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HEALTHCARE SAFETY INVESTIGATION BRANCH

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Treating COVID-19 patients using Continuous Positive Airway Pressure (CPAP) outside of a critical care unit

Independent report by the
Healthcare Safety Investigation Branch NI-003087

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About HSIB

We conduct independent investigations of patient safety concerns in NHS-funded care across England. Most harm in healthcare results from problems within the systems and processes that determine how care is delivered. Our investigations identify the contributory factors that have led to harm or the potential for harm to patients. The safety recommendations we make aim to improve healthcare systems and processes, to reduce risk and improve safety.

We work closely with patients, families and healthcare staff affected by patient safety incidents, and we never attribute blame or liability.

Considerations in light of coronavirus (COVID-19)

A number of HSIB national investigation reports were in progress when the COVID-19 pandemic significantly affected the UK in 2020. Much of the work associated with developing the reports necessarily ceased as HSIB's response was redirected.

For this national report, the investigation continued as the pandemic progressed due to its association with COVID-19.

A note of acknowledgement

HSIB thanks Terry's family, who shared the events documented in this report. They gave generously of their time and were involved and supportive throughout the investigation. In accordance with their wishes, Terry is referred to by name throughout this report.

HSIB also thanks the healthcare staff for their engagement with the investigation, and for their openness and willingness to support improvements in this area of care.

About Terry

Terry was married to Pat. Together they had six children. Terry is described as a “real family man” who loved his grandchildren and “loved helping people”. He previously worked as a butcher and enjoyed building things in his spare time. Terry loved Christmas and decorated his home with amazing Christmas lights. This was a yearly commitment through which he raised money for charity, dressing up as Father Christmas and showering the street and its excited children and their parents in pretend snow. Terry had decorated his house prior to his admission to hospital in December with the help of his son. In the year Terry died, he had raised £4,000 for charity.

About the report

This report is intended for healthcare organisations, policy makers and the public to help improve patient safety in relation to the management of patients with COVID-19 being treated with non-invasive respiratory support, for example continuous positive airway pressure (CPAP), in non-critical care environments. For readers less familiar with this area of healthcare, medical terms are explained within the report.

Disclaimer

Non-invasive ventilation, high-flow nasal oxygen and continuous positive airway pressure (CPAP) are used as forms of non-invasive respiratory support for those with respiratory failure, which has not responded to conventional oxygen therapy. This investigation report is primarily focussed on the use of CPAP as a form of non-invasive respiratory support outside of the critical care unit. Some of the principles of care for patients receiving CPAP in this report will also be applicable to patients receiving non-invasive ventilation and high-flow nasal oxygen; however, the specifics of monitoring and staffing requirements may be different.

Our investigations

Our investigators and analysts have diverse experience of healthcare and other safety-critical industries and are trained in human factors and safety science. We consult widely in England and internationally to ensure that our work is informed by appropriate clinical and other relevant expertise.

We undertake patient safety investigations through two programmes:

National investigations

Concerns about patient safety in any area of NHS-funded healthcare in England can be referred to us by any person, group or organisation. We review these concerns against our investigation criteria to decide whether to conduct a national investigation. National investigation reports are published on our website and include safety recommendations for specific organisations. These organisations are requested to respond to our safety recommendations within 90 days, and we publish their responses on our **website**.

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We investigate incidents in NHS maternity services that meet criteria set out within one of the following national maternity healthcare programmes:

- Royal College of Obstetricians and Gynaecologists' 'Each Baby Counts' report
- MBRRACE-UK 'Saving Lives, Improving Mothers' Care' report.

Incidents are referred to us by the NHS trust where the incident took place, and, where an incident meets the criteria, our investigation replaces the trust's own local investigation. Our investigation report is shared with the family and trust, and the trust is responsible for carrying out any safety recommendations made in the report.

In addition, we identify and examine recurring themes that arise from trust-level investigations in order to make safety recommendations to local and national organisations for system-level improvements in maternity services.

For full information on our national and maternity investigations please **visit our website**.

Executive Summary

Background

This investigation explores the issues associated with caring for patients attending hospital with COVID-19 who need help with their breathing. Often this help takes the form of oxygen therapy, where oxygen is given through a face mask or through little tubes that sit in the nose. Even with oxygen therapy, however, some patients still cannot take in enough oxygen to breathe. When this happens, a patient is described as being in respiratory failure. These patients' oxygen levels may be improved by using a special device that delivers a flow of oxygen-enriched air at a constant pressure through tubing and a mask, or hood, worn by the patient. This is known as continuous positive airway pressure (CPAP). CPAP is a form of non-invasive (that is, used outside the body) respiratory support that is used when the patient is awake and able to breathe on their own.

CPAP is often used to support a patient's breathing in critical care or high-dependency units, where there are high numbers of staff to patients. Staff in these units are trained and familiar with the use of non-invasive respiratory support. During the first and second waves of the COVID-19 pandemic, however, many more patients needed CPAP than there were beds in critical care and high-dependency units. Thus, hospitals had to create alternative areas and arrangements for delivering and caring for patients who needed CPAP.

This investigation explores the use of CPAP outside of critical care and high-dependency units during the COVID-19 pandemic. Specifically, the investigation explores the risks of caring for acutely unwell patients requiring CPAP in the side rooms of general wards.

As an example, which is referred to as 'the reference event', the investigation considered the death of Terry, who was admitted to hospital with symptoms of COVID-19 and required support with his breathing using CPAP. Terry was cared for in the side room of a medical ward. On the second day after his admission to hospital, Terry was found on the floor next to his bed, having called for assistance. Terry's CPAP tubing had become disconnected from his mask, meaning that Terry's breathing was not supported. Staff attempted to resuscitate Terry. They were not successful and Terry died.

The investigation's findings aim to improve the safety of patients being treated in side rooms and other clinical areas outside of a critical care unit, and so improve care for patients across the NHS. The findings and conclusions of this investigation may be applicable to other conditions that require patients to be cared for in a side room.

The reference event - December 2020

Terry's family telephoned for an ambulance after Terry had become increasingly unwell at home with symptoms of COVID-19. He was admitted to the emergency department of his local hospital and was initially given oxygen therapy via a facemask to support his breathing. Other recommended medications for treating COVID-19 were started after Terry tested positive for the infection.

Despite oxygen therapy, Terry's oxygen kept dropping below acceptable levels. The decision was made to start non-invasive respiratory support using CPAP. Because CPAP is an aerosol-generating procedure, meaning small airborne particles (aerosols) can be released from the respiratory tract when it is used, Terry required nursing in a side room to reduce the risk of COVID-19 cross-infection to other patients and staff. Terry was therefore transferred to a side room on a medical ward to receive CPAP. Terry found the CPAP mask uncomfortable, and it caused him anxiety at times.

Terry's condition, including his changing oxygen requirements, was monitored. In addition to care given by medical and nursing staff on the ward, Terry was regularly seen by nurses from the critical care outreach team. He was also seen by a doctor from the critical care unit.

At approximately 20:05 hours on Terry's second day after admission, Terry called for help using his call bell. The ward was extremely busy at this time because of a staff shortage, coupled with competing clinical priorities and a new patient arriving on the ward with more admissions expected. A nurse was putting on her personal protective equipment ready to enter Terry's room and looked though the observation window. She could see Terry lying unmoving on the floor with his head under the bed. The CPAP machine and other alarms, which would normally alert staff to a potential problem, could not be heard outside of the side room.

On entering the side room, the nurse pressed the emergency buzzer and asked for the resuscitation team to be called. Terry still had the CPAP mask on his face but the tubing was disconnected. Terry did not respond to resuscitation attempts and died.

National investigation

During the peaks of the COVID-19 pandemic, increased numbers of people required admission to hospital because of respiratory failure. There was a corresponding increase in patients requiring non-invasive respiratory support with CPAP. CPAP is an aerosol-generating procedure, meaning it can result in the release of airborne particles (aerosols) from the respiratory tract (that is, the organs involved in breathing). When someone is suspected or known to be suffering from an infectious agent such as COVID-19, these particles pose a risk of infection to others. Therefore, patients with suspected or known COVID-19

who needed CPAP were treated in special areas to reduce the chance of infecting others. Such areas included negative pressure side rooms (that is, a room where the air pressure inside the room is lower than that outside the room) or specific clinical areas, such as a respiratory support unit, to which groups of patients requiring CPAP could be moved.

The Healthcare Safety Investigation Branch (HSIB) contacted the hospital where the reference event occurred. The trust at which the reference event took place (referred to in this report as 'the Trust') welcomed HSIB's involvement and collaborated with information gathering. Early evidence gathering found that national bodies had recently developed guidance and recommendations in relation to the use of CPAP outside of critical care settings. The Chief Investigator authorised a national safety investigation to identify if the guidance and recommendations from the national bodies addressed the safety issues identified from the reference event.

The investigation highlights areas that have been recognised as significant during the NHS response to the COVID-19 pandemic to date, in particular:

- workforce gaps and skills needed to meet demand, both on general wards and in critical care environments
- challenges with delivering treatment outside normal clinical areas
- challenges for staff working outside their normal clinical areas
- the use of equipment that may have design limitations, particularly if used outside the environment for which it was intended.

Findings

The investigation found the following:

- Patients with COVID-19 who are treated with CPAP require close monitoring and observation. Caring for such acutely unwell patients in side rooms on general wards poses a safety risk as, unless there is central monitoring (that is, where staff at the central nurses' station can observe patients via monitors that duplicate the bedside monitors screens and alarms), staff will not be able to easily see the patient. Furthermore, equipment alarms designed to alert staff to a problem often cannot be heard outside of the room.
- There are staffing challenges and other pressures associated with caring for acutely unwell patients who require non-invasive respiratory support, such as CPAP, outside of critical care or high-dependency units.

- During the first and second waves of the COVID-19 pandemic, staffing levels were affected by the need for staff to self-isolate. More recent Public Health England guidance produced during the HSIB investigation – which removes the need for fully vaccinated people (provided certain criteria is met) to self-isolate after contact with a person with COVID-19 - may mitigate against the staffing challenges seen during the reference case.

- Staff caring for patients with COVID-19 requiring CPAP on general wards need training and competency assessment to feel confident in delivering care.

- National guidelines define a mandatory nurse-to-patient ratio for patients receiving acute non-invasive ventilation (NIV) of 1:2 (that is, one nurse should care for no more than two patients) until the patient is weaned to nocturnal (night-time) NIV only. This ratio reflects the fact that patients receiving acute NIV are at risk of deterioration, unplanned admission to a critical care unit and death. The national guidance is clear that although the nurse-to-patient ratio in a respiratory support unit would be 1:4, increased acuity of illness requires additional staff on the unit. In the reference event, it was not possible to achieve these nurse-to-patient ratios on a medical ward.

- National guidance documents from the Intensive Care Society, the British Thoracic Society, Getting It Right First Time and others published during the HSIB investigation make recommendations that addressed the safety risks identified. The published guidance includes the following:

    - Hospitals should establish respiratory support units that are staffed in line with existing national recommendations. This includes a minimum nurse-to-patient ratio of 1:4, with nurses trained in administering CPAP and high-flow nasal oxygen.

    - Patients requiring non-invasive respiratory support such as CPAP should be centrally monitored. Central monitoring allows patients to be observed and equipment alarms to be heard at the central nurses' station.

    - Hospitals should have protocols that define the frequency of nursing review (that is, how often a nurse checks on a patient), especially for acutely unwell patients located in side rooms.

    - Hospitals should have checklists for the safe use of CPAP/NIV outside of critical care and high-dependency units. For example, the British Thoracic Society and Intensive Care Society (2021a) guidance on establishing respiratory support units includes a checklist for the safe use of CPAP/NIV outside of critical care and high-dependency units.

- Minimum safe staffing levels should be followed when caring for patients who require non-invasive respiratory support.

- Where possible, organisations should procure CPAP devices that allow remote monitoring.

- Staff caring for patients requiring non-invasive respiratory support outside of critical care settings should meet training and competency requirements.

Because recommendations have already been made by national bodies in recently published guidance, this report makes no safety recommendations. HSIB encourages organisations to act on the national guidance and resultant recommendations when caring for patients with COVID-19 requiring non-invasive respiratory support, including CPAP, outside of a critical care setting.

Based on the above findings:

HSIB asks healthcare providers to consider the following safety questions

Safety question 1:
Do you have an operational policy that includes the areas of the hospital where non-invasive respiratory support can be provided? Does your operational policy include the minimum safe level of staff competencies, the minimum nurse-to-patient ratio for patients receiving non-invasive respiratory support on the ward, and the minimum frequency of clinical review? Standard requirements that should be included in an operational policy can be found in the 'Inspiring change' report (National Confidential Enquiry into Patient Outcome and Death, 2017), joint guidance by the British Thoracic Society and Intensive Care Society (2021a) on developing and implementing respiratory support units, and the Getting It Right First Time (2021) review of respiratory medicine.

Safety question 2:
Do you use side rooms to care for patients requiring non-invasive respiratory support? If so, how do you ensure that monitors and alarms can be seen and heard by staff when outside of the room? Do you have central monitoring?

Safety question 3:
Do your continuous positive airway pressure (CPAP) devices have the capability for remote monitoring?

Safety question 4:
Do you have the required staff and skill mix to care for patients requiring non-invasive respiratory support in side rooms on a general ward? How are issues with staffing and workload escalated and responded to? Are senior trust personnel aware and involved?

Safety question 5:
Do your staff have the required training and competency assessments to care for patients requiring non-invasive respiratory support? Examples of appropriate training and competency assessments include the 'COVID-19 skills preparation course' (European Society of Intensive Care Medicine, 2021) and the 'National competency framework for registered practitioners: level 1, patients and enhanced care areas' (National Outreach Forum and Critical Care Networks – National Nurse Leads, 2018).

Safety question 6:
Do your staff complete a checklist (for example, the 'SAFER NIV/CPAP – a checklist for use in pandemic response and on respiratory support units' or similar) (British Thoracic Society and Intensive Care Society, 2021a) when a decision has been made to initiate non-invasive ventilation/continuous positive airway pressure (CPAP) and at every shift change?

Contents

1 Background and context

1.1 COVID-19

1.1.1 Coronavirus disease (COVID-19) is caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus. This report refers to COVID-19 throughout to encompass both terms for ease of reference.

1.1.2 In the UK, the first cases of COVID-19 were confirmed on 31 January 2020 and the first death was reported on 5 February 2020. By 7 March 2020, there were 316 confirmed cases of COVID-19 in the UK and a further 4 people had died (**Healthcare Safety Investigation Branch, 2020a**). On 11 March 2020, the World Health Organization (2020) declared a pandemic. The pandemic continued to progress rapidly and, on 23 March 2020, the prime minister announced a full lockdown across England.

1.1.3 COVID-19 infection varies in severity from no symptoms in some individuals to severe pneumonia in others. People who are older, male, from deprived areas or from Black and Asian minority ethnic groups have a higher chance of developing severe disease. The chance of severe disease in adults also increases with obesity and in those with co-morbidities (such as chronic obstructive pulmonary disease, cystic fibrosis, asthma, cardiovascular disease and diabetes), frailty, impaired immunity or a reduced ability to cough and clear secretions. Patients with severe symptoms of COVID-19 can deteriorate rapidly, and older patients with co-morbidities may have a higher chance of deteriorating (National Institute for Health and Care Excellence, 2021a).

1.1.4 The National Institute for Health and Care Excellence (NICE) has developed guidelines to maximise patient safety, optimise treatment, protect staff from infection and make the best use of NHS resources (National Institute for Health and Care Excellence, 2021b). These guidelines include recommendations around providing usual care during the pandemic (such as critical care or systemic anti-cancer treatments), and for managing symptoms (including at the end of life) and suspected/confirmed pneumonia in patients with COVID-19. NICE has also developed rapid evidence summaries focusing on whether certain medications (such as non-steroidal anti-inflammatory drugs) increase the severity or length of the COVID-19 illness, and advice on the safety and efficacy of COVID-19 treatments (National Institute for Health and Care Excellence, 2021a).

1.2 Patients with COVID-19 who need help with their breathing

1.2.1 The SARS-CoV-2 infection that causes COVID-19 typically causes respiratory symptoms, and patients with severe illness are likely to develop respiratory failure (Guan et al, 2020). A significant proportion of people attending

hospital with COVID-19 need help to maintain their oxygen levels within a target range. Often this help takes the form of oxygen therapy, where oxygen is given through a face mask or through little tubes that sit in the nose. Even with oxygen therapy, however, some patients still cannot take in enough oxygen to breath. When this happens, a patient is described as being in respiratory failure.

1.2.2 Oxygen therapy is guided by the level of oxygen in a patient's blood, known as their oxygen saturation level. The target range for oxygen levels, according to NICE guidelines (National Institute for Health and Care Excellence, 2021a) for oxygen use during the COVID-19 pandemic, is 92–96% (or 88–92% for patients with certain pre-existing conditions, such as chronic obstructive pulmonary disease). The rate of breathing (the respiratory rate) and the breathing pattern will also be observed. The expected respiratory rate in a healthy adult is 12–20 breaths per minute.

1.2.3 During the first wave of the COVID-19 pandemic (which peaked between the end of March and early April 2020 in England), almost three quarters of patients who were admitted to critical care received invasive mechanical ventilation (Intensive Care National Audit and Research Centre, 2020). This means the patient was attached to a machine (often called a mechanical ventilator) to help them breathe when they could not breathe on their own. Patients are connected to the ventilator with a hollow tube (artificial airway) that goes in their mouth and down into their main airway. The machine helps make sure the body receives enough oxygen. The patient is given medicine to keep them asleep and comfortable during this type of ventilation.

1.2.4 This changed as options for providing respiratory support to patients with COVID-19 expanded (Torjesen, 2021). Getting It Right First Time (2020) reported that using non-invasive forms of ventilation, such as continuous positive airway pressure (CPAP) and high-flow nasal oxygen, could reduce the need for invasive ventilation. As understanding of COVID-19 progressed, innovations in practice using non-invasive respiratory support outside of critical care settings were implemented (Lawton et al, 2021; Ashish et al, 2020; Walker et al, 2020; Nightingale et al 2020).

1.2.5 In March 2020, NHS England and NHS Improvement (2020a) produced guidance stating that CPAP was the preferred form of non-invasive respiratory support for patients with COVID-19 who were unable to maintain their oxygen levels within a safe range. CPAP was not intended to replace invasive mechanical ventilation if it was needed. Following the release of this guidance, there was an increase in the number of people requiring non-invasive respiratory support during the peaks of the COVID-19 pandemic (British Thoracic Society and Intensive Care Society, 2021a).

1.2.6 CPAP delivers a flow of oxygen-enriched air at a constant pressure through tubing, which is connected to a mask or hood worn by the patient (see figure 1). It is used with patients who can breathe on their own. CPAP keeps a patient's alveoli (the small sacs at the end of the body's breathing tubes) open at the end of an out-breath. This increases the patient's oxygenation and reduces the work of breathing.

1.2.7 Hoods and masks can be distressing for patients, and have been described by those wearing them as causing a sense of claustrophobia and breathlessness.

Figure 1 Example of CPAP devices using a mask or hood

Image courtesy of **Intersurgical Ltd**, 2021

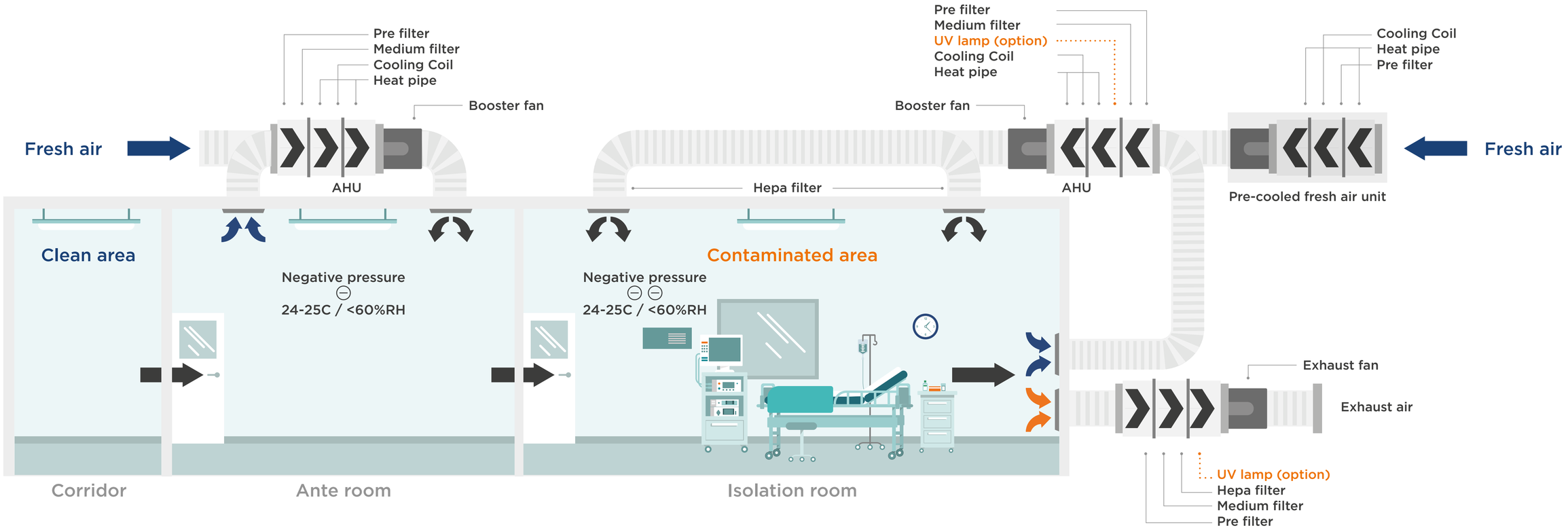
1.2.8 In 2021, the British Thoracic Society and Intensive Care Society (2021b) produced joint guidance that referred to the use of CPAP. The guidance detailed which patients could be looked after in non-critical care settings and what criteria should be used to move them to areas with higher-acuity treatments (options for more specialist interventions).

1.2.9 A large trial of non-invasive respiratory support (the RECOVERY-RS trial) was launched in April 2020. The findings, published in August 2021, showed a reduced need for invasive ventilation in patients with COVID-19 who were treated with CPAP compared with conventional oxygen therapy (National Institute for Health Research, 2021).

1.2.10 CPAP is on the Public Health England (2021a) list of aerosol-generating procedures, meaning small airborne particles (aerosols) can be released from the respiratory tract when it is used. These particles pose a risk of infecting others. As such, patients who needed aerosol-generating procedures such as CPAP were initially cared for in negative pressure side rooms (see section 1.2.11). As the number of patients requiring CPAP increased, patients were grouped together in specific ward areas.

1.2.11 In negative pressure rooms, the air pressure inside the room is lower than the air pressure outside the room. This means that when the door is opened, potentially contaminated air or other dangerous particles from inside the room will not flow out into non-contaminated areas. Instead, non-contaminated filtered air flows into the negative pressure room. Contaminated air is sucked out of the room via exhaust systems, which have filters to clean the air before it is pumped away from the healthcare facility (see figure 2)

Figure 2 Example of a negative pressure side room



1.3 Pathways of care for patients with and without COVID-19

1.3.1 Public Health England (2020) has provided guidance to help organisations develop patient pathways according to the patient's chance of having COVID-19. The guidance recommended that patients with respiratory symptoms should be assessed in a segregated area, ideally a single room pending test results. The three recommended COVID-19 pathways are as follows:

- High risk: individuals who are confirmed to have COVID-19 by a PCR test or who are symptomatic and suspected to have COVID-19 (awaiting test result). This is sometimes referred to as the red pathway.

- Medium risk: individuals who have no symptoms of COVID-19 and are waiting for a PCR test result, and those who are asymptomatic for COVID-19 but who are known to have had contact with another person with the disease.

- Low risk: individuals who have no symptoms of COVID-19 and a confirmed negative PCR test. This is sometimes referred to as the green pathway.

1.3.2 In addition to assigning patients to a pathway, organisations were expected to undertake local risk assessments to manage patients attending their healthcare facilities. The risk assessment was expected to consider the ventilation in the area and the prevalence of patients with confirmed or suspected COVID-19 (red/high-risk pathway).

1.3.3 The healthcare setting where investigation of the reference event was undertaken had red and green pathways. All patients were swabbed on arrival at the hospital. The hospital created a 'COVID result pending' isolation admissions unit, which consisted of side rooms. Following a PCR test result, patients were grouped together on the appropriate ward.

1.4 National Early Warning Score (NEWS)

1.4.1 NEWS is a tool developed by the Royal College of Physicians to standardise the assessment and response of acutely ill patients. Its use aims to improve the detection of and response to clinical deterioration in adult patients. In December 2017 an updated version of NEWS, called NEWS2, was published and endorsed by NHS England and NHS Improvement for use in acute and ambulance settings (Royal College of Physicians, 2017). NEWS2 should supplement clinical judgement when assessing a patient's condition (Royal College of Physicians, 2020).

1.4.2 The physiological parameters that form the basis of NEWS2 include:

- respiratory rate
- oxygen saturation
- systolic blood pressure
- pulse rate
- level of consciousness or new confusion
- temperature.

1.4.3 A score is allocated to each parameter as it is measured, with the total score reflecting the patient's health. The score is increased by 2 points for patients who require supplemental oxygen to maintain their recommended oxygen saturation level (that is, the level of oxygen in the patient's blood) (Royal College of Physicians, 2017).

1.4.4 A low NEWS2 (1–4 points) should prompt assessment by a competent registered nurse or equivalent, who should decide whether the frequency of clinical monitoring needs changing or clinical care should be escalated. A high NEWS2 (7 points or more) is a key trigger threshold that should prompt emergency assessment by a clinical team or critical care outreach team with critical care competencies, who will consider transferring the patient to a higher-dependency care area (see figure 3) (Royal College of Physicians, 2017).

Figure 3 NEWS2 thresholds and triggers

Reproduced from: Royal College of Physicians. National Early Warning Score (NEWS)2: Standardising the assessment of acute-illness severity in the NHS. Updated report of a working party

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

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

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

1.4.5 Clinical judgement should always be used, even if the NEWS2 is within the expected range.

1.4.6 In April 2020, the Royal College of Physicians (2020) released guidance that emphasised the place of NEWS2 in managing patients with COVID-19. The guidance highlighted that, once hospitalised and treated with oxygen, a patient's oxygen requirements might increase rapidly if their respiratory function deteriorated, but that this might not result in any additional significant increase in the NEWS2. The difficulties in identifying clinical deterioration in patients with COVID-19 on general hospital wards was also shared in an HSIB report (**Healthcare Safety Investigation Branch, 2020b**). Therefore, in patients with COVID-19, all staff should be aware that any increase in oxygen requirements should trigger escalation to a healthcare professional for a decision about any changes required to treatment.

1.5 Critical care outreach team (CCOT)

1.5.1 CCOTs provide intensive care for patients with, or at risk of, critical illness who are receiving care in locations outside of a critical care unit (National Institute for Health and Care Excellence, 2018). CCOTs support clinical staff and patients in a variety of scenarios, including managing conditions such as sepsis and treatment-escalation planning.

1.5.2 The main role of a CCOT is to identify and institute treatment in patients who are deteriorating within the hospital but are being cared for outside of a critical care unit. The aim of this support is to help prevent the patient's admission to critical care or to make sure that they are admitted to a critical care bed in a timely manner to ensure the best outcome.

1.5.3 The Trust where the reference event occurred had a 24/7 CCOT service, which was maintained throughout the peaks of COVID-19 admissions.

2 The reference event – December 2020

This investigation used the following patient safety incident, referred to as 'the reference event', to consider the safety risks of treating patients with COVID-19 with continuous positive airway pressure (CPAP) respiratory support outside of critical care or high-dependency units. Specifically, the Patient, Terry, was cared for in a side room on a medical ward.

Terry's fluctuating National Early Warning Score (NEWS) and oxygen requirements were not unusual for patients admitted to hospital with COVID-19 who required support with their breathing. Terry was treated in line with national guidelines. To help readers of this report with a clinical background to better understand decision-making, a full chronology can be found in **Appendix 1**. The current section is intentionally brief on clinical detail as the safety risk relates specifically to treating patients with COVID-19 with CPAP outside of critical care and high-dependency units.

2 Details of the event

Before admission to hospital

2.1.1 Terry was 73 years old at the time of his admission to hospital. He had type 2 diabetes, coronary artery disease, asthma, a high cholesterol level and hypothyroidism. He had undergone coronary artery bypass graft surgery in 2004 and was taking medicine for an abnormal heart rhythm. At the time of his admission, Terry was under the care of a doctor for syncope (fainting or passing out). Terry lived independently at home with his wife, and was described as an active man who did not like to ask for help.

2.1.2 Terry's wife was receiving care from the hospital as an outpatient. She had tested positive for COVID-19 prior to Terry and did not have any symptoms other than mild leg pain.

Monday

2.1.3 Terry's wife told the investigation that Terry had been feeling unwell for a few days. During a weekend in mid-December 2020, Terry told his daughter, "I don't feel too good."

2.1.4 Terry's wife said he started to feel more unwell on the Monday. He dropped a cup of tea while sitting down and later collapsed on his way to the toilet. Terry collapsed again in the kitchen and an ambulance was called.

2.1.5 The ambulance 'patient-reporting form' documents the ambulance crew's clinical assessment of Terry. It records that the ambulance crew administered oxygen after finding that Terry's oxygen levels were lower than the expected range. Terry's physiological parameters, including his respiratory rate, heart rate, blood pressure and blood sugar level, were all higher than expected. The crew documented that Terry 'looks unwell'. Terry was taken to the local emergency department (ED).

2.1.6 The medical records show that Terry was examined on arrival in the ED by a specialty trainee doctor (ST1). Terry's oxygen levels remained low, so oxygen therapy continued to be administered. Terry's breathing and pulse rate remained raised and, his chest sounds indicated he had a possible infection. Terry had a cough. He was able to talk in full sentences and was fully alert and orientated to time and place.

2.1.7 The ED doctor's recorded impression on initial examination was that Terry had an infection (sepsis), secondary to COVID-19. Terry's medical notes say (and staff confirmed at interview) that the plan was for him to:

- have a chest X-ray
- be given fluids via a tube into his veins
- be given antibiotics (the medical records refer to Terry's blood results and it was thought he had sepsis; NICE guidance suggests antibiotics should not be used for preventing or treating COVID-19 unless there is clinical suspicion of an additional bacterial infection) (National Institute for Health and Care Excellence, 2021b)
- have an electrocardiogram (ECG) of his heart
- have blood taken for analysis, including blood cultures and arterial blood gases
- reach an oxygen saturation level greater than 94% (the target range for oxygen levels, according to NICE guidelines for oxygen use during COVID-19, was 92–96% in people without underlying chronic obstructive airway disease) (National Institute for Health and Care Excellence, 2021a).

2.1.8 At 21:15 hours, Terry's had a National Early Warning Score (NEWS) of 8 (a high score; **see section 1.4**), which prompted escalation to the on-call medical team. Observation of Terry continued and by 23:00 hours his NEWS had reduced.

2.1.9 Examination and tests results confirmed Terry was in respiratory failure, probably as a result of COVID-19 infection. Oxygen therapy continued via a face mask, along with antibiotics and other treatments for COVID-19, including the steroid dexamethasone. At the time, dexamethasone was strongly recommended for people with COVID-19 who needed supplemental oxygen to meet their prescribed oxygen saturation levels (National Institute for Health and Care Excellence, 2021b).

2.1.10 The medical and nursing records indicate that Terry was referred to the critical care outreach team (CCOT) (**see section 1.5**) for a review of his case.

Tuesday

2.1.11 The medical notes state that Terry was seen by a consultant physician at 08:38 hours. The consultant confirmed that Terry was for full active resuscitation, meaning that if his condition deteriorated and his heart stopped, he would receive cardiopulmonary resuscitation. The consultant told the investigation that this decision was made based on the fact that Terry was usually independent and active. Terry's chest X-ray was reviewed and was found to indicate that Terry was suffering from COVID-19 pneumonitis. Terry's oxygen saturations were lower than his target range and the percentage of oxygen being given via a face mask was increased. He was alert and orientated to time and place and did not describe any chest pain.

2.1.12 According to the medical records, Terry was moved from the ED to a ward at 13:30 hours. The ward comprised side rooms only to help limit the risk of infection. The investigation was told that patients were cared for on this ward until a diagnosis of COVID-19 was either confirmed or ruled out by a PCR test – the pathway for a 'query COVID-19' admission. The nursing records indicate that Terry was given a call bell and that observations were recorded every 1-2 hours. Terry's PCR test was positive for COVID-19, meaning that Terry would follow the red pathway of care (**see section 1.3**).

2.1.13 According to the medical records and staff interviews, Terry required further reviews by the medical team and CCOT during that day because of increasing oxygen requirements. His medical records state that, at 14:43 hours, he was requiring a high percentage of oxygen to maintain target oxygen saturations. Terry told the doctor that he had some chest pain and was noted to be short of breath, but able to speak in full sentences. A plan was made to switch to humidified oxygen, and to continue observations and escalate to the medical staff if he deteriorated. The doctor recorded in the medical records that they discussed the plan with the CCOT, who were also reviewing Terry.

2.1.14 Terry was seen by the CCOT at 17:23 hours. At the time of the team's visit, Terry was talking on the telephone to his wife and they documented that he appeared comfortable in bed. He was talking in full sentences. The CCOT considered that Terry was stable at the time of their review, but documented that they could be called for further reviews, support and help with care if required.

2.1.15 The clinical notes record that hourly observations were undertaken for Terry. At 23:00 hours his NEWS was high (7), his oxygen saturations were below his target range and his respiratory rate was higher than expected. The nurse caring for Terry alerted the nurse in charge, the on-call doctor and the CCOT. The nurse also changed Terry's oxygen mask to one that allowed the delivery of a higher percentage of oxygen, as his oxygen saturation levels were dropping further on moderate exertion, such as trying to sit up in bed. Terry was encouraged to lie on his tummy, known as 'prone positioning'. Prone positioning has been shown to improve oxygenation and decrease the need for invasive ventilation (Pérez-Nieto et al, 2020). Terry was unable to lie on his tummy but was able to lie on his side. The medical records state that Terry's increasing oxygen requirements were discussed with the medical team, and a plan was made to start Terry on CPAP.

2.1.16 The hospital had set up a respiratory high-dependency unit during the first wave of the pandemic to look after the sickest patients with COVID-19 pneumonia who were either not suitable for admission to the critical care unit, or who could be managed with CPAP pending their recovery (or transfer to the critical care unit if their condition deteriorated). At the time of Terry's admission, this space was being used as a vaccination centre and the hospital had not re-established a respiratory high-dependency unit.

2.1.17 The investigation was told that the respiratory ward was full. The notes record a plan to transfer Terry to a medical ward that had a negative pressure side room (**see section 1.2.11**).

Wednesday

2.1.18 At approximately 01:50 hours, Terry was transferred into the last negative pressure side room available on the medical ward in accordance with the Trust's escalation plan. The ward had 20 beds, two of which were negative pressure side rooms. The side room in which Terry was located was directly opposite the nurses' station.

2.1.19 Terry was started on CPAP. The pressure settings, timings and alarms of the CPAP machine could be adjusted by controls on the front panel. The machine was set up, and the settings could be altered depending upon

Terry's oxygen levels. The ward did not have central monitoring at the nurses' station and a nurse had to be physically in the side room to see the machine display and hear any alarms.

2.1.20 According to Terry's medical records, the plan was to increase Terry's oxygen saturations to within target range, continue hourly observations, continue with CPAP, and titrate oxygen and pressure settings as required. It was recorded in the medical records and confirmed at interview that the CCOT advised they would continue to review Terry, and to contact them if there was a need for an urgent review.

2.1.21 The nursing records report that Terry's bed was in the lower position with his bed rails up and his call bell within easy reach, to ensure his safety and that he would not fall from the bed.

2.1.22 At approximately 05:00 hours, the medical notes record that Terry became distressed and agitated and refer to Terry trying to get out of bed. His NEWS was 10. He was seen again by the CCOT. Terry underwent catheterisation and his oxygen was increased. His CPAP mask was temporarily removed to allow him to have a drink. Terry was prescribed and administered morphine 5mg orally to alleviate his distress.

2.1.23 It was recorded in the medical records and confirmed at interview with staff that Terry responded well to reassurance, and it was thought likely that Terry had experienced an anxiety attack caused by wearing the CPAP mask. The rationale for CPAP was further explained to Terry, and he understood it would help him with his breathing and agreed to keep the mask on.

2.1.24 Terry was seen by a respiratory consultant on the ward round at 10:09 hours. It was noted that Terry's oxygen levels were within the target range. However, the consultant saw that the oxygen tubing was kinked; once this had been fixed, Terry's oxygen levels further improved. At the time of the consultation Terry was alert and tolerating CPAP. Terry said his mouth felt dry. He asked if his catheter could come out, and it was explained it should stay in for the next 24 hours. The plan was 'to continue intravenous fluids, aim for oxygen saturations between 90–94%, all breaks off CPAP for food and drink, and ongoing CCOT review'.

2.1.25 Terry was seen throughout the day by the CCOT as part of their routine reviews.

2.1.26 Terry's son visited the ward at 11:16 hours. He was not able to see Terry because of national restrictions on visiting patients. Terry's son spoke to a junior doctor, who subsequently telephoned Terry's wife at his son's request to update her on Terry's condition.

2.1.27 The nursing entry in the medical records entered at 13:42 hours record that, Terry remained alert and orientated, and was drinking fluids but was not hungry. No falls had been reported and the bed remained in its low position with a call bell within easy reach.

2.1.28 During the afternoon, Terry's NEWS was again high (8). He was seen by the CCOT. The medical records state that his oxygen levels were lower than the target range, so the settings of the CPAP machine were adjusted and his oxygen levels subsequently improved to within the normal range. His blood gases suggested worsening respiratory failure. The CCOT discussed Terry with the critical care team, who agreed to review him.

2.1.29 A senior clinical fellow from critical care examined Terry on the ward. The doctor recorded in the medical records, and told the investigation at interview, that Terry was in type 1 respiratory failure because of COVID-19 and that he had increasing oxygen requirements. Terry's oxygen saturations were at the top end of his target range, and therefore the oxygen therapy was reduced a little and his saturations were maintained.

2.1.30 At the time of the critical care examination, Terry had a higher than expected respiratory rate of 23 breaths per minute and a heart rate of 122bpm (Terry had a history of an abnormal heart rhythm and therefore an additional medicine was added to help control his heart rate). His temperature was within the expected range, and he was fully alert and orientated. An anti-viral medicine was prescribed, which was in keeping with national trial guidance for COVID-19 (National Institute for Health and Care Excellence, 2021b). It was agreed that if Terry deteriorated or his oxygen requirements increased, he would be reviewed for possible admission to the critical care unit. At this time there was a bed available on the critical care unit; however, a clinical decision was made that this was not yet necessary. The investigation was told this this decision was made in discussion with the consultant intensivist on critical care and was recorded in the notes.

2.1.31 The medical records show that the CCOT routinely reviewed Terry. CCOT recorded at 18:24 hours his blood gases were slightly improved, but he was still in type 1 respiratory failure. The CCOT discussed Terry with the consultant intensivist on critical care and agreed to continue with the current plan.

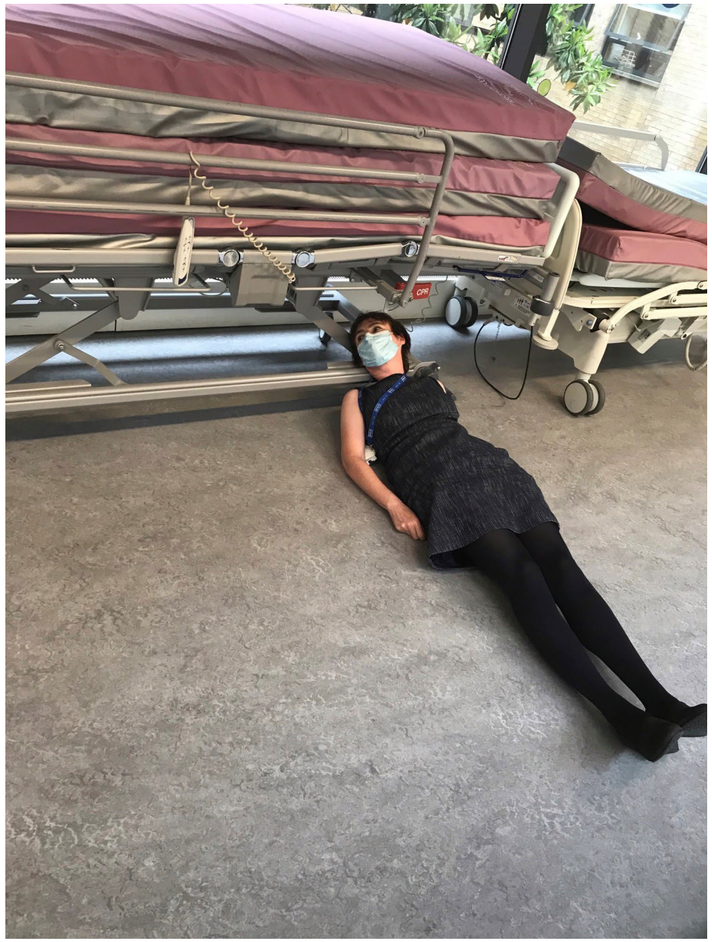
2.1.32 At 18:59 hours, the evening doctor reviewed Terry at the request of the day doctor. It was recorded in the medical records and confirmed at interview that there was no change in the plan.

2.1.33 The nursing handover finished at 20:00 hours. At this time, there were two registered nurses on duty and two healthcare assistants. This was fewer than the planned staffing numbers of three registered nurses and three healthcare assistants. At interview, the staff said they were very concerned about the number of sick or confused patients for the staff available and escalated their concerns. The nurses told the investigation they split the ward so that they had 10 patients each.

2.1.34 Terry used his call bell. The investigation was told the call bell was pressed at some point at the end of nursing handover. The nurse caring for Terry conducted some blood transfusion observations on another patient and then went to answer Terry's call bell. The nurse saw Terry on the floor of the side room. At 20:12 hours (time taken from the electronic log of the call in the switchboard) an emergency call was made. She called to the other nurse who said she would take over the care of Terry and prepared to enter the room.

2.1.35 When the other nurse entered the room to assess Terry on the floor, she described it as "very noisy – all alarms were going – CPAP, monitor, IVI [intravenous infusion]". The nurse described hearing these sounds as she entered the room, and that she could not hear anything outside of the room. The nurse stated at interview that Terry was lying on the floor at the foot of the bed with his head slightly under the bed on the bed frame (see figure 4). The CPAP mask was still on Terry's face, but the tubing connecting the mask to the CPAP machine was disconnected. The rails of the bed were still up. There was blood on the floor from a wound to Terry's head. The intravenous cannula had become removed from Terry's hand and the catheter was no longer in place.

Figure 4 Model showing the position of Terry when the nurse entered the side room. Terry was lying at the foot of the bed, with his head against the bedframe (shown by the pointed finger). The side rails of the bed are up, as in the reference event, but the bed has three mattresses whereas Terry was lying on only one



2.1.36 The resuscitation team entered the room and started resuscitation in accordance with Resuscitation Council (2021) guidelines. The critical care unit was contacted. Terry did not recover from his cardiac arrest and died.

2.1.37 The Trust told the investigation and wrote in its own investigation report that: 'It was not clear whether Terry had a cardiac arrest likely due to a lack of oxygen and then fell from the bed or whether he fell from the bed and then his oxygen levels dropped.' The cause of Terry's death was recorded as COVID-19 pneumonia, and Terry's underlying conditions were recorded in part 2 of the death certificate.

3 Involvement of the Healthcare Safety Investigation Branch

This section of the report outlines how HSIB was alerted to the safety risk of caring for patients with COVID-19 requiring continuous positive airway pressure (CPAP) outside of a critical care or high-dependency unit. It describes the criteria HSIB used to decide whether to go ahead with the investigation, and the methods and evidence used in the investigation process.

3.1 Notification of the reference event

3.1.1 A member of NHS staff at the reference site notified HSIB of the reference event. The referral was submitted anonymously through HSIB's online portal and described a patient with COVID-19 being found on the floor of a side room with the CPAP machine disconnected. The referrer raised concerns about the Patient being on a medical ward and the reduced staffing levels.

3.2 Decision to conduct a national investigation

3.2.1 The investigation visited the NHS Trust where the reference event occurred to observe the areas in which the Patient underwent care. The investigation also visited the Patient's family to gain further information and a richer understanding of events. The evidence gathered was assessed against HSIB's investigation criteria.

3.2.2 Following analysis of the preliminary information gathered, it was agreed that the safety issues identified in the reference event met the criteria for a national investigation, and this was authorised by HSIB's Chief Investigator. A summary of the analysis against HSIB's investigation criteria is given below.

Outcome impact – what was, or is, the impact of the safety issue on people and services across the healthcare system?

3.2.3 Patients with COVID-19 requiring non-invasive respiratory support require a close level of supervision by a healthcare professional. When a patient is in a side room, they cannot be seen or heard unless there is a healthcare professional present in the room, or if there is CCTV monitoring that is displayed to a central monitoring station.

3.2.4 If patients cannot be seen and CPAP alarms cannot heard, patients may deteriorate without staff being aware of this and able to respond in a timely way. Furthermore, patients may become disconnected from their respiratory support without the knowledge of staff, putting patients at risk of significant harm and death.

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

3.2.5 NHS England and NHS Improvement (2020a) has provided guidance stating that CPAP is the preferred form of non-invasive respiratory support for patients with COVID-19 who are unable to maintain their oxygen levels within a safe range. Significant numbers of people require non-invasive breathing support during the peaks of the COVID-19 pandemic (British Thoracic Society and Intensive Care Society, 2021a; National Institute for Health Research, 2021). As there are insufficient beds in critical care and high-dependency units to care for the numbers of patients requiring CPAP during these peaks, patients are cared for in other areas, including on general wards. Thus, this safety issue was widespread during the first and second waves of the pandemic and may occur again. The safety issue affects all hospitals seeing large numbers of patients with COVID-19.

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

3.2.6 There are opportunities for HSIB to complement existing national work on caring for patients with COVID-19 who require CPAP outside of critical care and high-dependency units. Specifically, by investigating a reference event, HSIB can demonstrate the systemic challenges of caring for patients requiring CPAP in side rooms. The investigation will highlight the importance of embedding recently published recommendations from national bodies.

3.3 Investigation scope

3.3.1 This investigation sought to understand the systemic factors influencing the care of patients on CPAP outside of critical care and high-dependency units. Specifically, the investigation considers the scenario of a patient in a side room on a medical ward. The investigation also sought to understand the implications of recommendations from national guidance, and whether further opportunities exist to mitigate the risk of treating patients with COVID-19 with CPAP outside of critical care and high-dependency settings.

3.3.2 This investigation explored situational factors (evidence of the situation at the time the event occurred) and contextual factors (factors likely to influence what people believe about the immediate situation and what is expected of them) (Chartered Institute of Ergonomics & Human Factors, 2020) surrounding the care of people with COVID-19 requiring CPAP in a side room of a medical ward, as opposed to in a critical care or high-dependency unit setting.

3.4 Evidence gathering and verification of findings

3.4.1 Multiple sources of evidence were gathered and analysed by the investigation, including:

- review of the Patient's clinical records
- review of national guidance and standards regarding the treatment of patients with COVID-19 with non-invasive respiratory support
- meetings with the Patient's wife and son
- interviews with staff members who were directly or indirectly involved in the reference event
- review of the Trust's internal serious incident investigation report
- review of research literature relevant to the safety risks.

Stakeholder engagement

3.4.2 Stakeholders across the healthcare system were interviewed to gain their perspectives on the safety risk of treating patients with COVID-19 with CPAP outside of critical care and high-dependency settings, and for the investigation to understand the emerging national guidance. Organisations included:

- The Intensive Care Society
- The British Thoracic Society
- Getting It Right First Time
- Public Health England
- NHS England and NHS Improvement
- The National Institute for Health and Care Excellence.

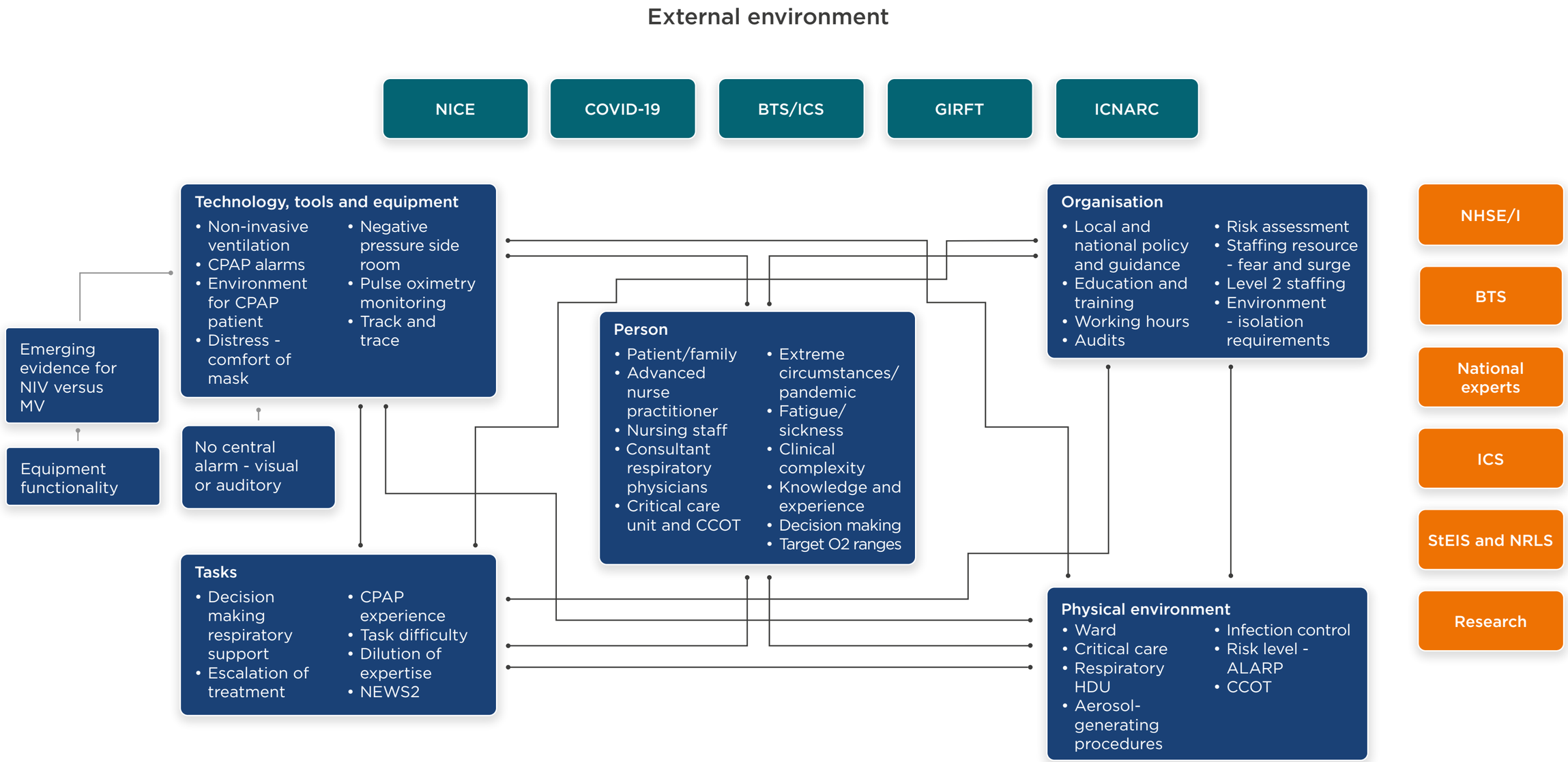
3.5 Systems analysis of the evidence

Systems Engineering Initiative for Patient Safety (SEIPS) framework

3.5.1 The investigation used a framework called SEIPS (Holden et al, 2013; Carayon et al, 2006) to inform the development of interview schedules and examine safety factors influencing the treatment of patients with COVID-19 using non-invasive respiratory support – specifically, with regard to caring for a patient requiring CPAP in a side room on a ward, and not in a critical care or high-dependency unit, in the context of a global pandemic. SEIPS provides a human factors framework for understanding work system interactions (that is, the external environment, organisation, internal environment, tools and technology, tasks and person-level factors) and work processes (including physical, cognitive and social/behavioural aspects), and how these combine to influence healthcare outcomes (see figure 5).

3.5.2 The findings were shared with the healthcare organisations involved in the reference event and with key stakeholders within the healthcare system. This enabled checking for factual accuracy and overall sense making.

Figure 5 Work system factors explored in this investigation



Note: this diagram provides a general overview of the areas explored as part of this investigation; the areas listed are not exhaustive. The investigation considered local and national policies and guidance, and practices evidenced in the research literature. This enabled a detailed analysis of how the healthcare system influenced the reference event and allowed potential recommendations for improvement to be considered.

ALARP, as low as reasonably practicable; BTS, British Thoracic Society; CCOT, critical care outreach team; CPAP, continuous positive airway pressure; GIRFT, Getting It Right First Time; HDU, high-dependency unit; ICNARC, Intensive Care National Audit & Research Centre; ICS, Intensive Care Society; MV, mechanical ventilation; NHSE/I, NHS England and NHS Improvement; NIV, non-invasive ventilation; NRLS, National Reporting and Learning System; StEIS, Strategic Executive Information System.

4 Findings and analysis of the reference event

This section describes the investigation's findings in relation to the reference event. It focusses on the system factors that contributed to the Patient, Terry, being treated with continuous positive airway pressure (CPAP) in a negative pressure side room on a medical ward. The following five main situational and contextual system factors were identified and analysed:

- rationale for admission to a negative pressure side room on a ward
- safety risks associated with monitoring a patient in a negative pressure side room on a ward
- workload, time pressures and staffing
- training in using CPAP for patients with COVID-19
- external influences.

4.1 Rationale for admission to a negative pressure side room on a ward

4.1.1 The first and second waves of the COVID-19 pandemic significantly increased demand on respiratory and critical care services, and increased the numbers of hospitalised patients requiring help with their breathing from non-invasive respiratory support such as CPAP and high-flow nasal oxygen (British Thoracic Society and Intensive Care Society, 2021a). These increased numbers meant that some such patients were cared for outside of critical care units.

4.1.2 CPAP is an aerosol-generating procedure, and so Terry required either a side room or to be grouped together in a bay with other patients being treated for COVID-19 with CPAP, to reduce the risk of cross-infection to other patients and staff (**see section 1.3**).

4.1.3 The trigger to consider escalating patients on general wards to a more specialist area, such as a respiratory support unit, for non-invasive respiratory support should be the patient's inability to maintain their oxygen saturations at at least 94% on inspired oxygen of less than 40% (British Thoracic Society, 2020). Terry met the criteria for care in a more specialist area as he was unable to maintain his target saturations above 94% on less than 40% oxygen. The designated respiratory ward for patients with COVID-19 at the time of Terry's admission was full, and the next appropriate location was a negative pressure side room on a medical ward.

4.1.4 The Intensive Care Society (2020) refers to the unprecedented pressure to rapidly increase capacity during the pandemic in its 'Intensive care 2020 and beyond' publication. During the first wave of the COVID-19 pandemic, the Trust had established a respiratory high-dependency unit (RHDU) (also referred to as a Respiratory Support Unit). This unit ensured that patients were grouped together in a single environment with the necessary medical and nursing expertise. After the first wave, the RHDU was closed as the need for such beds declined. At the time of Terry's admission, this space was being used as a COVID-19 vaccination centre.

4.1.5 The Trust told the investigation that its plan for reopening the RHDU was based on the number of COVID-19-positive patients requiring respiratory support. The need to enact the escalation plan and reopen the RHDU was routinely reviewed at 'flow meetings', which were held three times per day. At each flow meeting there was a standing agenda item to review the number of COVID-19-positive patients in relation to the current and predicted number of beds available. The number of patients anticipated to require non-invasive respiratory support in the next 24 hours was also discussed.

4.1.6 A week after Terry's admission, the RHDU was re-established in response to a need for additional capacity to care for patients with COVID-19 who required non-invasive respiratory support. The investigation was told that this area will remain a permanent RHDU.

4.1.7 The investigation was told that the respiratory physicians carried a Wi-Fi telephone and were available to give advice and assess patients every day between 08:00 and 19:00 hours. The respiratory physicians worked very closely with the hospital's critical care doctors and critical care outreach team (CCOT). Nursing staff said that support from the respiratory team and CCOT was very much valued.

4.1.8 The investigation was told that, at the time Terry was transferred to a negative pressure side room, the hospital was predicting a deficit of 52 beds – in other words, in the next few hours there were predicted to be 52 more patients needing admission than there were hospital beds available. The hospital was described by staff interviewed as being under "incredible pressure". Although there were beds available in the critical care unit at the time, clinical staff and managers were predicting that these beds would soon be occupied and that support from other hospitals in the region would be needed to manage the number of critically ill patients.

4.1.9 When Terry's oxygen saturations fell outside of the target range despite being on CPAP, his care was escalated to the critical care team for advice. At interview, the senior clinical fellow and the consultant intensivist said that they felt it was appropriate for Terry to stay on the ward at the time of their review. This was because Terry had shown improvements in his blood oxygenation levels (from analysis of his latest blood gas results) and remained fully alert.

4.1.10 This decision was made against a background of high numbers of admissions of COVID-19-positive patients, some of who would require immediate admission to the critical care unit. Furthermore, although critical care beds were available, the consultant intensivist said that if Terry had been admitted to critical care then it is highly likely this would have been for full invasive mechanical ventilation requiring a breathing tube to be inserted and attached to a machine (a ventilator) that would do all the work of breathing for Terry. A consultant respiratory doctor told the investigation that this was a last-resort treatment option because Terry had underlying conditions that would make coming off a ventilator difficult and leave him with a potentially poor functional status following critical care if he survived. Evidence suggests there is a high risk of death in this scenario (Intensive Care National Audit and Research Centre, 2020).

4.2 Safety risks associated with monitoring a patient in a negative pressure side room on a ward

4.2.1 The negative pressure side room on the ward had an anteroom (see figure 6). This is an airlocked room that provides staff with an area to change into or out of personal protective equipment, and to prepare for other tasks before attending a patient.

Figure 6a The door and window to the anteroom of the negative pressure side room

Figure 6b The open external door leading to the anteroom and the door to the room where Terry was being treated

Behind this closed door is where Terry was being treated

4.2.2 The staff caring for Terry described him as being anxious. CPAP masks can be distressing for patients, and the use of low doses of opioids can be considered to reduce the sensation of breathlessness (NHS England and NHS Improvement, 2020a). Terry was prescribed and given a low-dose opioid to reduce his sensation of breathlessness. The Intensive Care Society states:

'The ability to care for an agitated patient on CPAP is not to be underestimated and the nursing care and [allied health professional] skill required to keep them out of [the intensive care unit] is vital.' (Intensive Care Society, 2020).

During interview, a CCOT staff member said that they felt it was "so unsafe to be in a side room without continual observation".

4.2.3 The side room was located close to the nurses' station. Because of the double doors, Terry could not be seen from the nurses' station and there are practicalities of privacy versus easy observation. Terry had a call bell. There were no audible or visual alerts to warn staff if he deteriorated and was unable to use his call bell. Monitoring equipment was present in the side room itself. There was no monitoring equipment at the central nurses' station. Staff were only aware of Terry's condition when they were in his room. This contrasts with critical care and other high-dependency units, which have central monitoring.

4.2.4 Various CPAP devices are available; analysis of these was outside the scope of the investigation. The CPAP machine used for Terry was on a sideboard in the negative pressure side room. The machine had inbuilt alarms, including an alarm for when tubing becomes disconnected (Breas Medical Ltd, 2017). These alarms were not audible or visible outside of the side room, and were not heard by staff until a nurse entered the room and found Terry on the floor.

4.3 Workload, time pressures and staffing

4.3.1 The investigation found that the staff on duty were required to complete several important tasks at the same time, and had a high workload at the time of Terry's admission. This was particularly evident at the time Terry used his call bell.

4.3.2 At the time Terry used his call bell, there were 16 inpatients on the ward and four planned admissions expected to arrive imminently.

4.3.3 Terry required a close level of supervision, referred to as level 1 enhanced care, as he was having non-invasive respiratory support to treat his symptoms associated with COVID-19 (Intensive Care Society, 2021).

4.3.4 The investigation was told that the medical ward on which Terry was located was usually staffed by three registered nurses (RNs) and three healthcare assistants (HCAs). On the night that Terry collapsed, there were two relatively junior RNs (both Band 5) and two HCAs. One agency nurse had arrived for work, but left when they found that patients with COVID-19 were being cared for on the ward. This scenario was described as "not uncommon" by staff. A subject matter advisor told the investigation that Terry was at high risk of deterioration given his oxygenation level, his National Early Warning Score (NEWS) and his need for frequent medical reviews. The advisor said that in a respiratory support unit setting and based on the acuity of his illness, Terry would have been cared for in a nurse-to-patient ratio of 1:2, as recommended by the British Thoracic Society 'Quality standards for acute non-invasive ventilation in adults' (Davies et al, 2018).

4.3.5 The RNs on duty described the situation as "chaos" when they arrived for their shift. During interviews, the RN's described the challenging circumstances they were experiencing. For example:

- One patient had just started blood transfusion and required frequent observations by an RN. These observations included assessment of their pulse rate, blood pressure, temperature and respiratory rate every 15 minutes after the start of transfusion to observe for transfusion reactions, in line with local and national guidance (Joint United Kingdom [UK] Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee, 2014).

- One patient was described as aggressive, confused and trying to leave the ward. They required 1:1 care from one HCA.

- There was a bay of four confused patients, requiring one HCA to remain in the bay at all times.

- One patient was admitted to the ward during the nursing handover. This patient was confused and at risk of falls.

- A new patient had arrived on the ward at shift handover, requiring the dayshift RN to stay late and admit the patient.

4.3.6 Staff told the investigation that when Terry used his call bell, there were several tasks that required their attention at the same time (in keeping with the situational context described above). The RN caring for Terry had competing clinical tasks, which required her to prioritise her care. Based on her perception of risk, she performed the blood transfusion observations on one of her patients before responding to Terry's call bell. The investigation was told this decision was made because she thought that answering Terry's

call bell and donning full personal protective equipment would take some time, and that the patient having a blood transfusion may suffer a reaction. In addition, she thought the observations could be done relatively quickly. She estimated the time taken for the observations at between 5 and 10 minutes, although this is based on her recall. She knew it was after handover from the day shift (that is, after 20:00 hours).

4.3.7 Site practitioners (healthcare professionals with a clinical qualification) were working in the Trust at night. Their role was to provide nursing and managerial support across the Trust. They were responsible for managing staffing levels and deciding which wards could admit new patients. One of the RNs called the site practitioner immediately after handover to make them aware of the staffing levels on the ward, which the nurse believed were insufficient to deliver safe care. She described feeling as if she was being "rude" as she was so anxious about patient safety, and described a desperate need for another staff member. She asked for the four incoming admissions to be 'staggered' as she felt they could not safely admit new patients and care for their current patients with the staff available. It was at this time she was called by her colleague to come quickly and saw Terry on the floor.

4.3.8 The lack of staff in the hospital against a rising number of patient admissions was described by staff interviewed as a real safety concern that caused everyone anxiety. Staff told the investigation they were fearful of the rising admissions, saying "Most shifts were a struggle to fill." Staff said they were anxious to go off duty and, when not in work, could not rest.

4.4 Training in using CPAP for patients with COVID-19

4.4.1 At interview, some nursing staff told the investigation they had minimal training in using CPAP and did not feel confident in caring for patients on CPAP.

4.4.2 Some RNs had previous experience of working with CPAP, but not in a pandemic situation and not for patients with acute breathing problems. Examples of their experience included:

- caring for patients requiring CPAP as a short-term clinical treatment for excess fluid in the lungs due to heart failure
- caring for patients who brought their own home CPAP devices, which they used to help them breathe at night.

These experiences of CPAP are very different to the circumstances in which the machines were used for patients with COVID-19.

4.4.3 Some staff reported that "in-house training on setting up CPAP" was available. They said the training was basic and did not prepare them for caring for such sick patients.

4.4.4 The investigation found that some CPAP training was delivered to ward nurses by respiratory clinical nurse specialists. This training was delivered on the ward when patients were receiving CPAP and was described as "very helpful".

4.4.5 The investigation was told that, during the day, expertise to help with CPAP was available from the CCOT or respiratory clinical nurse specialists. All staff directly involved in the investigation said they appreciated the support offered by the CCOT and respiratory team. At night, the CCOT remained available and was described as 'responsive'; respiratory clinical nurse specialists were not available.

4.4.6 Competency frameworks are used to ensure staff members have the knowledge, skills and behaviours required to perform their role (National Outreach Forum and Critical Care Networks – National Nurse Leads, 2018). The investigation was told that staff on the medical ward were not required to complete a clinical competency assessment for caring for patients requiring non-invasive respiratory support. The investigation was mindful that, at the time of Terry's admission, there were no national recommendations for competency frameworks on the use of CPAP outside of traditional critical care and high-dependency units.

4.5 External influences

4.5.1 In addition to the situational and contextual factors described above, the investigation was told by staff that factors outside of the organisation's control added to the challenges of caring for patients such as Terry.

4.5.2 One of these factors was the request by NHS England and NHS Improvement (2020b) for healthcare providers to accelerate the return of non-COVID-19-related health services. This prompted a drive to restore all normal services. First and follow-up outpatient attendances (either face-to-face or virtually) were expected to be fully restored. At the time of Terry's admission (December 2020), the second wave of the pandemic was accelerating, and the hospital was trying to restore services as well as plan for another surge of patients with COVID-19. Staff at the Trust told the investigation that this tested the resilience of staffing plans, and the investigation heard about the daily challenge of trying to safely staff the hospital. Staff told the investigation: "We were expected to do business as usual [in Wave 2] when at one point a third of our workforce were off. I wish we had been allowed to cancel routine work for the second wave."

4.5.3 The investigation was told that staffing became increasingly challenging to manage in the second wave of the pandemic because of the number of staff self-isolating. Staff who had been notified by the NHS COVID-19 app or NHS Test and Trace that they were a close contact of a person with COVID-19 were required to isolate for 10 days. Several staff lived in multi-person households (with their families or in house shares) and received repeated instructions to self-isolate. In August 2021, the UK government removed the requirement for fully vaccinated people to self-isolate following a positive COVID-19 contact (Public Health England, 2021b). This may mitigate the staffing burden.

4.5.4 Staffing was also described as challenging because the vaccination programme was underway at the time of Terry's admission, with some staff members deployed to support the vaccination centre.

4.5.5 The leadership team at the reference Trust included operational and executive staff. The investigation was told they had at least three capacity and staffing meetings each day. The first and second waves of the COVID-19 pandemic required NHS staff to be redeployed across departments and specialties, and some staff were unable to work in COVID-19-designated areas because of personal health issues. The investigation was told that there were no barriers to requesting extra bank and agency staff, and that such decisions were fully supported by the leadership team. Staff told the investigation: "I felt heard" and "I felt supported." However, there was a far greater demand for staff than there were staff available to work in COVID-19 wards.

Key findings

- Terry was transferred to a negative pressure side room on a medical ward to enable CPAP to start. This decision was made because the COVID-19 respiratory ward with other patients requiring CPAP was full, and the side room was the next place to care for a patient requiring an aerosol-generating procedure. The hospital was under extreme pressure and predicting higher numbers of patients than beds available.

- An RHDU was established the week after Terry's admission. At the time of his admission, this area was being used as a COVID-19 vaccination centre.

- There was a bed available on the critical care unit. A clinical decision was made – based on assessment by the multidisciplinary team, including critical care medical staff and the CCOT – not to admit Terry to the critical care unit at that time.

- The type of CPAP machine Terry was using had inbuilt alarms. These alarms were not audible or visible outside the side room. There was no central monitoring at the nurses' station. Staff were only aware of Terry's condition when they were in his room.

- Staff had a very high workload that was beyond their ability to safely manage. There were competing clinical priorities and staff had to prioritise tasks.

- Terry was at high risk of deterioration, given his oxygenation level, his NEWS and his need for frequent medical reviews. In a respiratory support unit setting, Terry would have had a 1:2 patient-to-nurse ratio based on the acuity of his illness, as recommended by the British Thoracic Society 'Quality standards for acute non-invasive ventilation in adults' (Davies, et al, 2018). It was not possible to achieve this staff-to-patient ratio in a negative pressure side room on a medical ward with the staffing available.

- Conflicting demands on staffing resources were apparent as the second COVID-19 wave started to take hold. There was pressure to maintain treatment and services for patients who did not have COVID-19 (for example, outpatient services, general surgery and cancer care), and staff were also redeployed to support the newly created COVID-19 vaccination centre.

- Some staff did not feel confident or competent to care for patients with COVID-19 who required non-invasive respiratory support on the ward.

Based on the above findings:

HSIB asks healthcare providers to consider the following safety questions

Safety question 1:
Do you have an operational policy that includes the areas of the hospital where non-invasive respiratory support can be provided? Does your operational policy include the minimum safe level of staff competencies, the minimum nurse-to-patient ratio for patients receiving non-invasive respiratory support on the ward, and the minimum frequency of clinical review? Standard requirements that should be included in an operational policy can be found in the 'Inspiring change' report (National Confidential Enquiry into Patient Outcome and Death, 2017), joint guidance by the British Thoracic Society and Intensive Care Society (2021a) on developing and implementing respiratory support units, and the Getting It Right First Time (2021) review of respiratory medicine.

Safety question 2:
Do you use side rooms to care for patients requiring non-invasive respiratory support? If so, how do you ensure that monitors and alarms can be seen and heard by staff when outside of the room? Do you have central monitoring?

Safety question 3:
Do your continuous positive airway pressure (CPAP) devices have the capability for remote monitoring?

Safety question 4:
Do you have the required staff and skill mix to care for patients requiring non-invasive respiratory support in side rooms on a general ward? How are issues with staffing and workload escalated and responded to? Are senior trust personnel aware and involved?

Safety question 5:
Do your staff have the required training and competency assessments to care for patients requiring non-invasive respiratory support? Examples of appropriate training and competency assessments include the 'COVID-19 skills preparation course' (European Society of Intensive Care Medicine, 2021) and the 'National competency framework for registered practitioners: level 1, patients and enhanced care areas' (National Outreach Forum and Critical Care Networks – National Nurse Leads, 2018).

Safety question 6:
Do your staff complete a checklist (for example, the 'SAFER NIV/CPAP – a checklist for use in pandemic response and on respiratory support units' or similar) (British Thoracic Society and Intensive Care Society, 2021a) when a decision has been made to initiate non-invasive ventilation/continuous positive airway pressure (CPAP) and at every shift change?

5 Findings and analysis from the wider investigation

This section sets out the findings from the investigation's analysis of treating patients with COVID-19 with non-invasive respiratory support outside of critical care and high-dependency environments in the context of the wider healthcare system.

The investigation considered published national policy and guidance in relation to treating patients with COVID-19 requiring non-invasive respiratory support outside of critical care and high-dependency environments (British Thoracic Society and Intensive Care Society, 2021b; Getting It Right First Time, 2021). The investigation found that the guidance addresses the safety issues identified in the reference event, and hence no safety recommendations are made by HSIB in this report. Rather, information and recommendations from the guidance that are relevant to the investigation's focus are detailed here for wider learning.

The findings are presented within the main theme of the environment for patients receiving continuous positive airway pressure (CPAP) outside of the critical care unit. These include a review of:

- Care for patients requiring non-invasive respiratory support outside of critical care and high-dependency units
- guidance for non-invasive respiratory support equipment and remote monitoring
- workforce challenges during a pandemic and creating a flexible workforce.

5.1 Care for patients requiring non-invasive respiratory support outside of critical care and high-dependency units

The investigation found that recently published guidance described the requirements of a suitable environment for patients with COVID-19 requiring non-invasive respiratory support outside of critical care and high-dependency units. The following summarises current national work in this area and the establishment of respiratory support units (RSUs).

5.1.1 Getting It Right First Time (GIRFT) has reported that RSUs delivering respiratory support (for example, CPAP) to patients with COVID-19 can reduce the burden on critical care services (Getting It Right First Time, 2020).

5.1.2 Delivering respiratory support (including CPAP) to patients with COVID-19 was a key treatment development in the first wave of the pandemic. This was demonstrated by the use of a new NHS procedural classification code for CPAP. In the month of its launch in April 2020, the new classification code was recorded 5,500 times, reflecting widespread uptake of CPAP; the code was documented approximately 5,000 times the following month (Getting It Right First Time, 2021). In August 2021, findings from the largest trial of non-invasive respiratory support to date (RECOVERY-RS) were published, and showed a reduced requirement for intubation in patients with COVID-19 treated with CPAP compared with conventional oxygen therapy (National Institute for Health Research, 2021).

5.1.3 Emergent guidance from national organisations during the first wave of the pandemic recommended that, ideally, CPAP for patients with COVID-19 should be delivered in negative pressure side rooms to minimise the risk of COVID-19 cross-infection to other patients and staff. It recognised that availability of such rooms might be limited, and therefore grouping patients together in a closed bay was also recommended (NHS England and NHS Improvement, 2020a).

5.1.4 Organisations were advised that patients with COVID-19 who required respiratory support in the form of CPAP should be appropriately monitored to identify deterioration that may indicate a need for invasive ventilation as part of the escalation plan. This required a robust process with clear clinical guidelines and effective communication between ward and critical care staff. Examples of clinical escalation guidelines can be found in guidance from NHS England and NHS Improvement (2020a), the initial British Thoracic Society (BTS) (2020) guidance documents and the BTS 'Quality standards for acute non-invasive ventilation in adults' (Davies et al, 2018).

5.1.5 In July 2021, joint guidance was published by the BTS and the Intensive Care Society (ICS) that referred to the use of CPAP, high-flow nasal oxygen (HFNO) and non-invasive ventilation (NIV) for patients with respiratory failure secondary to COVID-19 (British Thoracic Society and Intensive Care Society, 2021a).

5.1.6 The guidance refers specifically to developing and implementing RSUs. RSUs are usually based on respiratory wards so that enhanced respiratory support can be delivered outside of the critical care environment. They have been reported to play a major role in maintaining critical care capacity, allowing an element of 'business as usual' while managing patients who need advanced support (Getting It Right First Time, 2021).

5.1.7 The joint BTS/ICS guidance states that patients with COVID-19 'may be looked after on general wards, RSUs or critical care units' (British Thoracic Society and Intensive Care Society, 2021a). The document provides guidance on which patients may be looked after in non-critical care settings and the criteria that should be used to escalate these patients to areas with higher-acuity treatments. The guidance makes a number of recommendations, including the following:

- There should be local protocols for delivering non-invasive forms of respiratory support, including CPAP, NIV and HFNO. Monitoring (specifically oxygen saturations, blood pressure and heart rhythm) should be available at each bed and displayed centrally.

- In hospitalised patients with COVID-19, oxygen saturation levels of 94% or less on 40% oxygen should act as a trigger for managing the patient in an RSU or critical care area.

- Oxygen saturation monitors should be clearly visible to staff, including when patients are in isolation rooms.

- Local protocols should be in place to detect disconnection from CPAP and NIV, and should include disconnection alarms on machines and defining the frequency of nursing review, especially for patients being nursed in side rooms. The frequency of nursing review will depend upon the patient's level of consciousness and dependency on non-invasive respiratory support.

5.2 Guidance for non-invasive respiratory support equipment and remote monitoring

5.2.1 Importantly, the joint BTS/ICS guidance states that:

'Machines used for CPAP and NIV should be designed for this purpose. All machines should, at a minimum, have a disconnection alarm.' (British Thoracic Society and Intensive Care Society, 2021)

5.2.2 The guidance specifies that when patients are nursed in a side room, the alarm should be audible from outside the room (British Thoracic Society and Intensive Care Society, 2021).

5.2.3 Appendix 1 of the joint guidance contains a checklist: 'Safer NIV/CPAP – a checklist for use in pandemic response and on respiratory support units.' The guidance advises completing this checklist on initiating NIV/CPAP and at every shift change (British Thoracic Society and Intensive Care Society, 2021).

5.2.4 The GIRFT review of respiratory medicine recommends that organisations:

'Procure CPAP devices with capability for remote monitoring where possible through co-ordinated discussions between respiratory and [intensive treatment] departments.' (Getting It Right First Time, 2021). The investigation was told by a subject matter advisor that CPAP machines with remote monitoring are not that common and were not widely used during the first and second waves of the pandemic.

5.3 Workforce challenges during a pandemic and creating a flexible workforce

The first and second waves of the COVID-19 pandemic exacerbated the challenges of safe staffing in a system already stretched in capacity. The pandemic has resulted in national bodies recognising that organisations must be able to flex and expand their enhanced care settings, with the necessary infrastructure and competencies to support fluctuations in demand. The following summarises current national work in this area:

5.3.1 In 2018, The Health Foundation, The King's Fund and the Nuffield Trust published a joint briefing that highlighted the scale of workforce challenges in healthcare (The Health Foundation, The King's Fund and Nuffield Trust, 2018). Key points included the following:

- Across NHS trusts, the report identified a shortage of more than 100,000 staff. The report projected that the gap between staff needed and the number available could reach almost 250,000 by 2030.
- The report noted that: 'Current workforce shortages are taking a significant toll on the health and wellbeing of staff.'

5.3.2 The needs of patients requiring non-invasive respiratory support (for example, CPAP) are greater than those requiring ordinary oxygen administration. These patients therefore require enhanced nursing, medical and allied health professional support. In the first and second waves of the COVID-19 pandemic, the challenge of providing suitable care environments grew as the number of patients with COVID-19 increased and hospitals had to provide care outside of critical care settings – often without remote monitoring.

5.3.3 According to GIRFT, the National Reporting and Learning System database saw an increase in reported incidents relating to delivery of the wrong type of respiratory support outside of specialist areas where there was confusion in terminology and type of NIV therapies between June 2019 and June 2020 (Getting It Right First Time, 2021).

5.3.4 Existing guidance for providing intensive care services (Intensive Care Society & The Faculty of Intensive Care Medicine, 2019) before the pandemic required review, given the impact of the pandemic on staffing and the volume of patients requiring NIV and invasive mechanical ventilation. NHS England and NHS Improvement (2020c) published new 'Advice on acute sector workforce models during COVID-19,' which suggested changes to non-pandemic staffing levels.

5.3.5 In 2009, the ICS published 'Levels of critical care for adult patients' (Intensive Care Society, 2009). This document aimed to help identify ward patients who might benefit from higher staffing ratios than were available on wards, and immediate access to senior clinical decision-makers and organ support. It described variations in the care of hospitalised critically ill patients and the interventions associated with their care. The COVID-19 pandemic demanded more enhanced care beds, and new guidance released in 2021 redefined the levels of care (Intensive Care Society, 2021).

5.3.6 In its 'Levels of adult critical care' consensus statement, the ICS states that they:

'support the ongoing multi-professional reviews of staffing, of which there are several; SEISMIC (Study to Evaluate the Impact of a nurse Staffing Model in Intensive Care) which looks at Nurse Staffing, [allied health professional] (specifically Physiotherapy, Occupational Therapy and Speech and Language) and pharmacy services. The aim being to develop an evidence base to reflect staffing based upon patient need, rather than "level of adult critical care".' (Intensive Care Society, 2021)

5.3.7 The Nursing and Midwifery Council (2020) has provided additional guidance. In addition, NHS England and NHS Improvement (2021) provides COVID-19 workforce guidance on its website.

5.3.8 The Royal College of Nursing has recognised that safe staffing during the first and second waves of the pandemic was a challenge and a concern. The College's website states:

'Nursing staff in almost all settings are facing challenges beyond what were ever expected. Staffing levels are poor in many places, on most shifts and care is being compromised as a result.' Royal College of Nursing (2021)

The website provides advice and guidance for staff who wish to report concerns about staffing levels.

5.3.9 In its latest joint guidance, the BTS/ICS specifically states that a 1:2 nurse-to-patient ratio is mandated for delivery of acute NIV until the patient is weaned to nocturnal NIV only (British Thoracic Society and Intensive Care Society, 2021a). This ratio reflects the fact that patients receiving acute NIV are at risk of deterioration, unplanned admission to a critical care unit and death. The GIRFT guidance recommends a minimum nurse-to-patient ratio in an RSU of 1:4, but the BTS/ICS notes that increased acuity of illness will require additional RSU staff (British Thoracic Society and Intensive Care Society, 2021a; Getting It Right First Time, 2020).

5.3.10 The staffing of RSUs is considered by GIRFT in their Respiratory Medicine report (Getting It Right First Time, 2021). The investigation was told by a subject matter advisor that a nurse-to-patient ratio of 1:4 is the minimum, provided the nurses are trained and competent in managing respiratory support. In addition to the increased nursing provision, RSUs require increased staffing from other healthcare workers, including medical, allied health professional (such as physiotherapy) and pharmacy staff, to support and manage these complex, vulnerable and very sick patients. To support such care, the report recommends that there should be a minimum of two respiratory consultant ward rounds each day for patients with COVID-19, including on weekends.

5.3.11 The GIRFT report highlights that to support the RSU in delivering CPAP, a mobile workforce team that can make assessments has been shown to be beneficial and should be part of a COVID-19 service (Getting It Right First Time, 2021).

5.3.12 Nationally, the COVID-19 pandemic has forced organisations to rapidly cross-skill a non-specialist workforce. This has resulted in a breadth of training resources, although the rapidity of their deployment means that the quality of this training has been under-evaluated (Intensive Care Society, 2020). The ICS has recognised the potential merit in working across disciplines to develop standards/competencies for intensive care (Intensive Care Society, 2020).

5.3.13 Examples of courses that have been used to train critical care staff include the C19_SPACE course from the European Society of Intensive Care Medicine (2021).

5.3.14 The joint BTS/ICS guidance recommends that local competencies should be made for nursing staff with protected time to achieve them (British Thoracic Society and Intensive Care Society, 2021b). An example is the national competency framework that has been developed for recognising and managing critically ill patients by the National Outreach Forum and Critical Care Networks – National Nurse Leads (2018). At a minimum, each member of the nursing staff on an RSU should be competent in using the unit's equipment, including NIV and CPAP machines, suction, HFNO, mechanical

insufflation–exsufflation therapy and monitoring equipment. Each hospital should have its own competency documents for this equipment (British Thoracic Society and Intensive Care Society, 2021b).

Key findings

The investigation found that the published 'Inspiring change' report (National Confidential Enquiry into Patient Outcome and Death, 2017), the British Thoracic Society 'Quality standards for acute non-invasive ventilation in adults' (Davies et al, 2018), joint guidance and recommendations by the BTS/ICS (British Thoracic Society and Intensive Care Society 2021a, 2021b), and recommendations and subsequent actions published by GIRFT (Getting It Right First Time, 2021) address the safety issues identified in the reference event with respect to caring for acutely unwell patients with COVID-19 outside of critical care environments. Therefore, no safety recommendations are made by HSIB in this report. HSIB supports implementing the recommendations made by these national bodies. These include the following:

- Hospitals should establish RSUs that are staffed in line with existing national recommendations. This includes a minimum nurse-to-patient ratio of 1:4, with nurses trained in administering CPAP and HFNO.
- Patients requiring non-invasive respiratory support such as CPAP should be centrally monitored. Central monitoring allows patients to be observed and equipment alarms to be heard at the central nurses' station.
- Hospitals should have protocols that define the frequency of nursing review (that is, how often a nurse checks on a patient), especially for acutely unwell patients located in side rooms.
- Hospitals should have checklists for the safe use of CPAP/NIV outside of critical care and high-dependency units. For example, the British Thoracic Society and Intensive Care Society (2021a) guidance on establishing respiratory support units includes a checklist for the safe use of CPAP/NIV outside of critical care and high-dependency units.
- Minimum safe staffing levels should be followed when caring for patients requiring non-invasive respiratory support.
- Where possible, organisations should procure CPAP devices that allow remote monitoring.
- Staff caring for patients requiring non-invasive respiratory support outside of critical care settings should meet training and competency requirements.

6 Appendix 1

Terry was 73 years old at the time of his admission to hospital. He was married with children. His medical history included type 2 diabetes, coronary heart disease, asthma, a high cholesterol level and hypothyroidism. He had undergone coronary artery bypass graft surgery in 2004 and was taking medicine for an abnormal heart rhythm (atrial fibrillation). At the time of his admission, Terry was under the care of a doctor for syncope (fainting or passing out). Terry lived independently at home with his wife, and was described as an active man who did not like to ask for help. The clinical chronology shown in table 1 was derived from Terry's clinical notes and interviews with staff. It is not verbatim from the clinical records and interviews, but covers some of Terry's relevant tests and results.

Table 1 Timing of key events

Monday 14 December 2020		
Time	**Situation and/or interventions**	**Action/plan**
18:54 hours	Ambulance dispatched	
19:25 hours	Paramedics' findings: • 92% SpO2 on air • 97% SpO2 on 15 litres oxygen • Respiratory rate: 40 breaths/minute • Pulse: 165bpm • ECG showed supraventricular tachycardia • BP: 143/70mmHg • Blood glucose: 18.7mmol/l • Temperature: 39.4C	Terry was taken to the ED on a blue-light transfer, arriving at 20:25
20:25 hours	Admitted to the ED and seen by a specialty doctor in training (ACCS ST1) • 91% SpO2 on air; given oxygen • Respiratory rate: 36 breaths/minute • Heart rate: 150bpm and irregular • ECG showed AF • Crackles at both lung bases were heard when listening to Terry's chest • Cough • GCS: 15/15 • Blood glucose: 15.6mmol/L	Treatment given: • Intravenous fluids and intravenous antibiotics Tests requested: • Chest X-ray • ECG • Blood levels, including blood cultures • ABGs Oxygen saturations targeted at >94% The ECG showed Terry was in AF and had right bundle branch block (Terry was known to have these conditions and was taking apixaban for his AF)
20:31 hours	ABGs: • pH: 7.50 (expected range: 7.35–7.45) • PaCO2: 3.76kPa (expected range: 4.7–6.0 kPa, 35.2–45mmHg) • PaO2: 7.91kPa (expected range: 11–13 kPa, 82.5–97.5mmHg) • HCO3: 22mmol/L (expected range: 22–26mmol/L) • Base excess: 0.0mmol/L (expected range: -2 to +2mmol/L)	Terry's blood gas results showed he had type 1 respiratory failure and respiratory alkalosis
21:15 hours	• NEWS: 8 • Alert; talking in full sentences • SpO2: 94% on 35% oxygen (8 litres/minute) via Venturi mask • Respiratory rate: 22 breaths/minute • Pulse: 138bpm • BP: 163/115mmHg • Temperature: 38.3C	Terry was referred to the on-call medical team
22:00 hours	• NEWS: 7 • Alert, talking in full sentences • SpO2: 92% on 35% oxygen (8 litres/minute) via Venturi mask • Respiratory rate: 19 breaths/minute • Pulse: 138bpm • BP: 149/79mmHg • Temperature: 38.2C	
23:00 hours	• NEWS: 4 • Alert • SpO2: 94% on 35% oxygen (8 litres/minute) via Venturi mask • Respiratory rate: 17 breaths/minute • Pulse: 107bpm • BP: 135/65mmHg	• Administered antibiotics and other prescribed medications, including dexamethasone • CCOT review requested

Table 1 Timing of key events (continued)

Tuesday 15 December 2020		
Time	**Situation and/or interventions**	**Action/plan**
00:26 hours	• NEWS: 4 • Alert • SpO2: 94% on 35% oxygen (8 litres/minute) via Venturi mask • Respiratory rate: 17 breaths/minute • Pulse: 105bpm • BP: 136/74mmHg	
08:38 hours	Consultant ward round • Chest X-ray: bilateral infiltrates in keeping with viral pneumonia • Alert, orientated and comfortable • No chest pain or palpitations • On 32% oxygen via Venturi mask • Eating and drinking well	For full active resuscitation Plan: • Antibiotics as according to Community Acquired Pneumonia (CAP) protocol • Dexamethasone 6mg/day • Monitor blood glucose; give insulin if raised and refer to diabetes nurse • Continue with current antibiotics • COVID-19 and flu swab • Test for atypical antigens • Continue with IV fluids • Repeat ECG • For full escalation • Liver ultrasound for deranged liver function tests • Viral hepatitis screen
13:30 hours	Moved from the ED to a side room on a ward (awaiting COVID-19 test result) • 40% oxygen (10 litres/minute) via Venturi mask • Alert and orientated • Call bell within easy reach and bed lowered • Mobile and independent • Observations every 2 hours • Nursing entries made every 1–2 hours	Terry tested positive for COVID-19 and was transferred through the red pathway as having COVID-19 pneumonia
14:43 hours	Seen by F1 doctor noted increased oxygen requirements • Alert; speaking in full sentences • Short of breath and chest pain • SpO2: 92% on 40% oxygen (10 litres/minute) via Venturi mask • Respiratory rate: 20 breaths/minute • Pulse: 89bpm • BP: 101/67mmHg • Capillary refill time: <2 seconds • Blood glucose: 16.4mmol/L ABGs: • pH: 7.47 (normal: 7.35–7.45) • PaCO2: 3.85kPa (expected range: 4.7–6.0kPa, 35.2–45mmHg) • PaO2: 11.8kPa (expected range: 11–13kPa, 82.5–97.5mmHg) • HCO3: 21mmol/L (expected range: 22–26mmol/L) • Base excess: 0.9mmol/l (expected range: -2 to +2mmol/l) Bloods: • Sodium: 135mmol/L • Potassium: 3.4mmol/L • Glucose: 15.5mmol/L • Lactate: 2.1mmol/L	• Target SpO2: 88–92% • Switch to humidified oxygen • Observations at least every 4 hours • Continue IV fluids • Monitor blood glucose • Encourage prone positioning • Continue according to the primary team's management • Contact and escalate in line with NEWS • Repeat ABGs if patient desaturates • Offer urine bottle to patient • Plan discussed with CCOT
17:23 hours	Seen by CCOT • Terry was talking on the telephone • SpO2: 90–94% on 40% oxygen (10 litres/minute) via Venturi mask • Respiratory rate: 22 breaths/minute • Temperature: within expected range • Equal air entry to chest with crackles audible throughout • IV fluids being administered and adequate diuresis • On antibiotics and steroids • Clinically stable	CCOT did not add to care, but instructed the nurse to call for re-review and help with care if Terry had any deterioration or increase in oxygen demand • Continue 40% humidified oxygen • Monitoring every 1–2 hours, including fluid balance • Respiratory review – ?remdesivir [Doctor would discuss with research team] • Daily bloods • ABGs if clinically indicated • Encourage self-proning • Target SpO2: 88–92% • Monitor blood glucose
23:00 hours	• NEWS: 7 - The nurse caring for Terry alerted the nurse in charge, the on-call doctor and the CCOT • SpO2 below target on 9 litres/minute oxygen; changed to a non-rebreather mask and 15 litres/minute oxygen • Poor urine output • Escalated to on-call doctor and CCOT • Transferred to a medical ward at 02:00 hours	• Plan to start CPAP • Monitor and repeat ABGs in a few hours
Written in retrospect due to acuity, but visit after 22:30 hours	History of desaturating to 86% on humidified 40% oxygen – increased to 60% but SpO2 only reached 89%. Started on 15 litres non-rebreathe bag; SpO2 improved to 96%, but dropped to as low as 76% on moderate exertion such as sitting up in bed ABGs taken on 15 litre non-rebreathe mask: • pH: 7.48 (expected range: 7.35–7.45) • PaCO2: 3.85kPa (expected range: 4.7–6.0kPa, 35.2–45mmHg) • PaO2: 9.76kPa (expected range: 11–13kPa, 82.5–97.5mmHg) • HCO3: 21.8mmol/L (expected range: 22–26mmol/L) • Base excess: 0.6mmol/l (expected range: -2 to +2mmol/l) Bloods: • Haemoglobin: 139g/l • Sodium: 134mmol/L • Potassium: 3.5mmol/L • Blood glucose: 11.7mmol/L • Lactate 3.3mmol/L • Capillary refill time: 3 seconds Observations on assessment: • Patient lying on side (unable to tolerate proning very well) • Speaking in full sentences, but does get short of breath • SpO2: 95% although desaturates • Respiratory rate: 29 breaths/minute; coarse breath sounds but equal air entry • Pulse: 93bpm • BP: 134/86mmHg • Temperature: 36.9C	

Table 1 Timing of key events (continued)

Tuesday 15 December 2020		
Time	**Situation and/or interventions**	**Action/plan**
01:06 hours	Seen by S/B senior house officer for increasing oxygen • Alert and orientated ABGs: • pH: 7.48 (expected range: 7.35–7.45) • PaCO2: 3.8kPa (expected range: 4.7–6.0kPa, 35.2–45mmHg) • PaO2: 9.76kPa (expected range: 11–13kPa, 82.5–97.5mmHg) • Lactate: 3.3mmol/l Bloods: • C-reactive protein: 332 • White cell count: 7.3×109/l • Lymphocytes: 0.4×109/l • Sodium: 131mmol/L • Potassium: 3.8mmol/L • Glucose: 15.5mmol/L Observations: • NEWS: 7 • Alert • SpO2: 94% on 15 litres/minute oxygen via non-rebreathe mask • Respiratory rate: 17 breaths/minute; reported feeling more breathless • Pulse: 105bpm • BP: 107/47mmHg • Temperature: 36.9C	Discussed with medical registrar and critical care registrar – both in agreement to start CPAP • If no improvement on CPAP, will need critical care escalation • Monitor fluid input and output • Continue with other planned treatments • Repeat bloods in morning
01:50 hours	Moved to a negative pressure side room on a medical ward Started on CPAP 10 cmH20 and 15 litres of oxygen initially, but weaned down to 5 litres with SpO2 >94% and respiratory rate 28–32 breaths/minute • NEWS: 6–7 • Alert and orientated	• Target SpO2: >94% • Continue hourly observations • Continue CPAP 10 cmH20 and 5 litres of oxygen • Titrate and wean oxygen according to oxygen levels • Strict fluid intake and output monitoring • Catheterise if poor urine output • Blood sugar monitoring • Repeat full bloods • Continue according to the medical team's plan • Respiratory review in the morning • Sit in a chair in the day if tolerated
05:08 hours	Reviewed by CCOT • NEWS: 10 • Temperature: 38.3C • Pulse: 174bpm Patient very agitated and distressed CPAP removed to allow a drink Patient reassured and given morphine sulphate 5mg orally CPAP put back on at 10 cmH20 and 8 litres of oxygen • Maintain target oxygen saturations >94% • Heart rate returned to 75bpm • Likely anxiety attack • Catheterised under aseptic technique – hourly urine	• ECG if becomes tachycardic • Give IV paracetamol when next due • Continue according to the previous plan
09:05 hours	• SpO2: 97% ABGs: • pH: 7.42 (expected range: 7.35–7.45) • PaCO2: 4.2kPa (expected range: 4.7–6.0kPa, 35.2–45mmHg) • PaO2: 12kPa (expected range: 11–13kPa, 82.5–97.5mmHg) • HCO3: 20mmol/L (expected range: 22–26mmol/L) • Base excess: –3.6mmol/l (expected range: -2 to +2mmol/L) Bloods: • Blood glucose: 5.8mmol/L	ex
10:09 hours	Respiratory consultant review Summary of interventions already in place Advised catheter to stay in longer • SpO2: 93% on 8 litres entrained CPAP; 100% once oxygen tubing unkinked • Weaned to 2 litres oxygen; SpO2: 98% • Alert and orientated, and tolerating CPAP • Crackles bilaterally • Catheter draining	• Continue IV fluids • Aim for fluid balance neutral to positive 500ml • Target SpO2: 90–94% • Allow breaks off CPAP for food and drink • Research team review • Ongoing CCOT review
10:51 hours	CCOT review • NEWS: 7 • SpO2: 95% on 8 litres entrained CPAP • Respiratory rate: 24 breaths/minute • Pulse: 117bpm • BP: 116/56mmHg • Temperature: 37.2C Bloods: • C-reactive protein: 332 • White cell count: 7.3×109/l • Glomerular filtration rate: 62ml/minute/1.7 m2 Nursing notes summarising the day shift and recorded at 13:42 refer to Terry taking breaks for drinking, but Terry did not want food	• Plan as above • Hourly observations
14:34 hours	CCOT review Terry had been mobilising to the commode; desaturating on arrival to 80% Switched to face shield for comfort CPAP increased to 12 cmH20 and oxygen increased to 15 litres; SpO2 slow to recover Discussed with critical care team, who will review; CPAP increased to 14 cmH20 and SpO2 improved to 92% Observations: • NEWS: 8 • SpO2: recorded as 84% ABGs: • pH: 7.45 (7.35–7.45) • PaCO2: 4.46kPa (expected range: 4.7–6.0kPa, 35.2–45mmHg) • PaO2: 6.21kPa (expected range: 11–13kPa, 82.5–97.5mmHg) • HCO3: 23.3mmol/L (expected range: 22–26mmol/L) Bloods: • Lactate: 1.9mmol/L	Plan for critical care doctor review
16:31 hours	Review by senior clinical fellow from critical care • SpO2: 86–87% on 15 litres entrained CPAP 12 cmH20 • Alert and orientated; GCS 15 • Reviewed latest blood results which included arterial blood gases (above) • Respiratory rate: 23 breaths/minute; bilateral and equal chest expansion • Pulse: 122bpm • BP: 129/90mmHg • Temperature: 36.8C • Capillary refill time: <2 seconds CPAP increased to 14cmH20; SpO2 responded slowly and patient mobilised to commode SpO2 increased to 92%; CPAP weaned to 12 cmH20 and SpO2 preserved at 95–96%	
18:24 hours	CCOT review • NEWS: 6 ABGs: • pH: 7.47 (7.35–7.45) • PaCO2: 4.03kPa (expected range: 4.7–6.0kPa, 35.2–45mmHg) • PaO2: 9.54kPa (expected range: 11–13kPa, 82.5–97.5mmHg) • HCO3: 22.4mmol/L (expected range: 22–26mmol/L) Bloods: • Sodium: 136mmol/L • Potassium: 3.6mmol/L • Glucose: 11.1mmol/L • Lactate: 1.9mmol/L	Discussed with consultant intensivist on critical care • Continue with current plan
18:59 Hours	Medical review • Alert, not drowsy; still breathless • SpO2: 80–96% on CPAP; 96% at time of examination • Respiratory rate: 25 breaths/minute; bilateral and equal chest expansion • Pulse: 117bpm • BP: 170/88mmHg • Temperature: 36.8C • Capillary refill time: <2 seconds ABGs: • pH: 7.41 (7.35–7.45) • PaCO2: 4.8kPa (expected range: 4.7–6.0kPa, 35.2–45mmHg) • PaO2: 11kPa (expected range: 11–13kPa, 82.5–97.5mmHg) • HCO3: 22.0mmol/L (expected range: 22–26mmol/L) • Base excess: –2.2mmol/L (expected range: -2 to +2mmol/l)	Continue antibiotics • Repeat ABGs • Escalate to critical care if clinical or ABGs worsen
20:12 hours	Cardiac arrest call made via switchboard; Terry had pressed the nurse call bell a few minutes before the nurse attended the side room Terry was found on the floor at the foot of the bed, as described in the main chronology	

ABG, arterial blood gas; ACCS, acute care common stem; AF, atrial fibrillation; BP, blood pressure; bpm, beats per minute; CCOT, critical care outreach team; CPAP, continuous positive airway pressure; ECG, electrocardiogram; ED, emergency department; GCS: Glasgow Coma Scale; HCO3, bicarbonate; kPa, kilopascal; mEq/l, milliequivalents per litre; mmHg, milligrams of mercury; mmol/l, millimoles per litre; NEWS, National Early Warning Score; PaO2, partial pressure of oxygen; PaCO2, partial pressure of carbon dioxide; SpO2, oxygen saturation

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