation of care

✗ Adequate education and training of staff.

✗ Appropriate and timely senior medical input.

✗ Timely referral to critical care.

Mrs J's story

Infrequent monitoring and technical problems with equipment meant that Mrs J went for long periods without the intravenous fluids she was supposed to have. She was also in hospital for three days before she saw a consultant.

What happened

Mrs J was aged 65. She had been diagnosed with oesophageal cancer in September. She started chemotherapy in October, with curative surgery planned for a later date. Early on 13 November Mrs J was admitted to hospital with increasing vomiting, diarrhoea and weakness. Her temperature was raised (38.2^{0}C). Blood tests showed a low white cell count, evidence of increased inflammation, and impaired kidney function. The working diagnosis was that Mrs J had chemotherapy-induced gastroenteritis, complicated by dehydration and impaired kidney function, with impending sepsis due to complications from chemotherapy.

An appropriate management plan was drawn up, covering intravenous fluids, further investigations, and the criteria for starting Mrs J on antibiotics. Later that day, Mrs J developed fever and she was given antibiotics. But for long periods she did not receive the prescribed fluids because of technical difficulties.

On 16 November Mrs J was seen by a consultant for the first time. Consideration was given to inserting a central venous line for fluid management and nutrition purposes. The next day a venous long line was inserted, but Mrs J's fluid intake was still less than intended and there were technical problems with the cannula. On 19 November Mrs J was seen by the consultant oncologist and nurse specialist. They noted that fluid replacement was not keeping up with the loss from continuing severe diarrhoea, and that Mrs J's nutrition was still poor. They considered feeding her intravenously. Fluid administration improved but observations continued to be infrequent. On 22 November Mrs J's condition deteriorated and she was moved to intensive care. Mrs J developed heart problems that did not respond to treatment, and she died on 28 November.

Mrs J's daughter told us that Mrs J had been denied a fighting chance to '*pull through*'. She said: '*My Dad is the worst affected, as he has lost his life companion. Mum did a lot for him and he has been struggling*'. She told us that: '*Mum would have wanted something to be learned by this and for this not to happen to others*'.

What we found

We found several shortcomings in the Trust's care of Mrs J. These included an important failure to administer and properly monitor her fluid intake, delayed senior medical input, poor communications between doctors and nurses, an inappropriate Do Not Attempt Resuscitation decision, and poor record keeping and physiological and nutrition monitoring. However, because of the severity of Mrs J's underlying disease and her reaction

'Patients should be assessed regularly during their hospital admission by staff with necessary competence.'

Royal College of Surgeons

to chemotherapy, we could not say whether she would have survived had these failings not occurred.

What happened next

In line with our recommendations, the Trust apologised to Mrs J's family and paid them compensation. They also drew up plans to prevent their failings happening again. Actions included: a revised policy on neutropenia, a revised early warning score policy and related training, new guidance for managing difficult venous cannulation, a review of handover arrangements between shifts of on-call doctors, and a staff training programme.

Summary of failings against standards

Clinical care

- ✕ Regular physiological monitoring using track and trigger systems.
- ✕ Accurate recognition of the severity of the illness.

Basic resuscitation with:

- ✕ • Large-volume fluid therapy
- ✕ • Vasopressor therapy if required to maintain adequate haemodynamics and tissue perfusion.

Organisation of care

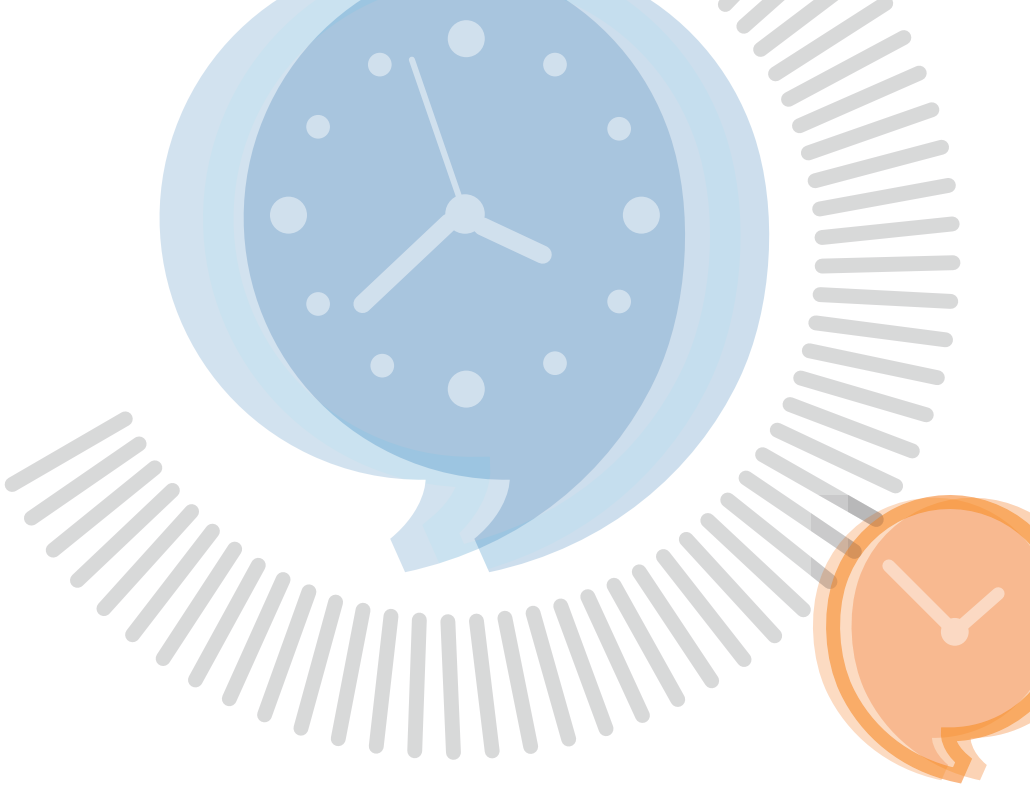
- ✕ Adequate education and training of staff.
- ✕ Appropriate and timely senior medical input.
- ✕ Timely referral to critical care.
- ✕ Formation and documentation of a management plan.
- ✕ Handover according to protocol.

Analysis

Summary of shortcomings

In the ten case stories described in this report, the shortcomings, compared with the applicable standards, are:

Standard	Number at variance
Clinical care	
Timely history and examination on admission or referral.	6
Investigations to determine:	7
• Indices of perfusion	5
• Indices of infection	4
• Source of infection	6
• Cultures of blood and other sites.	5
Regular physiological monitoring using track and trigger systems.	3
Accurate recognition of severity of the illness.	7
Basic resuscitation with:	8
• Large-volume fluid therapy	7
• Intravenous broad-spectrum antibiotics after taking cultures	7
• Vasopressor therapy if required to maintain adequate haemodynamics and tissue perfusion.	5
All of these actions to commence immediately on recognition of severe sepsis and to be completed within six hours.	5
Source control to be performed as soon as possible after initial fluid resuscitation.	4



Standard	Number at variance
Organisation of care	
Adequate education and training of staff.	2
Appropriate and timely senior medical input.	6
Timely referral to critical care.	5
Formation and documentation of a management plan.	1
Handover according to protocol.	1
Appropriate and timely referral for source control.	1

Discussion

In this section of the report, we build on existing knowledge to develop the themes from our casework. We then make our call to action for a range of organisations in our 'learning points' and in our recommendations.

Complaints to the Ombudsman are not necessarily representative of usual care – they are selected particularly by outcomes that are poor (or at least worse than expected), and dissatisfaction with the service. These case stories do not represent the overall standard of care in the NHS. We acknowledge that clinical teams cannot enjoy the benefit of foresight when they manage these very challenging cases. But a number of themes emerge from these stories that resonate with what is known about how things go wrong in the care of dangerously ill patients.

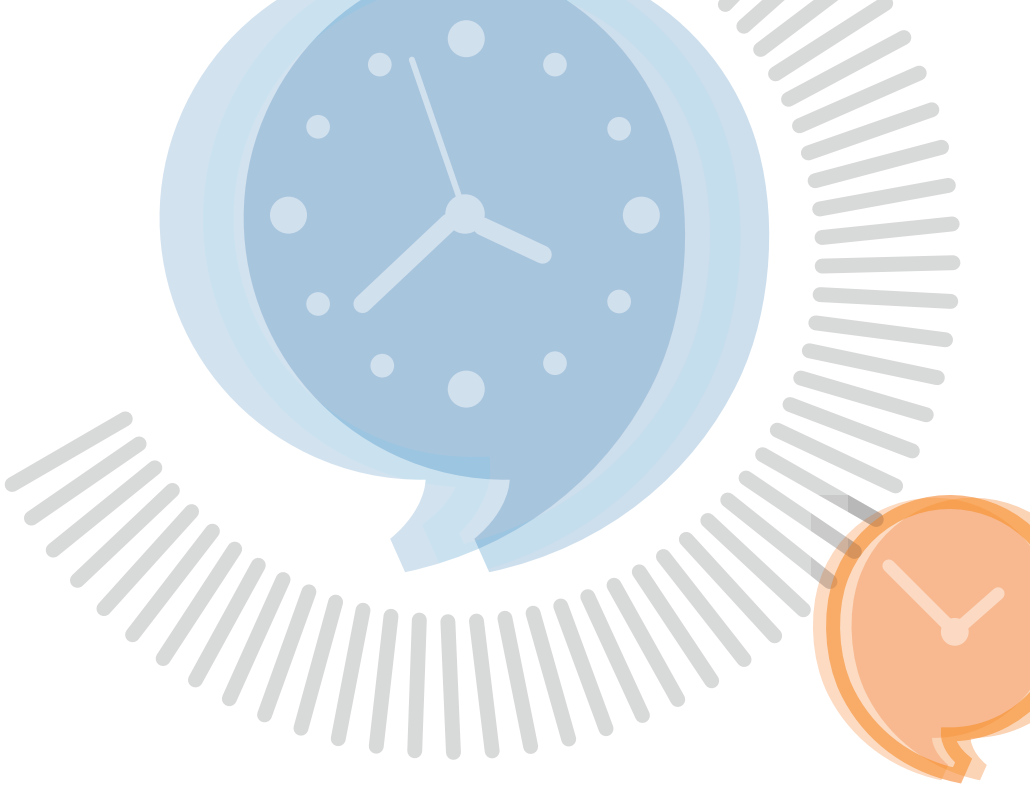
While selection bias may have influenced our analysis of the failings in these cases, the following recurring shortcomings are of particular note and concern:

- lack of timely history and examination (including adequate nurse triage) on presentation
- lack of necessary investigations
- failure to recognise the severity of the illness
- inadequate first-line treatment with fluids and antibiotics
- delays in administering first-line treatment
- inadequate physiological monitoring of vital signs
- delay in source control of infection
- delay in senior medical input, and
- the lack of timely referral to critical care.

These shortcomings can be summed up as inadequacy of initial assessment, failure to recognise critical illness, and consequent delay in emergency treatment.

What is already known

The learning points from these cases are not new. For example, in 2007 the National Patient Safety Agency published an analysis of acutely ill patients reported to them as having died following shortcomings in medical care. They concluded that staff can take too long to recognise that patients are deteriorating and do not always act to address this once identified; and that the right staff are not always available. In the same year, the National Confidential Enquiry into Patient Outcome and Death reported a review of emergency hospital admissions: 35% did not receive care consistent with good practice; in 7% the initial assessment was poor or unacceptable; 49% had not been seen by a consultant within 12 hours; and 8% did not receive observations appropriate for their condition. The lack of improvement resulting from these previous initiatives is disappointing.



These aspects of NHS performance must be improved, and systemic attention is required. Quite apart from the lives that can be saved and the improved experiences of patients and their families, there are substantial potential savings in healthcare costs. The UK Sepsis Trust estimates that there are some 100,000 hospital admissions for sepsis each year, with an average cost of about £20,000 each. Just following the 'sepsis six' principles (Appendix 1) could save some £4,000 per episode; the potential total saving, even after taking account of the increased costs related to improved survival, amounts to £196 million a year.

The findings in this report raise questions about why standards are not being met. This is not to do with 'bad people'. Workplace challenges faced by doctors and nurses are likely to be relevant. So too is the issue of delay in senior clinical input. The skills necessary for early identification of patients at risk of severe sepsis are high level, and develop with long experience. Some senior consultants are concerned that the very processes that have been put in place by the NHS to improve quality and consistency may have had unforeseen consequences. For example, protocols and care pathways which seek to (and certainly do) reduce omissions and improve documentation of care may lead to a 'tick-box mentality', and the loss of critical thinking skills and clinical acumen. There are real problems of access to the many guidelines and policies, and some clinicians find it difficult to keep up-to-date.

Systemic change

The key learning point to be drawn from this report is the pressing need to address these shortcomings in a systemic way. Importantly, that is about the attitudes and values individuals bring to their work, the way that they interact with their colleagues, and how they behave – their working culture.

While much of the emphasis is on what happens in emergency departments, these clinical challenges also present to primary care, the ambulance service, and on hospital wards. Action is necessary to ensure compliance with standards throughout the healthcare system in a way that joins up its various parts. These are set out in our learning points on page 49 following this discussion. The UK Sepsis Trust and the College of Emergency Medicine have given detailed consideration to this and their evidence is included at page 60.

Standards are set nationally but implemented locally. Actions need to be taken at many levels. These include the NHS Commissioning Board, regulators of healthcare, the Royal Colleges responsible for professional education

'All health professionals should be aware of the features and potential consequences of maternal sepsis – suspicion should lead to urgent hospital referral.'

Royal College of Obstetricians and Gynaecologists

and training, NHS trusts, local commissioning groups and individual clinical teams. Leaders in the NHS should consider how services can be organised more effectively, staff supported better, how that can be overseen by NHS trust boards, and how healthcare regulatory organisations can be charged with addressing these issues during service reviews.

Organisations need to be aware of the pitfalls of unintended consequences when making illness-specific changes. More general changes should improve the care of other acute situations as well. Robust systems should include 'safety net' arrangements.

In the following paragraphs, we break down some of the individual issues we have identified.

The initial assessment

The first interaction between someone coming to an emergency department and the service is the nurse triage – the immediate assessment by a nurse of the patient's problem and condition.

Problems encountered include this being undertaken poorly, perhaps with no track and trigger early warning score being calculated, or necessary action not being taken. The cases of Mr F and Mr E (pages 12 and 25) particularly illustrate these issues. This leads to delay that is potentially disastrous in the care of the critically ill. The standards that apply are set out in general terms by the Nursing and Midwifery Council's Code of Conduct (NMC's Code of Conduct), and specifically in guidance on the management of the acutely unwell patient.

Delay

Emergency departments are busy, and sometimes chaotic, places. Staff must often prioritise in difficult circumstances, and decide which of several important and urgent tasks they should do next. The same issues apply to acute medical units and clinical decision units, where many such patients are managed. Assessment is not always straightforward. For example, some patients, particularly the elderly and those with neutropenia (as in the case of Mr C, page 32), may have severe infection without raised temperature. The features can be relatively nonspecific – patients can be sicker than they look – so the urgency of the situation is less obvious than in those with trauma or other medical emergencies. The real difficulties in picking out the relatively small proportion of patients with infection who are progressing to critical illness should not be underestimated. Improved clinical process should lead to a greater appreciation of the

potential risks for patients with apparently uncomplicated infection.

Delay in implementing treatment plans, particularly fluid and antibiotic administration, are a concern as well. In the urgent situation, the prescriber has a responsibility to ensure timely administration.

Medical review

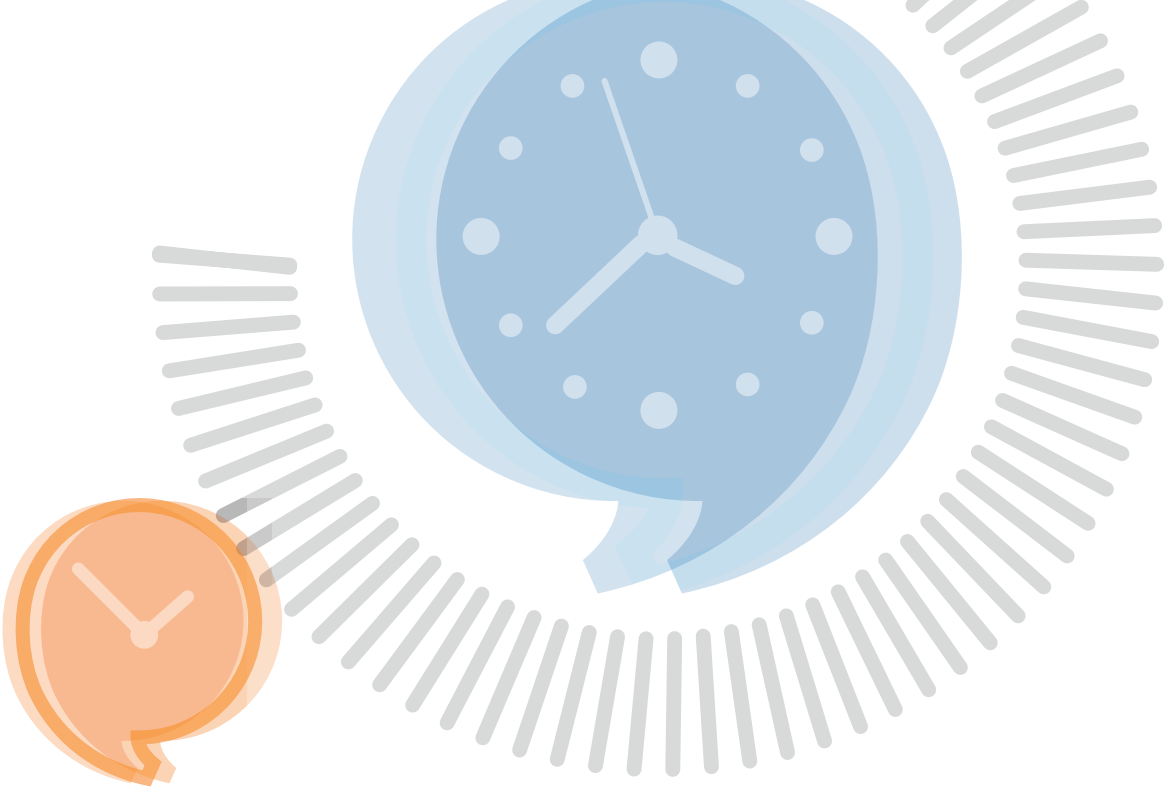
Problems with medical review – particularly delay, failing to consider all relevant available information, and inadequate investigation – were recurring features in these stories. (The differing ways in which clinical teams had difficulty with diagnosis are particularly illustrated by the cases of Mr C, Mr D, Mrs K, Child B and Mrs G.) The inevitable consequence was delay in constructing an optimum treatment plan. The applicable standards are set out in general terms by the GMC guidance on good medical practice. This aspect of the service can be improved by sufficient levels of staffing, more readily available senior medical staff, better support for junior staff, improved training, the use of protocols and care pathways, and regular service review and audit. The timely availability of senior staff is crucial both to good patient care and the supervision and support of trainee doctors. This is being addressed nationally by such initiatives as 'the seven-day hospital'.

Achieving standards

The various and complex characteristics of good practice are brought together in the sepsis care bundles, and they should be applied universally. There are striking differences between hospitals in adherence to guidelines. In institutions where there is no sepsis care pathway, or where audits show non-compliance with the College of Emergency Medicine standards, the increased risks should be reflected by an entry in the trust's risk register.

After admission to hospital

Some of the case stories, particularly those of Mr C, Mrs A, Mrs K and Mrs G, illustrate the difficulties experienced when sepsis develops on hospital wards some time after admission. Important information becomes available at different times and from various staff in a way that is different to the focus in emergency departments. The care setting is less acute, and access to senior staff less immediately available. The UK Sepsis Trust has carefully considered how this might be addressed (Appendix 2).



Before reaching hospital

Just as the similarities between the early stages of severe sepsis and other more common self-limiting conditions (for example, flu) make recognition difficult for health professionals, they also make it hard for patients to know when they may be in serious trouble. The UK Sepsis Group has suggested a helpful list of warning signs:

- **S**lurred speech;
- **E**xtreme muscle pain;
- **P**assing no urine;
- **S**evere breathlessness;
- '***I** feel I might die*'; and
- **S**kin mottled or discoloured.

To these might be added a feeling of faintness on sitting or standing. But these are not easy health education messages to get across.

Most of these case stories describe problems encountered in hospital. But that of Mr D (page 22) occurred in a general practice setting. There are questions about the adequacy of clinical assessment in primary care, and the recognition of severe sepsis and critical illness. Early warning scores are generally used only in hospital. GPs need to ensure that immediate lines of communication with appropriate specialists are open for advice.

While we have not received complaints about the management of severe sepsis by the ambulance service, there are opportunities for care to be improved before patients arrive at hospital. That becomes more important when journey times to hospital are longer. Assessment could be improved – most ambulances do not have facilities to measure temperature.

Early warning scores are not calculated out of hospital. It should be possible to develop protocols for the administration of large-volume fluids in pre-hospital care, and there is scope to extend the circumstances in which paramedics could give antibiotics.

Education, training and research

Ethical considerations have made it difficult to do prospective clinical research in critical illness, but there is an overwhelming specialist consensus that in severe sepsis, early fluid resuscitation and antibiotic treatment improve outcomes. The delays experienced in the stories described here are in large part a consequence of shortcomings by doctors and nurses, and are the major cause for concern. The specific standards applied by the Ombudsman are the Surviving Sepsis

'Early warning scores are not an option – they are essential to identify the deteriorating patient.'

Royal College of Physicians

Campaign's guidance on immediate care, which was previously accepted by NHS Evidence. Again, the service issues should be addressed by training, support and supervision of junior clinicians, the use of care pathways, and service review.

There are many valid research questions in improving understanding. Those particularly important at the moment include optimal fluid resuscitation; the development of clinical tools in and outside hospitals, which would be highly predictive of severe sepsis; the development of technology to allow patient testing for blood marker indicators of severe sepsis and causative germs at the bedside; and the reasons that clinical teams do not adhere to guidelines.

Antibiotics

The immediate administration of antibiotics in severe sepsis is essential. Delay in giving antibiotics leads to worse outcomes in severe sepsis (a four-hour delay in administering antibiotics increases mortality from 15% to 45%). At the same time, the wider context of antibiotic use has to be taken into account. Indiscriminate overuse of antibiotics leads to an increase in antibiotic side-effects – some of which are serious, for example, Clostridium difficile diarrhoea (C.diff). There is international concern about the increased emergence of bacteria resistant to commonly used antibiotics, for example, methicillin resistant Staphyllococcus aureus (MRSA), which is particularly a feature of health systems where the use of antibiotics is less regulated. These factors are drivers to reduce antibiotic prescription, and must be reconciled with the equally important need for immediate antibiotic treatment for the seriously ill. Microbiology departments should inform appropriate antibiotic choices for their local care pathways. But sepsis is not only about hospital acquired infections – it is about the recognition of dangerous deterioration in patients whose infection was acquired in the community.

Service organisation

The examples of poor communication between doctors and other healthcare workers within a team raise questions about the organisation, functioning and working culture of these services. Good clinical records are essential for safe communication between the several clinical teams that will usually be involved in the care of critical illness – poor records are a risk for adverse events and reflect badly on the quality of the service. The relevant standards are those of the GMC and the NMC professional organisations.

Clinical audit

The audit of clinical practice against clear, agreed standards, including the monitoring of clinical outcomes, is an important driver to improving care. The College of Emergency Medicine audit described in Appendix 2 is a good example. Death is easy to measure, but is influenced by very many factors apart from the quality of care. Better measures of clinical performance are the intervals leading up to key treatment interventions, for example the 'door to needle time' that transformed the care of heart attack a generation ago. In sepsis, the time intervals from arrival to the administration of large volumes of fluid and antibiotics are important measures and should be recorded routinely. Benefit from audit is greatest when it is conducted widely rather than locally, ideally with national collection of data.

'Emergency departments should have a sepsis pathway.'

The College of Emergency Medicine

Our recommendations

The principal concerns arising from our sepsis casework are initial assessment, initial treatment, delays and staff training. The NHS must address these issues as a 'whole system' to improve outcomes and reduce avoidable deaths.

1. Improving recognition

1.1 NICE will produce guidance to support GPs, ambulance staff and hospital clinicians to recognise severe sepsis in people at an early stage, so enabling earlier treatment which is known to improve outcomes. This should include the use of early warning scores, good practice in clinical assessment, best use of IT in managing available data, and new technology for near patient investigation (for example to measure blood lactate levels).

1.2 NHS England will prioritise a workstream on clinical deterioration including the early recognition of sepsis, and this may include helping providers of acute services to identify ways by which senior clinical staff are involved in patient management in a timely way.

1.3 The providers of acute services should identify ways by which senior clinical staff become involved early in the management of patients with severe sepsis.

1.4 NHS England will support the development of a public awareness campaign among vulnerable groups such as the immuno-compromised.

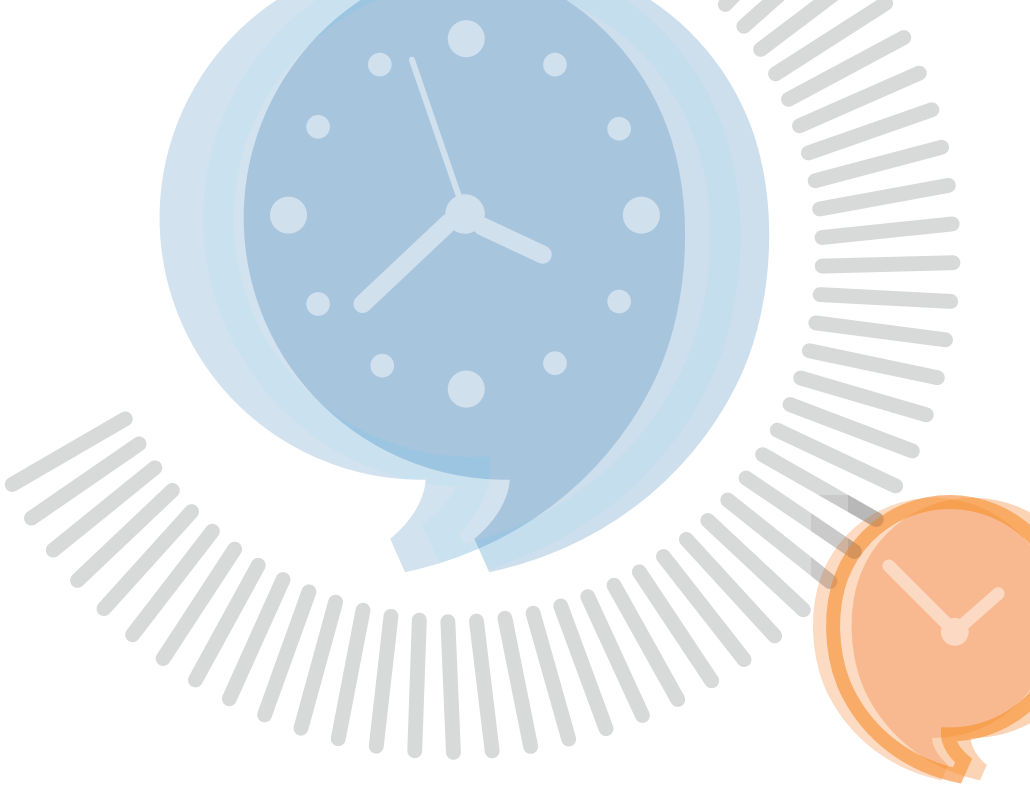
1.5 Education and training institutions should emphasise the importance of clinical staff listening to the relatives of patients as they can be the first to recognise the deterioration of the patient.

2. Improving treatment

2.1 NICE will include in guidance on sepsis the most clinical and cost effective management of people with severe sepsis, particularly in relation to the initial recognition and diagnosis of the condition and the timely use of antibiotics and fluid resuscitation.

2.2 Provider organisations should ensure full integration of available clinical guidance into their own clinical processes and systems to ensure timely treatment.

2.3 Provider organisations should foster attitudes and behaviours among their front-line staff which values critical clinical thinking, the timely availability of senior decision makers, focused priorities, and the prompt implementation of clinical plans.



3. Continuous improvement

3.1 NICE will prepare a quality standard for the management of severe sepsis against which national audit should take place. The NHS should ensure appropriate data collection (examples of which should include times from arrival to commencement of fluid resuscitation and antibiotic administration, and the proportion of patients with infection screened for sepsis). This should be mandatory and linked to commissioning arrangements.

4. Research

4.1 Clinical practice should be underpinned by robust information. Current research questions worthy of sponsorship include optimal fluid replacement; the development clinical tools highly predictive of severe sepsis applicable in primary care; development of near patient investigations applicable out-of-hospital and in emergency departments; and the reasons clinical guidance is not adhered to.

Conclusion

Our recommendations have been developed and agreed with the support and commitment of organisations who will be helping to implement them.

We believe that these actions will help to reduce the deaths and disabilities caused by sepsis.

Glossary

Abscess

A collection of fluid within infected tissue that contains large numbers of white blood cells.

Adenitis

Inflammation and enlargement of lymph glands, which may be painful.

Central venous line

A fine tube passed into one of the great veins in the chest, enabling the measurement of pressure to inform whether or not the circulation is adequately filled with fluid; and to administer fluids in a more reliable way than peripheral intravenous lines.

Chemotherapy

The use of powerful drugs that are toxic to cells, usually to treat cancer. Such drugs suppress the normal function of the bone marrow, leading to reduced resistance and impaired response to infection. (See also Neutropenia.)

Early warning score

An index calculated from the observation of vital signs used in patient monitoring, to ensure consistency in planning necessary further action.

Fluid resuscitation

The administration of a substantial volume (typically one litre or more) of fluid intravenously to support blood circulation.

Haemodynamics

The function of the circulation determined clinically – particularly by consideration of heart rate, blood pressure, peripheral tissue perfusion, and central venous pressure.

Inflammation

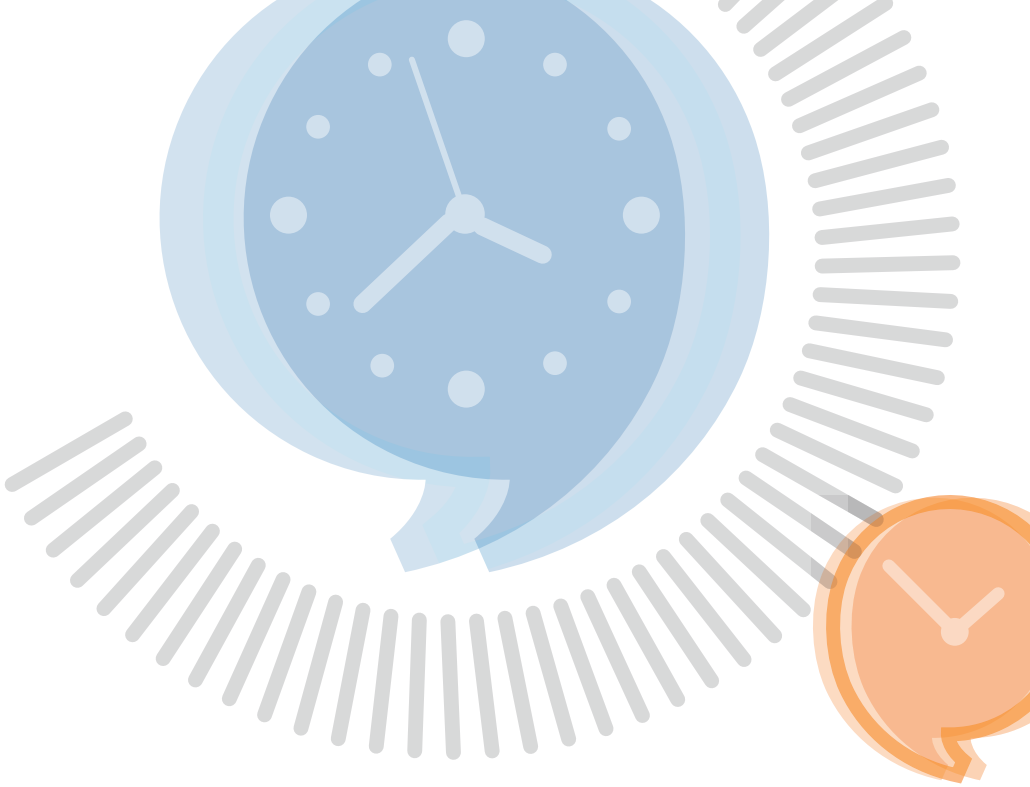
A complex cascade of events the body makes to defend itself against infectious micro-organisms, other harmful substances, and injuries.

Inflammatory markers

Blood tests that may indicate the degree of active inflammation in the body as a whole. Those most commonly considered are the white blood cell count, the C-reactive protein level, and the erythrocyte sedimentation rate. These measures have to be considered in the overall clinical context.

Necrotising fasciitis

Fast-spreading bacterial infection causing tissue death. It can only be treated by urgent and radical surgical removal of infected tissue. (Sometimes known colloquially as the 'flesh eating disease'.)



Neutropenia

A low level of white blood cells in the blood, leading to increased risk of infection and impaired response to it. The usual cause is severe disease of the bone marrow, often caused by treatment for cancer. Sepsis developing in the presence of neutropenia is described as 'neutropenic sepsis'.

Palliative

Treatment given with the intent of easing symptoms, rather than extending life.

Perfusion

Blood circulation through the body systems, assessed clinically by interpretation of physiological observations, the warmth of the hands and feet, and by the rate at which colour returns to tissue after it is compressed.

Physiological observations and monitoring

A set of measurements of vital functions – temperature, pulse, blood pressure, respirations, oxygen saturation and level of consciousness – enabling assessment of the severity of illness. Used to calculate the early warning score.

Pneumonia

A severe infection of the lungs, causing them (in part) to become solid with inflammatory fluid.

Pus

The fluid present in an abscess (see Abscess). It is always cloudy, is often green in colour because of the number of white blood cells present, and is sometimes foul-smelling.

Sepsis

The presence of infection, with evidence of abnormal physiological observations or blood-test results, indicating that the body is making a systemic inflammatory response to defend itself.

Severe sepsis

The features of sepsis, but with additional clinical features such as low blood pressure, indicating impairment of the blood circulation; and/or abnormal blood-test results, indicating that vital bodily functions are beginning to fail (particularly the kidneys, liver, and the blood-clotting function).

Septic shock

When low blood pressure due to sepsis does not respond to intravenous fluid replacement.

Source control

An intervention by surgery or the insertion of a drainage tube for localised severe infection such as an abscess or gangrene.

Sepsis care bundles

A group of interventions that, when implemented together, achieve better outcomes than if implemented singly, derived from the Surviving Sepsis Campaign international guidelines.

Track and trigger

A clinical system in which the early warning score is used to determine the level and urgency of medical review, or the involvement of other clinical teams.

Triage

A clinical process based on the presenting symptom or injury and the measurement of vital signs, used to determine the level of priority for necessary further action.

Vasopressors

Drugs that constrict small blood vessels, so increasing the resistance of the circulation and increasing blood pressure.

Appendix 1 - Standards of care

The Ombudsman's role was set up by Parliament nearly 50 years ago to help individuals and the general public.

We are not part of government or the NHS: our role is to investigate complaints that individuals have been treated unfairly or have received poor service from government departments and other public organisations, and the NHS in England. We ask people to complain to the organisation they are unhappy about before bringing their complaint to us.

Our powers are set out in law and the service is free for everyone. The law gives us the power to investigate individual complaints, and to produce a report on our findings that recommends how mistakes can be put right. If the investigations find big or repeated mistakes, we share this information with regulators to help them do their job.

We share information about our work with Parliament to help them hold government and the NHS in England to account for the service those organisations provide and the way they handle complaints.

We are empowered to investigate complaints about the NHS in England by virtue of the *Health Service Commissioners Act 1993*. In general terms, when determining complaints we begin by comparing what actually happened with what should have happened. To do so, we seek to establish a clear understanding of the evidence, and of the standards that applied at the time the events complained about occurred.

We usually take advice from clinical advisers, who are independent of the organisations complained about, in order to better understand the clinical aspects of a complaint. Specifically, we assess whether or not an act or omission on the part of the organisation or individual complained about constitutes a departure from the applicable standard. If so, we then assess whether, in all the circumstances, those acts or omissions fell so far short of the applicable standard that they constituted service failure.

If we find that service failure has resulted in an injustice, we will uphold the complaint.

General standards of care

The *NHS Constitution* (published 2009, updated 2012) states:

- '[Patients] *have the right to be treated with a professional standard of care, by appropriately qualified and experienced staff in a properly approved or registered organisation that meets required levels of safety and quality.*
- '[Staff] *have a duty to accept professional accountability and maintain the standards of professional practice as set by the appropriate regulatory body.*'

Ombudsman's Principles:

1. Getting it right
2. Being customer focused
3. Being open and accountable
4. Acting fairly and proportionately
5. Putting things right
6. Seeking continuous improvement

Professional standards

The GMC guidance for doctors *Good Medical Practice* (2006) includes:

- Good doctors must keep their knowledge and skills up to date.
- Good clinical care must include: adequately assessing the patient's condition, providing or arranging advice, investigations or treatment where necessary and referring to another practitioner when this is appropriate.

The Nursing and Midwifery Council's *The code: Standards of conduct, performance and ethics for nurses and midwives* (the NMC Code of Conduct) (2008):

- '[The NMC Code of Conduct] *is the foundation of good nursing and midwifery practice and is a key tool in safeguarding the health and well-being of the public.*
- '[Nurses] *are personally accountable for actions and omissions in* [their] *practice and must always be able to justify* [their] *decisions.*'

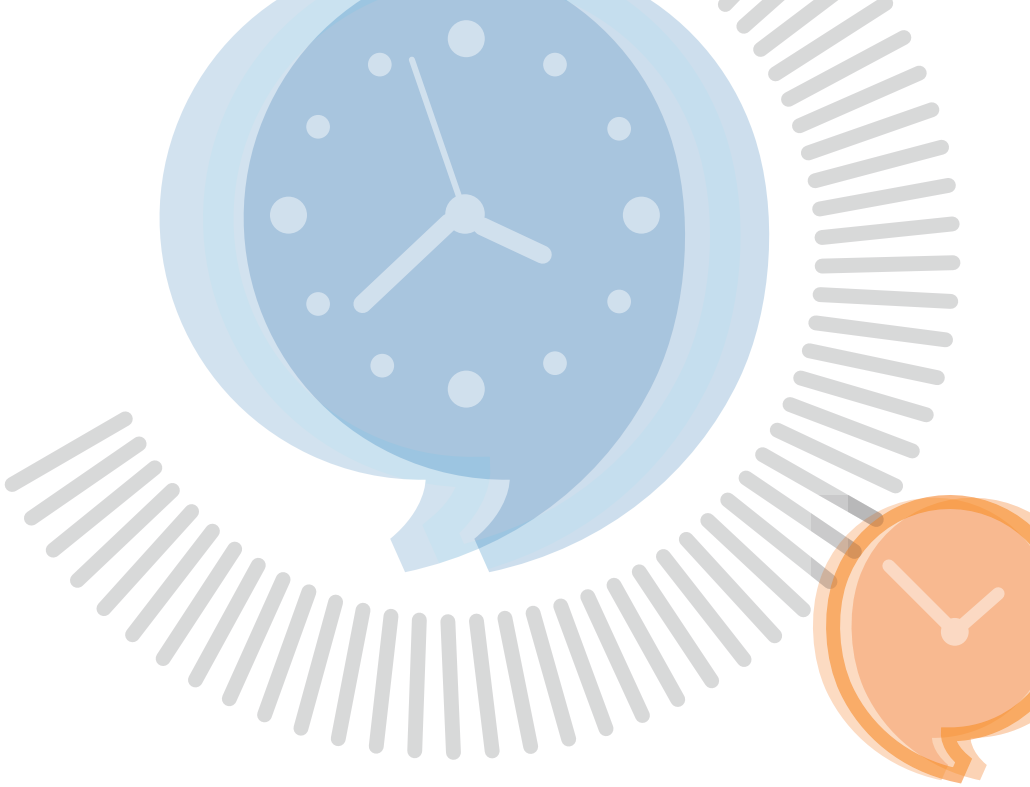
Clinical standards

A number of organisations have published guidance on the essentials of recognition, general care, monitoring and treatment of the acutely and/or critically ill patient.

These include:

- NICE, Clinical Guideline 50, *Acutely ill patients in hospital – Recognition of and response to acute illness in adults in hospital* (2007).
  www.nice.org.uk
- NPSA, Reference 0559, *Safer care for the acutely ill patient: learning from serious incidents* (2007).
  www.nrls.npsa.nhs.uk
- NCEPOD, *Emergency Admissions: A journey in the right direction?* (2007).
  www.ncepod.org.uk
- Royal College of Physicians, *National Early Warning Score (NEWS): Standardising the assessment of acute-illness severity in the NHS – Report of a working party* (2012).
  www.rcplondon.ac.uk

The Royal College of Surgeons has published two reports recently on the specific challenges faced in the provision of quality care for those needing emergency and high-risk surgery (2011). Points emphasised in these reports include the need to afford priority to the acutely ill; the timely input of senior decision makers; the importance of prompt recognition and



treatment; and the immediate care of severe sepsis. Their reports can be found at:
www.rcseng.ac.uk/publications

The Royal College of Obstetricians and Gynaecologists has similarly addressed the issues specifically relating to maternity, where sepsis is now the most common cause of mortality related to childbirth:

- Royal College of Obstetricians and Gynaecologists, Guideline 64b, *Bacterial Sepsis following Pregnancy* (2012). **www.rcog.org.uk**

Hospitals cannot function effectively without adequate staff, infrastructure, support, organisation, and management. The Society for Acute Medicine has published a helpful *Quality Standards for Acute Medical Units*, available at:
www.acutemedicine.org.uk

In Scotland, there have been recent helpful educational initiatives with similar learning messages.

- NHS Scotland, *Joint Collaborative Driver Diagram and Change Package Sepsis* (2012). **www.knowledge.scot.nhs.uk**
- University of Glasgow, *Sepsis: Improving care, improving outcome* (2012). **www.gla.ac.uk**

Standards for the management of acute sepsis

The Surviving Sepsis Campaign is an international collaboration of clinical specialists. It has produced very detailed, evidence-based guidance, published most recently as:

- RP Dellinger, MM Levy, Andrew Rhodes, et al, 2013. Surviving Sepsis Campaign: International guidelines for management of severe sepsis and septic shock 2012. *Critical Care Medicine* 2013; 41: 580-637.

Care bundles – groups of interventions that, when implemented together, achieve better outcomes than if implemented singly – have been derived from the Surviving Sepsis Campaign and are available online at:

www.survivingsepsis.org

The UK Sepsis Trust has summarised the key tasks for immediate care – the 'sepsis six'. These are:

- give high-flow oxygen
- take blood cultures
- give intravenous antibiotics
- start intravenous fluid resuscitation
- check haemoglobin and lactate
- monitor accurate hourly urine output.

Summary

In the investigation of complaints in which the central issue is the clinical management of severe sepsis, our advisers and caseworkers draw these various standards and guidelines together in a way that can be summarised as follows:

For the provision of clinical care:

- Timely history and examination on admission or referral.
- Investigations to determine:
  - Indices of perfusion
  - Indices of infection
  - Source of infection
  - Cultures of blood and other sites.
- Regular physiological monitoring using track and trigger systems.
- Accurate recognition of the severity of the illness.
- Basic resuscitation with:
  - Large-volume fluid therapy (at least 30ml/kg challenge initially)
  - Intravenous broad-spectrum antibiotics after taking cultures
  - Oxygen
  - Vasopressor therapy if required to maintain adequate circulation.
- All of this to commence immediately on recognition of severe sepsis and to be completed within six hours of presentation.
- Source control (drainage of infected fluid collections) to be performed as soon as possible after initial resuscitation.

For the organisation of care:

- Adequate education and training of staff.
- Appropriate and timely senior medical input.

'When early warning scores indicate critical illness or deterioration, sepsis is a likely cause.'

The UK Sepsis Trust

- Timely referral to critical care.
- Formation and documentation of a management plan.
- Protocol for handover.
- Appropriate and timely referral for source control.
- Availability of appropriate drugs, equipment and diagnostic facilities at all times in acute hospitals receiving emergency patients.

Each case story described in this report includes a table of the shortcomings we identified, based on the standards in this summary.

Appendix 2 - Invited evidence from the UK Sepsis Trust

We gratefully acknowledge a very detailed and most helpful briefing report from the UK Sepsis Trust.

Points of particular relevance to our concerns are:

1. Overview

Most cases of sepsis are caused by a community-acquired bacterial infection that is sensitive to antibiotic treatment. Less than 20% relate to healthcare-associated infections. Sepsis is common, with an incidence similar to heart attack, and mortality similar to lung cancer. It brings a substantial cost burden to the NHS, with each hospital admission costing about £20,000.

2. Shortcomings in the delivery of healthcare

Healthcare systems across the world have struggled to implement the Surviving Sepsis guidelines on resuscitation. In the UK in 2008, less than 20% of cases in 18 participating hospitals met the standards.

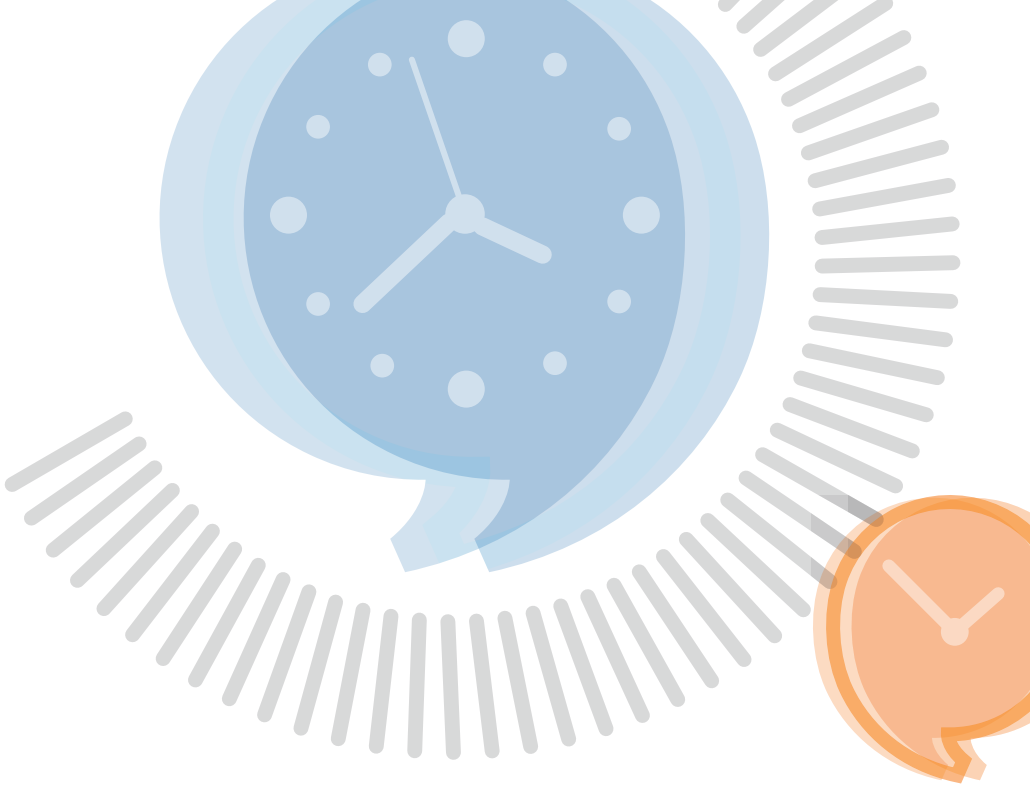
3. Key priorities for change in clinical practice

3.1 Recognition

Early diagnosis of sepsis reduces mortality. Screening tools and automated alerts are available but are not in widespread use. Where clinical information is stored electronically, software systems can detect sepsis before the clinical team has suspected it. A multidisciplinary and multispecialty approach to sepsis care improves outcomes, and needs to be supported by continuing education, implementation of protocols, data collection and audit, and feedback to facilitate continuous improvement.

3.2 Key therapeutic interventions

The reliable, early delivery of basic treatments like fluids and antibiotics has the greatest impact on improving outcomes. Identifying the causative organism by blood culture enables more focused antibiotics to be used, reducing complications and the risk of emerging antibiotic resistance. Each hour of delay in antibiotic administration increases the risk of death – delay also leads to longer hospital stays and thus greater cost. Compliance with current guidelines improves outcomes to the extent of saving one life for every four cases where it is implemented.



3.3 Systems (of care provision) change

Different systems are required to meet the needs of sepsis patients according to where they are being cared for. In the community, the issues concern recognition. In ambulances, there are opportunities for prehospital care. In emergency departments, where all necessary information is collected at about the same time, performance for sepsis contrasts unfavourably with that for other conditions such as myocardial infarction. In hospital wards, where the necessary information is collected at different times and in different formats, there are opportunities for automatic screening and end-of-shift review. There are ways to enhance the interfaces between all parts of the health system so as to reduce the time before treatment is started.

3.4 Communication and escalation

When there is no response to initial treatment, the involvement of senior staff and critical care specialists in decision making is needed. Delay in obtaining such support is common, and contributes to poor patient outcomes. No standards have yet been agreed to help manage these delays.

4. Priorities for strengthening the clinical evidence base

4.1 Administration of intravenous fluids

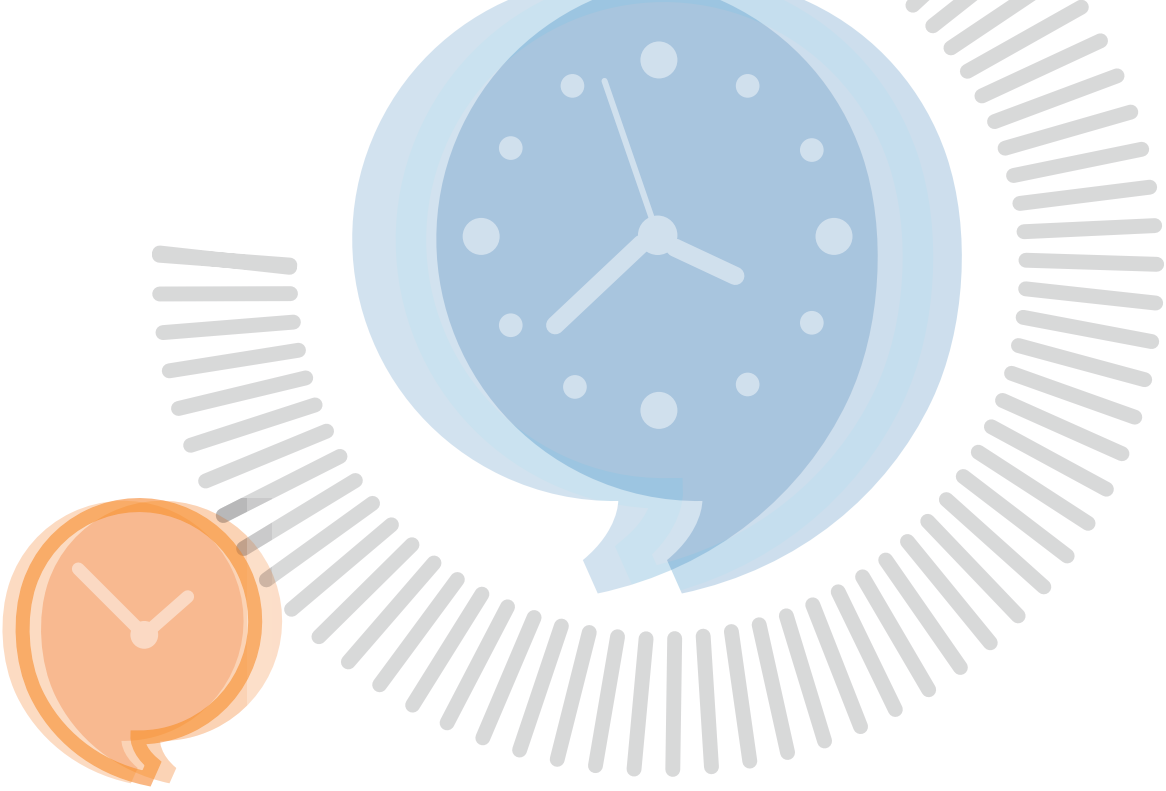
Restoring blood volume is a central tenet of sepsis treatment. The volume needed, and the rate of infusion, are not clear. The efficacy of fluid challenge is uncertain, and clarity on these matters will inform the design of prehospital care practice.

4.2 Prehospital recognition

The development of screening tools to detect sepsis reliably out of hospital would provide opportunities to shorten the period before antibiotics are administered.

4.3 Interface between primary and secondary care

There is no information available on the incidence of sepsis presenting to primary care and to the ambulance service. Such information is necessary to develop the collaborative clinical pathways that have been effective in improving outcomes for other critical conditions.



4.4 Biomarkers and rapid pathogen identification

The evaluation of measurement of substances in the blood to enable earlier confirmation of suspected sepsis and define its severity could reduce treatment delays. New technologies to identify the causative bacterium earlier would enable the cost and safety benefits of changing to more selective antibiotics to be achieved sooner.

5. Barriers to improving clinical outcomes

5.1 Public health data

Information on incidence and outcomes is limited to intensive care patients. Shortcomings in the international classification of disease codes for sepsis have resulted in under-recording. Death certificates are often incomplete, illogical, or inaccurate. In turn, this confounds disease monitoring.

5.2 Awareness and training

Although the GMC provides general guidance on the undergraduate curriculum, detail is the prerogative of individual medical schools. Sepsis as a topic is covered variably, and tends to be a matter for postgraduate education. Its complexity requires reinforcement by a rolling programme of education for which time is difficult to identify.

5.3 Resources

While greater benefits may be achieved by improving basic care, providing the invasive aspects of the resuscitation bundle requires high dependency capacity and highly skilled staff, which are not always available.

5.4 Acceptance of guidelines

The ways that clinicians work, and the complexity of the evidence, explain why it always takes time to change clinical practice. Sepsis is still not always accepted as an emergency in the way that heart attack is. The benefits of first concentrating on non-contentious basic interventions are recognised.

Appendix 3 - Evidence from the College of Emergency Medicine

The following is evidence given to us by the College of Emergency Medicine.

Introduction

The College was aware of the launch of the Surviving Sepsis Campaign and fully supported it, because the potential reduction in death, suffering and disability for patients is enormous. In 2008 an expert panel, including emergency physicians, consultants in intensive care and nurse consultants met on several occasions to develop a set of clinical standards, which were published and distributed to all consultants and emergency departments in May 2009. This is one of several initiatives the Clinical Effectiveness Committee is currently taking to focus on quality care and safety for sick patients presenting to emergency departments.

Following publication of these standards, one year was allowed for the implementation of these changes and the introduction of a care pathway for this important group of patients. This was followed in 2011 by a national audit against the College's standards. 160 emergency departments (74%) participated and it was completed on 31 January 2012. On 18 May 2012 each participating trust was sent an individualised report containing their audit result, and direct comparisons with national results, so their performance could be clearly seen.

This audit covered key areas of quality of care:

- Recording of vital signs on arrival (temperature, pulse, blood pressure, and so on).
- Oxygen delivery on arrival.
- Taking of important blood tests, including culture for bacteria in the blood.
- Timely administration of powerful antibiotics.
- Starting intravenous fluids to restore or maintain blood pressure.
- Measuring the amount of urine to monitor response to treatment.

A detailed report with full findings is available at the College of Emergency Medicine website.

www.collemergencymed.ac.uk

In summary, the results of the audit indicated that approximately 80% of patients receive good quality care, but that in the remaining 20% care is substandard. We are also aware, from previous smaller departmental audits and from the literature, that there are occasional catastrophes both within emergency departments and in hospital. This is a condition that can and does occur on the wards and is not exclusively an emergency

'Once a septic patient has been identified, they should be managed as an urgent priority.'

The College of Emergency Medicine

department problem. Another striking feature was the variation between hospitals, and this is a common finding in our audits that we have been conducting for ten years. The development of the standard and the audit was the Clinical Effectiveness Committee addressing these very issues.

It is also important to note that a septic patient is not like an accident victim or heart attack patient, where the diagnosis and the need for urgent treatment are usually immediately obvious. Septic patients present in many ways, with vague symptoms, and may be elderly with several illnesses (called co-morbidities) which disguise and complicate the diagnosis. Emergency departments are very busy, with ambulances and walk-in patients, arriving frequently, and it is not easy to identify this group of patients quickly in a complex environment. There are lots of pressures with chest-pain patients, strokes, severe pain, psychiatric conditions, distressed relatives, drunk or abusive patients, and so on. Frequently there are several patients requiring urgent treatment at the same time.

Following the audit, in July 2012 the following recommendations were made by the College and widely distributed to senior emergency department clinicians and trust clinical effectiveness/clinical audit teams.

Recommendation 1

It is clear from the audit results that some departments have successfully implemented a sepsis pathway, but other departments have not yet done so. If an emergency department has not put in place a system which identifies the potentially septic patient on arrival, this should be introduced at the earliest opportunity to prevent lives from being lost unnecessarily.

Recommendation 2

Once a septic patient has been identified, they should be managed as an urgent priority, ensuring early delivery of intravenous fluids and antibiotics. This should occur within one hour of arrival, wherever possible.

Recommendation 3

Prescription of oxygen and the initiation of urine output measurement are well below the required standard across emergency departments. This should be emphasised in training programmes and departmental protocols.

Recommendation 4

The College recommends that this audit is repeated in two years.

In addition to these recommendations, the College has had further discussions on how we can act upon the findings of the audit:

Action 1

A fresh national awareness campaign on the importance of early diagnosis and treatment across the specialty before the repeat audit.

Action 2

Communication with chief executives, trust boards and emerging clinical commissioning groups to make them aware and encourage support.

Action 3

Early intervention of senior staff and extending the hours, especially in the evenings and weekends, where consultants are on the 'shop floor', which will require recruiting more consultants in some hospitals.

Action 4

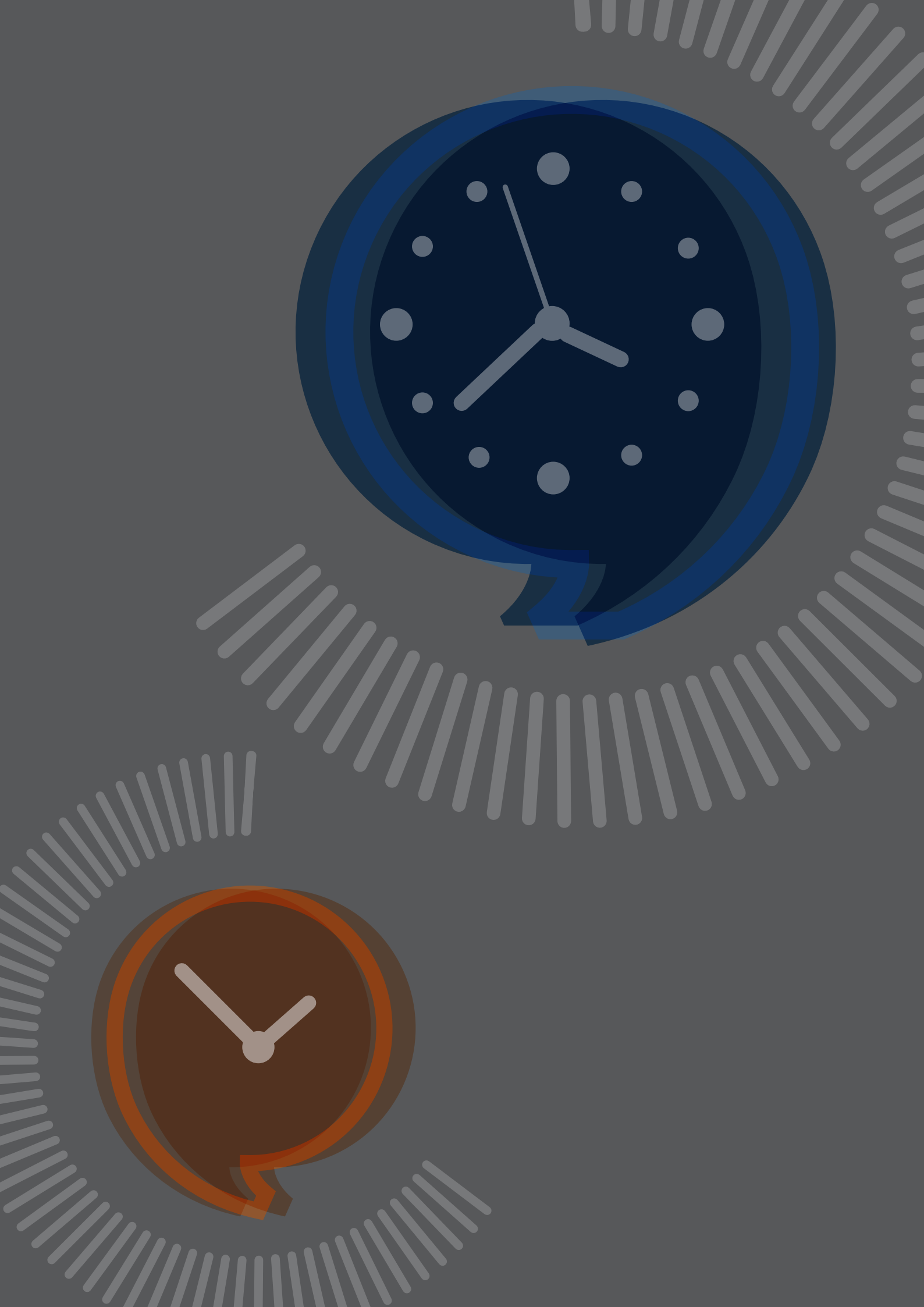
Renewed emphasis and frequency of training for nursing and medical staff in departmental and specialist training programmes.

Action 5

Engaging more with nursing staff so that the departmental care pathways are jointly prepared and implemented.

Action 6

Ensuring all emergency departments have a blood gas machine in the department that can measure lactate, so that results are available in minutes.



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